# Does Meditation Have a Specific Effect?

## A Systematic Experimental Evaluation of a Mental Silence Orientated Definition

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# Abstract

Meditation and its underlying ideas are increasingly popular in Western society but the practice itself has been subjected to little high quality scientific scrutiny.

In this thesis I describe the outcomes of a research programme aimed at addressing this deficiency. A comprehensive systematic review and meta-analysis of the entire English-speaking database of randomised controlled trials clearly demonstrates that the extant data is characterised by a number of methodological and conceptual flaws. As a result there is currently no consistent evidence of a specific effect associated with meditation. The most fundamentally important of these flaws, I propose, is the lack of a consistent and meaningful definition of meditation.

Exploring the original descriptions of the meditative experience reveals that a key feature of meditation is the experience of *mental silence*. Despite this, Western definitions characterise meditation as a method of relaxation, focusing of attention or cognitive modification. The poor performance of meditation in scientific studies may be explained by the fact that definitions of meditation used by Western scientists do not appear to reflect the understanding of meditation as described in the Eastern traditions from which it originated.

To explore the salience of the *mental silence* concept I first conducted a survey of 348 meditators who used a single homogenous form of meditation called *Sahaja Yoga* which focuses on the experience of *mental silence* as its defining feature, to assess their functional health and its relationship with their meditative practices. This survey demonstrated that these meditators had not only better mental and physical health but also that a consistent relationship between health, especially mental health, and self-reported experience of *mental silence* existed.

To investigate the possibility of whether or not this relationship was causal, a series of increasingly rigorous clinical studies were implemented. Two separate observational and case control studies of participants suffering from 1)menopausal symptoms, and 2) attention deficit hyperactivity disorder demonstrated promising outcomes. These were followed by a small but well-designed RCT of meditation for asthma, then the largest RCT of meditation for occupational stress currently in the literature. The latter two studies were specifically designed to exclude non-specific "placebo" effects. The outcomes of these studies provided strong evidence that *mental silence* is associated with a specific, therapeutic effect.

Finally, in a heuristic physiological study *mental silence* meditators manifested reductions in skin temperature during meditation thereby contradicting the "reduced physiological arousal" conceptualisation of meditation. This and other data are discussed and the possibility that the *mental silence* experience is associated with a unique pattern of physiological activity is proposed.

In conclusion, there is credible evidence to support the idea that *Sahaja Yoga* meditation, and hence the *mental silence* experience that typifies it, is associated with unique effects. The ramifications for the fields of meditation research, consciousness and religious studies and healthcare are discussed. Future studies are proposed that focus on further examination of the *mental silence* state and potential mechanisms by which its specific effects may occur with emphasis on immunogenetic markers and neuroimaging.

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## Originality statement

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# Conflict of interest statement

The author has no direct or indirect financial interest in the meditation techniques described in this document.

The author did not develop the *Sahaja Yoga* meditation technique or any aspect of it. Permission to use this technique in the various studies described herein was granted on the condition that it should not be commercialised or misappropriated as a result.

The author does his best to meditate on a daily basis.

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# Publications arising from this work

**Papers**

Manocha R. Why meditation? *Australian Family Physician*. 2000;29(12):1135–8.

Manocha R, Marks GB, Kenchington P, Peters D, Salome CM. *Sahaja Yoga* in the management of moderate to severe asthma: a randomised controlled trial. *Thorax*. 2002;57(2):110–5.

Harrison L, Manocha R, Rubia K. *Sahaja Yoga* meditation as a family treatment programme for children with attention deficit hyperactivity disorder. *Clinical Child Psychology and Psychiatry*. 2004;9(4):479–497.

Manocha R, Semmar B, Black D. A pilot study of a *mental silence* form of meditation for perimenopausal women. *Journal of Clinical Psychology in Medical Settings*. 2007;14(3):266–273.

**Conferences, Selected Oral Presentations**

Manocha R. A randomised controlled trial of *mental silence* meditation for work stress, 10th International Congress of Behavioural Medicine, Tokyo, Japan, Aug 27-30, 2008.

Manocha R, Black D. A review of meditation RCTs- Important insights for future research, 3rd International Congress on Complementary Medicine Research 2008, Sydney, Australia, 29-31 march, 2008.

Manocha R. Short and long term effects of meditation on mental health of full-time workers seeking help for work stress, World Psychiatry Association, "Working together for mental health: partnerships for policy and practice”, Melbourne Australia, Nov 28-Dec 2, 2007.

Manocha R. Meditation as a psychobehavioural management tool for menopausal symptoms, attention deficit hyperactivity disorder and asthma, World Psychiatry Association , “Working together for mental health: partnerships for policy and practice”, Melbourne Australia, Nov 28-Dec 2, 2007.

Manocha R, Harrison L, Bhasale A, Rubia K. Meditation as an adjunctive management strategy for children with ADHD, 6th International Congress of Neuropsychiatry, Sydney, Australia, 10-14 Sep, 2006.

Manocha R. *Sahaja* state and therapeutic consciousness: High quality empirical evidence for a new definition of meditation, Towards a Science of Consciousness, Tucson, Arizona, 7-11 April, 2004.

# Chapter 1. Introduction

In 2000 Pirrotta et al. published the results of a widely publicised survey of family physicians in Australia[1]. Remarkably it reported that almost 80% of respondents had recommended meditation to patients at some time in the course of their practice, yet less than 35% had any formal training or education in the field. This reflects, on the one hand, the growing legitimacy of what was once regarded as a fringe concept and on the other, a lack of quality education on the topic. The medical community's manifest interest in meditation is often construed by consumers as tacit endorsement of the practice.

Meditation arose from an ancient spiritual tradition centred in India. It has achieved substantial popularity in Western societies as a therapeutic tool as well as a method of self development. In both the East and West it is widely perceived to have potent, specific effects on both the body and mind. In Australia, a survey of a randomly selected but representative sample drawn from the state of Western Australia (n = 1,033) found that 11% of respondents had practiced meditation at least once[2]. This reflects trends in other countries. In the United States for instance, a survey administered to 31,000 representative adults, conducted in 2002 as part of the National Health Interview Survey (NHIS) of the Centers [sic] for Disease Control and Prevention (CDC), showed that 8% of respondents had practiced meditation at some time[3].

### The Conundrum

Despite widespread and burgeoning community enthusiasm and a substantial body of peer-reviewed publications concerning meditation, the systematic review of the literature reported in Chapter 2 clearly demonstrates that there is no consistent scientific evidence to support the perception that meditation has specific health benefits.

An extensive search of the scientific literature identified 3,500 peer-reviewed publications that featured "meditation" as a key word. Yet, of these, only 135 (approximately 4%) fulfilled the very basic requirements of experimental evaluation, i.e. they were prospective trials using control groups and random allocation. Importantly, even within this subset of more rigorous studies, there is no convincing evidence that meditation has a specific effect. In fact within this set of randomised controlled trials (RCTs), there appeared to be an inverse relationship between methodological rigour and likelihood of an outcome that is favourable to meditation.

## 1.1 The problem of method validity

A general reading of the total literature makes it obvious that method validity is the major challenge to meditation research. More specifically, the main problems are: first, the use of appropriate control strategies to exclude non-specific effects (more widely known as the "placebo effect"), second, the need for randomization and other strategies to eliminate bias and third and most importantly, a consistent and meaningful definition of meditation.

### 1.1.1 Excluding non-specific effects

Plausible control groups are critical in behaviour therapy research because of the need to exclude the important confounding effects of non-specific factors (such as placebo, therapeutic contact, researcher expectations etc). Expectation alone, for instance, has been shown in a number of studies to positively influence the apparent effect of meditation[4]. The essential criteria for a control strategy in meditation trials should be, first, convincing plausibility as an active intervention in its own right and, second, a process that involves relaxation and reduction of somatic arousal (since these are the nearest conventionally understood phenomena that resemble meditation).

### 1.1.2 Randomization and other strategies to control for bias

The literature search revealed that a large number of controlled meditation trials had been carried out using dissimilar cohorts in non-randomized trials. The need for randomization to exclude selection bias is obvious; yet as indicated above, only a minority of trials (less than 4% of the total number of peer-reviewed publications) used random allocation of participants to study treatments.

### 1.1.3 A definition of meditation

Defining meditation has proved a difficult challenge for modern researchers. Conceptual definitions of meditation vary widely but generally lack empirical confirmation. The authoritative National Centre for Complementary and Alternative Medicine (a department of the National Institutes of Health) in the United States in 2006 defined meditation as "a conscious mental process that induces a set of integrated physiological changes termed the *Relaxation Response*"[5]. Yet the most original and authentic traditional treatises on meditation define it as an experience of *mental silence*. For example in the *Katha Upanishad*, as follows: "When the five senses and the mind are still, and reason itself rests in silence, then begins the path supreme"[6]. Such a conceptualization contrasts sharply with many of the contemporary understandings of meditation put forward in the West; probably the most pervasive of which is as a method of achieving reduced physiological arousal, or in another words relaxation.

It is difficult to make conclusions about meditation when the definition of the independent variable itself varies from study to study, if not from person to person. A homogenous definition of meditation is essential for further progress in this field and yet, after almost 40 years of research the scientific community is unable to provide a truly consensus definition. Some argue that this is because meditation is actually a broad collection of disparate methods however it might be equally argued that the lack of consistent definition is symptomatic of our poor understanding.

**An Hypothesis**

In this thesis I propose that one of the main reasons for the paucity of convincing evidence with regard to meditation is because Western scientists have failed to apprehend the key idea that underlies the meditation tradition: that is, meditation is traditionally defined in Eastern cultures as the experience of *mental silence*. Modern Western understandings of meditation vary, but probably the most common understanding is that it is a method for eliciting reduction in physiological arousal. The notion that meditation involves a state of consciousness "beyond thought" seems all but absent from modern Western scientific literature on meditation.

**Testing the hypothesis**

I designed a multifaceted series of studies to test the effects of the traditional *mental silence* concept of meditation in a variety of contexts including:

1. psychobehavioural
2. medical
3. pathophysiological
4. physiological
5. subjective experiences (self report data)
6. objective changes (path physiological severity, medication consumption etc)
7. epidemilogical (population surveys).

Each study represented a progression in methodological rigor toward the final goal of implementing a definitive experiment that addressed the key methodological problems currently characterizing the extant research literature, i.e. a well-designed RCT that employs plausible control methods, strategies to eliminate bias and appropriate statistical analyses.

The *Sahaja Yoga* meditation technique was used because it utilizes a traditional understanding of meditation, in which *mental silence* is regarded as the defining feature, vis-à-vis modern understandings of meditation.

**The results**

A national survey of regular meditators clearly demonstrated that they experienced better health scores in comparison to Australian population norms and that these scores correlated significantly with the key defining aspects of the the variable of interest, i.e. *mental silence*.

Interventional study outcomes also appeared to support the *mental silence* definition. Both uncontrolled and non-randomized controlled studies suggested that a substantial effect might be linked with meditation techniques that feature *mental silence*.

Finally two RCTs, using highly plausible control methods and rigorous randomization procedures were implemented. Compared to the other RCTs uncovered by our extensive review of the scientific literature these trials were amongst the most rigorous ever conducted. Remarkably, despite the high level of methodological rigor in my RCTs the *mental silence* intervention again demonstrated relatively convincing significant effects.

**Conclusions**

By implementing this methodological strategy it is possible to propose a different, more scientifically verified understanding of meditation that also happens to be closely aligned with traditional ideas. The *Sahaja Yoga* meditation technique utilizes a *mental silence* orientated understanding of meditation, which differs from definitions currently prevalent in the West. Perhaps because of this, my studies clearly show it to be associated with a specific effect.

In this thesis it is argued that in the extant literature, no other approach to meditation is associated with a consistent level of evidence to validate a specific effect. Thus by rejecting the Western conceptualizations of meditation, and favouring *mental silence*, a fundamentally Eastern one, it does appear possible to use experimental methodology to generate supportive scientific evidence for the hypothesis being put forward in this dissertation.

## 1.2 Ramifications

The possibility that the *mental silence* construct is associated with specific effects, many of them health related, raises important research questions which will be explored in this thesis. These are:

- Can it be concluded that *mental silence* and its associated yogic philosophy provides a basis for a taxonomy of meditation that is practically useful in the delivery of healthcare? This question is based on the wide range of applications in medicine, psychology and neuroscience on which *Sahaja Yoga* meditation (SYM) interventions have been shown to have a specific effect. Moreover, meditation is particularly relevant to the growing field of complementary medicine because it represents an entire genre of complementary and alternative medicine (CAM) modalities. It is contended that the apparent therapeutic effects of *mental silence* position this genre of CAM in a new category with practical relevance.

- Does meditation have the potential to make a significant contribution to the nascent field of consciousness research? It is argued that it is able to do this by providing empirical evidence for a relationship between a well defined, supramundane state of consciousness and health/wellbeing. Implications for our understanding of religion and spirituality are discussed in the concluding chapters of this dissertation.

# Chapter 2. Scientific Status of Meditation

## 2.1 Introduction

There are a large number of reviews on the topic of meditation in the peer reviewed journal literature. Their conclusions are remarkably diverse, ranging from overwhelmingly positive to considerably negative. These disparities are explainable by factors such as the methodological standards set by the reviewers, whether or not the researchers were interested in differentiating between specific and non-specific effects and the researcher's own affiliations. Generally speaking, the more rigorous the standards set by the reviewers, the less likely they were to express enthusiasm for meditation.

For example, despite great enthusiasm in recent years amongst researchers, clinicians and consumers for *Mindfulness* meditation, Bishop concluded in his review: "At present, very little is known about the effectiveness of this approach…The available evidence does not support a strong endorsement of this approach at present."[7]

A review by King on the cardiovascular benefits of Transcendental Meditation (TM) concluded positively by stating that "Transcendental meditation shows promise as a preventive and treatment method for coronary heart disease. Transcendental meditation is associated with decreased hypertension…"[8]. Yet when Canter reviewed studies of TM's effect on hypertension he concluded that: "All the randomized clinical trials of TM published to date have important methodological weaknesses and are potentially biased by the affiliation of authors to the TM organization. There is at present insufficient good-quality evidence to conclude whether or not TM has a cumulative positive effect on blood pressure"[9]. The difference between these two interpretations may be explained by the fact that Canter is an independent reviewer who used rigorous criteria to select well designed, independently conducted randomized controlled trials (RCTs) whereas King included non-randomized trials, surveys and other less reliable sources of data. Significantly, King and his co-authors are employed by a subsidiary of the TM organization.

Probably the most thorough and up to date review of meditation research was published in 2007 by a team led by Ospina, specifically contracted by the US Department of Health and Human Services to assess the evidence base[10]. They included both randomized and non-randomized trials. In their assessment of more than 800 studies they concluded:

> Many uncertainties surround the practice of meditation. Scientific research on meditation practices does not appear to have a common theoretical perspective and is characterized by poor methodological quality. *Firm conclusions on the effects of meditation in healthcare cannot be drawn based on the available evidence*.

Ospina's review represented a massive effort by a large team of researchers. Its thorough and comprehensive nature ensures that its contribution to the field of meditation research will be of great value. There are a number of features in the review's design however that would seem to prevent important questions about specific effects and related issues from being clearly answered, such as:

1. The inclusion of a wide variety of comparative studies, not just RCTs.

2. Techniques that may not be widely accepted as meditation, such as Yoga, Tai Chi and *Qigong*. These practices include meditation as a component of their practice but also include many other practices such as physical exercise, dietary modification and other lifestyle choices whose confounding and non-specific effects are difficult to separate from any effects of meditation.

3. Effect size calculations did not seem to take into account the heterogeneity of control groups and their widely varying ability to confound outcomes since the control methods themselves elicit both non-specific and, in some cases, specific effects.

These considerations bring us back to the most important issue in the ongoing effort to reconcile the differing polemics from science, ancient tradition and pop culture. Which is not the question about whether meditation has *any* effect, because it clearly does have, but whether or not meditation has any *specific* effect. Clearly the RCT evidence is the only segment of the literature that could possibly answer this question. Despite this there are currently no published reviews aimed at specifically and comprehensively appraising the RCT evidence nor have there been comprehensive reviews closely examining RCT methodology and its relationship to study outcomes.

A thorough and specific review of the entire English speaking, peer-reviewed, RCT database was clearly necessary to address this important knowledge gap. This was undertaken as the first step in this thesis.

## 2.2 Search process

Literature searches were conducted using computerized databases, that included MEDLINE, PsycINFO, Current Contents, EMBASE, Biological Reports, CINAHL, Web of Science and Scopus as well as Internet (Google) and paper searches. The search term was “meditation”. The search was conducted between 2000 and 2007. More than 3,000 journal publications that featured “meditation” as a key word were identified. These were cross matched against search-terms such as “random”, “randomized”, “randomization”, “trial”, “clinical trial”. Studies were scrutinized by inspection of the abstracts. If these contained insufficient detail to determine eligibility, the full texts were obtained. Studies were included in the review if they met the following criteria:

- they were prospective, observational studies
- there was random allocation of participants to a meditation-orientated intervention arm and at least one comparison arm
- they were in English
- they had been published in a peer-reviewed journal.

As a result, 133 RCTs were identified. These were checked by a second researcher to confirm eligibility. The data on various criteria of each study were extracted using a predetermined data extraction protocol (see Appendix 1). A second independent researcher was contracted to conduct the same data extraction and the two outcomes were compared. Differences between the two data sets were minimal and any difference in interpretation was resolved by discussion, debate and ultimately consensus with a third, senior researcher. A fourth researcher was contracted to conduct independent cross checks for factual and numerical accuracy between the final report, source documents and the extracted data.

### 2.2.1 Non-English and 'grey literature'

It was decided to confine the terms of the review to RCTs published in peer-reviewed, English-speaking journals. This therefore excluded reports from non-English journals and the grey literature — theses, unpublished studies, conference proceedings and reports on the Internet. The author did not have the skills or resources to assess non-English journals. Whereas a cursory inspection of the grey literature revealed only 5

RCTs, all of which were very small trials lacking in important methodological and analytical detail.

### 2.2.2 Publication bias – 'bottom drawer effect'

It is widely accepted that positive studies are more likely to be published than negative ones. For example, the Institutional Review Board of the Johns Hopkins University conducted a follow-up of several hundred studies that it had approved to ascertain how many had actually reached publication and found that positive studies were 2.5 times more likely to be published than negative ones[11] and that this phenomenon is associated more with failure of the authors to submit the study than with rejection from journals[12].

Generally speaking, publication bias is an important factor which needs to be taken into account, since the weight of unpublished, negative studies can significantly change the conclusions of any review that would otherwise report positive findings. In the case of meditation however, I believe that publication bias is probably not yet a significant issue for the purposes of answering fundamental questions about meditation since:

- the majority of studies do not report strongly positive findings in favour of meditation

- in depth quantitative meta-analytical assessment is not yet possible due to the heterogeneity of the studies that have been published.

### 2.2.3 Results

In order to maximize the utility of this review it is divided into two major sections:

- Section 2.3 Descriptive review – of approximately 118 published RCTs

- Section 2.4 Meta-analytic review – of 54 RCTs that reported sufficient data to enable calculation of effect sizes for each intervention.

## 2.3 Descriptive review

### 2.3.1 Overview

The trials were assessed and sorted using the data extraction criteria described in Appendix 1. Publications describing follow-up studies or sub-analyses of larger trials were incorporated into the critical assessment of the main publication reporting the trial.

A number of important general patterns and facts became apparent upon preliminary inspection of the descriptive data. These are summarized below. While more than 3,%00 scientific papers on or about meditation have been published in the peer-reviewed literature in the past 40 years, the number of RCTs is substantially smaller, comprising less than 4% of the total database (this is discussed further and illustrated graphically in Chapter 3). Publication dates of RCTs ranged from 1973 to the present day. A graph of the frequency of RCT publication per year from 1973–2007 is presented in Figure 2.1.

A wide variety of outcome measures were employed in these RCTs. These might be broadly categorized and described as follows:

- Subjective measures were the most popular, used in approximately 200 studies. The most common are validated self-report questionnaires such as the State Trait Anxiety Inventory (STAI) and other measures of anxiety, the Symptom Checklist 90 Revised (SCL90R) and other measures of wellbeing and functional health, as well as disease-specific symptom and quality of life measures. They are primarily psycho-behavioural in nature.

- Objective measures were used in approximately 150 instances. The most common were physiological measures of autonomic activity, most commonly heart rate (HR), blood pressure (BP) and electrodermal activity.

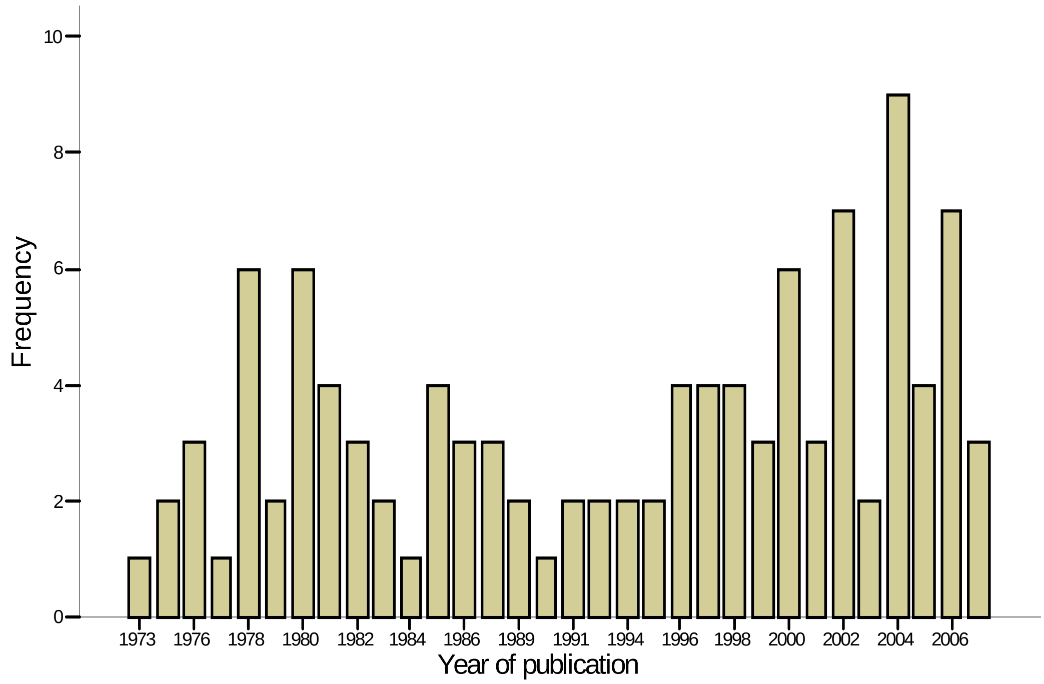


Figure 2.1 Frequency of publications on meditation for years 1973–2007.

Meditation has been applied to many different types of participants, the most common being university students (32 studies) and hospital/clinic outpatients, i.e. individuals with specific medical or psychological diagnoses (20 studies).

The most popular topics of study were anxiety, physiological effects, hypertension/heart disease, stress/adjustment and chronic illness.

More than 50% of the trials reported using a control method that had little plausibility as a therapeutic intervention (such as strategies like “waiting list” or “reading”) and therefore minimal likelihood of controlling for non-specific effects. In fact, trials comparing meditation to inactive or low “face validity” control strategies were considerably more likely to report positive findings compared to trials using more credible (that is, high "face validity"), active control methods suggesting that non-specific effects are a major confounder in such studies. Hence appropriate use of control methods is a major methodological issue that must be addressed for useful progress in this field.

Blinding is critical to ensure that participant's perceptions do not confound the study. Similarly the experimenters, raters, analysts and instructors ought to be similarly blinded wherever possible and appropriate. Despite this only a small minority of studies reported specific attempts to blind participants or researchers to comparison methods, the hypothesis of the study and the nature of their treatment group allocation and even amongst these the blinding strategies were generally inconsistently applied.

Inappropriate statistical analyses are a major limitation in many studies, especially those conducted prior to the 1990s. Appropriate statistical methods were used in a maximum of 56 studies. In fact, only 54 studies provided sufficient data (means and standard deviations or their non-parametric equivalents) to enable proper statistical meta-analysis.

Half of the studies used 20 participants or less per treatment arm and almost two thirds used less than 30 per treatment arm. Small sample size increases the chance of a type 2 error and sample size of less than 20 per treatment arm is generally unsuited to standard statistical analysis.

Fifteen studies, despite describing themselves (and being reported in the journal databases) as RCTs, clearly used a non-randomized methodology. These were excluded, leaving 118 studies for in-depth assessment.

After filtering the dataset of 118 studies for methodological characteristics essential for reliable outcomes such as having more than 20 participants per intervention group, the use of control methods likely to control for non-specific effects and correct statistical analysis strategies, *only 5 RCTs appear to be of sufficient methodological quality*.

Clearly at this stage the majority of meditation research is exploratory, rather than definitive, despite 40 years of scientific interest.

### 2.3.2 Importance of randomization and experimental design

The National Health and Medical Research Council offers the following comment on the value of RCTs:

> Well-designed and conducted RCTs are the best source of evidence for effects of interventions because randomization minimizes biases that may occur when individuals are allocated in an open fashion to the intervention or control groups. It also minimizes or eliminates confounding due to an unequal distribution between the groups, of factors that influence the clinical outcome under study.[13]

For instance, taking a single clinical problem such as work stress, of the 12 controlled studies that this review found in the journal literature, 8 used an RCT design and 4 used non-randomized controlled trial (NRT) design. The NRTs all reported that meditation produced substantial positive effects, whereas the studies using RCTs reported substantially less positive outcomes.

Of the 133 RCTs identified for this review, 15 of these reported minor or major violations of basic RCT methodology, suggesting that the authors did not really understand the importance of randomisation and its impact on the reliability of the study's outcome. Most of these violations occurred in trials that were undertaken prior to 1990 and all were published in behavioural science journals. Despite describing themselves (and being reported in the journal databases) as RCTs, each described major violations by clearly adopting a methodology that prevented truly random allocation. For example, Fling claims to have “randomly assigned 61 undergraduate volunteers”[14] in her trial but later indicated in the methods section that midway through recruiting, she had added another treatment arm and modified the inclusion criteria. Gaylord describes how her participants were “randomly assigned to one of three treatment groups”[15] in the abstract but in the methods section states:

> …most participants were randomly assigned. However random assignment was not possible in all cases. In each group there were a few participants who self-selected and requested assignment changes. Because of limitations in the subject pools, these requests were ‘honoured’.

In several instances either the corresponding abstract or database citation described the trial as randomized, when in fact it was not. For example the PsycINFO database provides the abstract of Smith’s trial in which it is stated that “36 undergraduates were assigned randomly”; however, the abstract of the article itself simply says that “experimental participants were divided into two groups” and indeed in the methods section of the paper it is stated that “participants whose schedules did not conflict with the weekly instructions times were assigned randomly (whereas) participants whose schedules did conflict…were assigned to the control group”[16]. Woolfolk’s trial stated that “assignment was random except when the restraints of scheduling made this impossible”[17].

The other excluded studies were by Shapiro[18], Gonzales[19], Harinath[20], Yalom[21], Schneider[22], Mehling[23], Katcher[24], Moritz[25], Peters[26, 27], Goldman[28].

### 2.3.3 Randomization method

With regard to the way in which randomization was reported, only 21 provided a full description of the randomization method; 42 provided a partial description (usually providing details of stratification but not how the randomization itself was performed); and 57 provided no description whatsoever. This data is presented in Table 2.1.

### 2.3.4 Comparison of baseline scores

Comparison of baseline measures is commonly reported as an indicator of how successful randomization was. If randomization has been performed correctly, the groups to be compared under different treatments should be similar in baseline characteristics, apart from the play of chance. Stratification in the randomization process further restricts the extent of chance imbalances. Although it is possible to use statistical tests to compare the balance and/or values of baseline characteristics between the study groups, some authors assert that this is inappropriate[29]. If randomization has been performed correctly, chance is the only explanation for any observed difference between groups at the outset of the study, in which case statistical tests become irrelevant. If 20 baseline characteristics are presented from a trial using simple randomization, it is more likely than not that at least one characteristic will show a significant imbalance between groups at two-sided $p < 0.05$ by chance alone[30].

While statistical tests are not a substitute for careful examination for any imbalances between study groups that may be practically important, these were used in the present review as a proxy indicator. This was done because the large volume of trials as well as the diversity of outcome measures and research paradigms prevented systematic and consistent assessment of baseline differences using any other schema. It is acknowledged that if there are imbalances that are considered important to the final study results, they should be accounted for by an adjusted analysis of the data and not simply denoted with a $p$ value.

Univariate or repeated measures analysis of covariance (ANCOVA) might presumably serve as a strategy to minimize the effect of any failure in the randomization process. As a proxy measure, those studies that used ANCOVA style comparisons with baseline data as the covariate were tallied. This revealed 14 studies that used this analytical approach in an attempt to adjust for potential shortcomings in randomisation.

In this review 72 studies compared baseline measures. Amongst those 72 studies that did report baseline comparisons, 20 reported statistically significant differences between groups on at least one measure prior to intervention. Given that each study used several outcome measures. Given the considerations outlined above these differences may well be explained by chance alone.

### 2.3.5 Allocation concealment and blinding

These issues are more important in behaviour therapy trials since the investigators are focused on factors that are strongly influenced by subjective impressions.

*Allocation concealment* is the procedure for protecting the randomization process so that the treatment to be allocated is not known before the participant is entered into the study[31].

Whereas *Blinding* relates to the masking of treatments after randomization to prevent the participant, the investigator and the raters from biasing the study. Blinding is an essential strategy for matching participants' expectations of benefit so that its associated effects on the outcome measures do not cause a biased interpretation of the data. Single blind studies require either the participant or investigator to be blinded to treatment assignment. Double blind studies require both to be blinded[31].

Shapiro[18] offers an example of the impact of inappropriate disclosure in a study of a stress management programme for women with breast cancer. In Shapiro's study, group assignment was disclosed to participants prior to baseline assessment. Analyses of baseline measures unexpectedly revealed statistically significant differences between groups on psychological functioning. This suggested that the failed randomization may have led to a "resentful demoralization" among those participants who were not allocated to the treatment arm of their choice. A hierarchical regression model indicated that this effect accounted for 47% of the variance, thereby highlighting the role of participant belief, preferences, and attributes and hence the importance of blinding. Similar phenomena have been reported in other trials, in which participants recruited for meditation studies were likely to be non-compliant if their expectations about learning meditation were not met[32].

Blinding of participants in meditation trials involves several considerations: First, participants must be blinded to the overall hypothesis of the study to preclude them from influencing the way in which they adhere to the intervention and respond to assessment procedures; particularly because so much of meditation research involves self-reported outcome measures.

Second, for the same reasons, participants must be blinded to the nature of the comparison intervention, as this could inform them of the trial hypothesis or influence their expectation of benefit. Participants themselves have preconceived ideas about which styles of intervention are likely to be effective and so there is a risk that if they were to discover what the comparison group is doing they might either become dissatisfied with the intervention to which they have been allocated or become overly confident that they will derive positive effects from the intervention.

These notions were practically confirmed in the various preliminary trials conducted in association with this thesis. A substantial proportion of participants had very specific preconceptions about meditation such that even if the control group used relaxation techniques or other semi-meditative comparisons, it was possible that these would not completely control for subject expectation, motivation and participation, particularly if the participants were recruited with the expectation that they would learn some form of meditation.

Third, the fact is that many author/investigators have direct or indirect interests in the outcomes of trials, whether because they are meditation instructors, proprietors of techniques, famous authorities or simply passionate about their beliefs. The presence of any of these factors emphasizes the need to minimize the influence of investigator bias. Simple steps to mitigate bias include the use of blinded assessors to collect outcome data, distance randomization methods and associated strategies to prevent investigators from knowing to which allocation participants belong.

Fourth, blinding also represents one of the basic mechanisms by which research-subject anonymity is maintained.

In this review, despite the considerations described above, only 35 studies reported that the raters were blinded whereas in 4 trials either directly or indirectly, by virtue of the methodological description, indicated that raters were definitely unblinded. This data is presented in Table 2.1.

Only 10 studies described steps to blind the participants with regard to the study hypothesis or the treatments that comparison groups were using, whereas in one study it was clear that participants were well aware either of the whole study hypothesis or part of it, such as the nature of the comparison intervention. In 2 trials, participants in the control group were actually informed that they were acting as controls. See Table 2.1.

Only 6 studies report steps to blind the lead investigators and/or the researchers responsible for statistical analysis to group identity. See Table 2.1.

In only 6 studies was it reported that steps had been taken to blind the trainers to the overall hypothesis of the study. Moreover in 21 studies one of the authors also delivered the intervention, suggesting that in these cases, blinding of the investigators was impossible.

Table 2.1 Numbers of studies at different levels of blinding.

| Blinding Level | Number of studies |
|---|---|
| Raters blinded | 35 |
| Participants blinded to comparison group intervention or study hypothesis | 10 |
| Statistician blinded to group allocation | 6 |
| Trainers blinded to hypothesis | 6 |

### 2.3.6 Control method

The design of RCTs for meditation (or any behaviour-based therapy for that matter) involves a number of unique challenges compared with pharmacological trials. While both categories of trial use an inactive placebo, the pharmaceutical trial uses an inert “sugar tablet” which appears similar to the medication being administered. The participant taking the “sugar tablet” is unable to ascertain whether or not they are taking the active or placebo treatment thus allowing the trial to control for confounding factors that may contribute to changes in the participants condition other than that caused by the treatment being studied.

The meditation trial however poses a unique challenge, since participants receiving the “inert” treatment must be involved in a placebo-like activity that nevertheless requires their active, conscious and conscientious involvement. They must also be sufficiently convinced of its authenticity to motivate them to participate at a level necessary to maintain the validity of the study.

In a recent editorial, Canter observed that those trials using inactive or less plausible control methods seem to report stronger effects in favour of meditation whereas those that use controls similar in plausibility and activity to meditation reported considerably less positive effects[9].

For example, when researchers have compared different types of behaviour therapy they have found that, despite their overt differences, they usually cause similar outcomes[33, 34]. This is presumably because the participant's participation and interaction with therapists, not to mention their conviction that they are involved in a therapeutic process appears to elicit non-specific effects such that even contradictory rationales for psychological and behavioural change can be equally effective. This phenomenon has been labelled the 'equivalence paradox'[35]. In the context of stress or anxiety for example, the equivalence paradox means that any form of stress management or psychotherapy may reduce stress or anxiety but not necessarily because of its specific properties. Rather, it appears to be due to the more generic effects common to all interactive therapy. A variety of factors present in almost every arm of every behavioural intervention are thought to be responsible for the non-specific effects that underlie the equivalence paradox.

For example, Carrington et al.[36] and Anderson et al.[37] both report multiple positive outcomes in favour of meditation when comparing meditation to a waiting list control strategy. However when Carrington et al. compared the same meditation technique to a highly credible and active control such as progressive muscle relaxation (PMR), they failed to demonstrate any differences in outcome.

Smith conducted a study in which he specifically controlled for expectancy of relief and found that non-meditators and meditators experienced the same degree of improvement within the same categories of expectancy[4], suggesting that a substantial proportion of the effect of meditation is non-specific. Sawada[38] in 1988, conducted a trial in which he compared meditation to a rest/relaxation strategy and asked participants to rate their expectations of improvement. Even prior to commencement of the trial, participants in the meditation group had significantly higher expectations of benefit than those in the rest/relaxation group. The participants in Sawada's trial were significantly in favour of meditation even though the more objective outcomes they experienced (physiological arousal and response to stress) were no different to those observed in the comparison group**.** This indicates that even interventions that may be psycho-physiologically equipotent may have different practical effects because of the way in which they are perceived by the participants. It also suggests that subjective measures are more prone to this kind of bias as compared to objective measures.

The impact of factors such as credibility and expectation is not limited to subjective outcomes. For instance there are some interesting observations in the literature about the impact of suggestion and expectation on lung function and asthma symptoms. Luparello[39], in a single blind study, gave nebulised saline to asthmatics but suggested that it was an allergen/irritant and observed that about 50% of participants manifested significant increases in airway resistance and reversed the changes when the same saline was introduced with the suggestion that it was therapeutic. In a double blind RCT crossover trial, Luparello told participants when he administered a bronchodilator agent (isoproterenol): "This is…a substance that will open up your airways and make it easier for you to breathe", a statement designed to create a positive expectation in the subject. When the same agent was given with a statement intended to create a negative expectation: "This is a bronchoconstrictor that will tighten up your airways and make it harder for you to breathe", it led to a significant attenuation (by almost 50%, $p < 0.02$) of the bronchodilator's effect. Subsequently a bronchoconstrictor (carbachol) was given with the same set of opposing statements to create two different expectations. The positive expectancy condition significantly attenuated the bronchoconstrictive effect of the carbachol by almost 40%, $p < 0.05$). MacFadden conducted further trials that produced bronchoconstriction in response to a suggestion and that intravenous atropine blocked this response[40]. Neild conducted an experiment which utilized suggestion to bring about bronchoconstriction using warmed and humidified saline[41]. In those participants who responded to the suggestions, the bronchoconstrictive effect (up to 15% reduction in FEV1) was significantly mitigated by administration of inhaled ipratropium bromide at normal dosage levels[41]. Thus Luparello, Macfadden and Neild's findings concluded that the effects of suggestion are potent, and may be mediated via the vagus nerve and are negated by anticholinergic agents.

Explanatory factors for this effect and their particular importance in behaviour therapy research include the following 3 categories:

**Category 1.** Factors which are common to all strategies such as social support or therapeutic contact[42]. Many clinical researchers have observed that controls with high face validity seem more likely to generate effects of similar magnitude to the intervention[43, 44]. Expectancy alone has also been shown in a number of studies positively to influence the apparent effect of meditation[4]. An important factor which relates to the plausibility of the control interventions is the participant's expectation that they will experience a benefit (or detriment)[45]. Despite this, only 24 studies took specific steps to gauge either the participants' expectation of benefit or the perceived credibility of the various interventions.

**Category 2.** The possibility that strategies that draw volunteers from the community without using a predetermined threshold of dysfunction end up recruiting samples containing significant proportions of participants with subclinical scores. These "worried well"[46] have little scope to improve, exerting a ceiling effect on the chosen measures and thus dilute any apparent effect of the intervention. In other words, behaviour therapy trials, especially trials that recruit from the general community, and even more especially those community-recruited trials seeking to demonstrate behavioural changes in normal participants (i.e. those with no diagnosed psychopathology) are fundamentally prone to type 2 errors in study design[47]. Since meditation was developed as a practice for everyday use by normal people rather than those with psychopathology, researchers have frequently recruited from the community. This issue is therefore of particular relevance to the work presented in this thesis.

**Category 3.** Other factors include regression to the mean. This is a phenomenon that most commonly occurs in studies in which participants are selected because they have extreme values on a certain variable, such as in clinical trials for which specific eligibility criteria are set. In this case, the participants will manifest an improvement simply because of the natural tendency for variables to approach the population mean over time, regardless of any effect (or lack thereof) from the intervention being studied[48],and poor choice of outcome measures which are not specific and sensitive enough to detect change.

Hence, since at the moment there is still no agreement on whether meditation has any specific effects when compared to interventions such as relaxation, rest or simply doing nothing, the need for a placebo equivalent to control for non-specific effects is of critical importance in this field and control strategies in meditation RCTs should be selected and designed specifically to accomplish this.

#### 2.3.6.1 Influence of control strategies on outcome

It seems obvious that the non-specific effect of any intervention is closely related to its credibility and plausibility as a therapeutic intervention i.e. its "face validity". Now, some of the effects associated with meditation must be non-specific, i.e. comprising a mixture of placebo, therapeutic contact, spontaneous improvement and so on, whereas some, hopefully, are specific to meditation alone. One might even propose that different meditation techniques have varying proportions of specific and non-specific effects. Within the context of an RCT, the control strategy should ideally:

- elicit all the non-specific effects that meditation might have, but have none of meditation's specific effects

- not have any specific effects of its own.

By fulfilling these criteria the control strategy makes the RCT methodology sensitive to any specific effects of meditation that might be detectable.

Control methods in meditation trials can be positioned on a spectrum based on their varying ability to elicit non-specific effects. At the low face validity end are those that are mostly passive and implausible (such as "waiting list") and therefore unlikely to control for non-specific factors, while at the other extreme are those that are mostly active and, by virtue of their credibility and active content are high face validity and much more able effectively to elicit and therefore control for non-specific effects. High face validity, active control strategies that elicit a respectable level of non-specific effect are however very resource intensive to devise and implement. Researchers with very limited resources therefore often opt for simpler, less demanding strategies with necessarily poorer control for non-specific effects. What impact does this tendency have on the reported outcomes and general scientific perceptions of meditation? This is explored below.

Examining the studies in this review, control methods were presumptively categorized according to their face-validity into low, moderate or high face validity categories.

The low face-validity controls used strategies that were:

- *Passive and unstructured*: Participants were involved in minimal or no activity relating to the trial and had no interaction with researchers as a result of being allocated to the control group (e.g. waiting list, no treatment, self-directed reading, or referral to community resources). This kind of comparator controls for minor non-specific effects, such as regression to the mean, the natural history of disease states and environmental factors common to all participants. It does not however, control for any non-specific effects that may be elicited by behaviour therapies.

The moderate face-validity controls use strategies that were:

- *Passive and structured*. These involved some sort of regular and structured interaction with personnel associated with the experiment (e.g. regular lectures, specific reading, structured educational sessions on unrelated topics, regular BP checks). This controls for the same confounders as

Category 1 in addition to the effects of therapeutic contact and sense of active involvement.

- *Active* in nature and generated some *expectation* of benefit but did not have effects or credibility as either a method of relaxation or meditation e.g. support groups, education about health factors measured in the study, or lectures on stress and lifestyle management. This controls for the same as Categories 2 and 3 in addition to the effects of social support, improved lifestyle, etc. Social support has been repeatedly demonstrated to be effective in improving mood and quality of life and reducing the severity of disease symptoms. “Standard treatment” was included in this category.

High face-validity controls use strategies that were:

- *Active* in nature but not designed to generate significant expectation of therapeutic benefit (e.g. exercise). This controls for the same as Category 2 in addition to the effects of regular physical activity. Regular physical exercise has been shown to improve mood.
- *Active* in nature, generated some *expectation* of benefit and elicited the simple physiological effects on *rest* but did not have specific credibility as a meditative method (e.g. PMR, other relaxation methods, hypnosis, biofeedback, psychotherapy).
- The same as above but also had *credibility as a meditative method* (e.g. meditation techniques, strategies designed to convincingly mimic meditation) or constituted a legitimate form of *psychotherapy* (e.g. desensitization, CBT, counselling).

The proportions of the sample using each form of control strategy are presented in Figure 2.2. A summary of the numbers of comparisons in each face-validity category is presented in Table 2.2. From a total of 118 studies (see Table 2.15 for summary of studies' characteristics), some of which involved more than 2 arms, 176 comparisons have been made of which 88 comparisons involved low face-validity controls. Importantly, 68 of the total 118 studies in this review involve only 2 arms (i.e. meditation compared to a single control strategy). Of these 68 studies, 44 involve low face-validity controls and 9 studies involve moderate face-validity controls. Thus the great majority of 2 arm RCTs in the extant literature do not take adequate steps to exclude non-specific effects. Looking at the total database of 118 studies (i.e. 176 comparisons), only 50 studies (58 comparisons) or less than half of the RCTs in the database, take serious steps to exclude non-specific effects.

Table 2.2 Numbers of comparisons in each category of control method.

| Category of control method | Number of comparisons from all studies | Number of comparisons from 2 arm studies |
|---|---|---|
| **Low face-validity**<br>Waiting list, standard treatment. no treatment, community resources, unstructured reading, structured reading, unstructured educational materials | 89 | 44 |
| **Moderate face-validity**<br>Educational classes, exercise journal writing, listening to music | 29 | 9 |
| **High face-validity**<br>Relaxation, rest, napping, hypnosis, biofeedback, visualisation, breathing, behaviour therapy, stress, management, group therapy, pseudo-, quasi-, anti-meditation | 58 | 15 |

Looking at just 2 arm RCTs, the number of reported positive effects reduced as the control strategy's face-validity increased. Significantly positive changes in favour of meditation at post-intervention were reported 88 times in association with low face-validity controls whereas when high face-validity controls were used, only 9 positive changes were reported.

When the entire dataset of 176 comparisons was examined a number of patterns became apparent (see Table 2.3). First, as with the 2 arm trial dataset, it was clear that comparisons involving low face-validity controls were much more likely to report significantly positive differences. Second, and somewhat surprisingly, even low face-validity controls generated substantially high reports of no significant differences rather than positive differences, suggesting that in many outcome measures the meditative techniques are relatively inert.

Notwithstanding this second observation it is clear that face-validity of the control method is an important confounding factor in meditation research. The relationship between outcome and face validity is represented in Figure 2.3.

Table 2.3 Numbers of positive, negative and no difference comparisons for each control face-validity category.

| **Control face-validity** | **Number of outcomes** | **Total number and % of differences reported** | | |
|---|---|---|---|---|
| | | **Positive** | **No significant difference** | **Negative** |
| Low | 387 | 34% | 66% | 0% |
| Moderate | 160 | 32% | 66% | 2% |
| High | 237 | 17% | 80% | 3% |

The observations above make it clear that while researchers with limited resources often opt for simpler, less demanding strategies with necessarily poorer control for non-specific effects the impact on the reliability of observations from these studies is considerable. Since it is not yet clear whether meditation has any specific effects, RCTs using controls from the highly active/plausible end of the spectrum are essential to answer the question about specific effects.

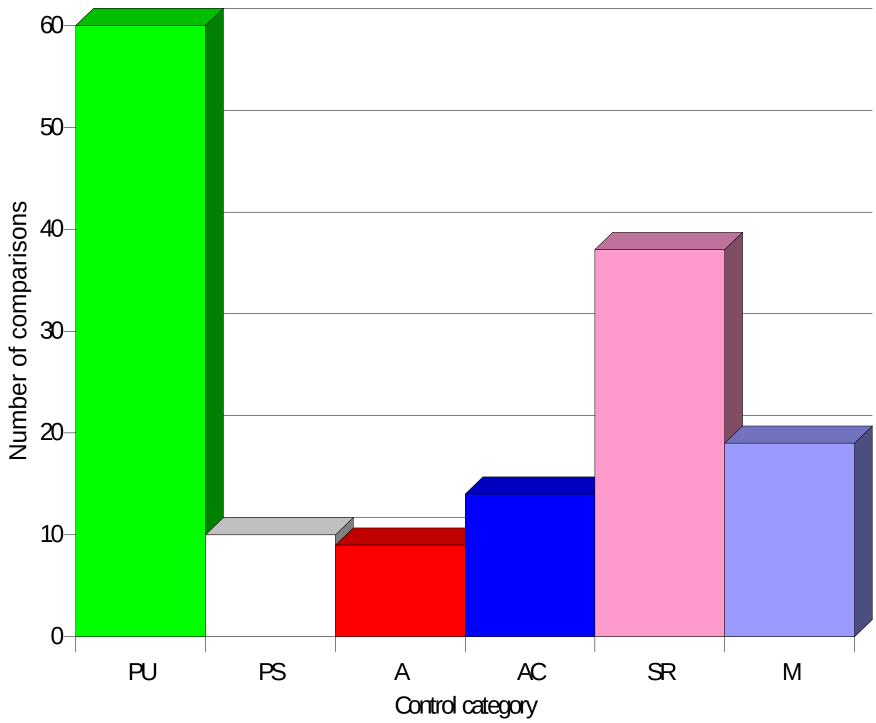


Figure 2.2 Frequency of different control methods by category.

**PU** = passive, unstructured; **PS** = passive, structured; **A** = active; **AC** = active, credible; **SR** = stress reduction; **M** = meditative or psychotherapeutic

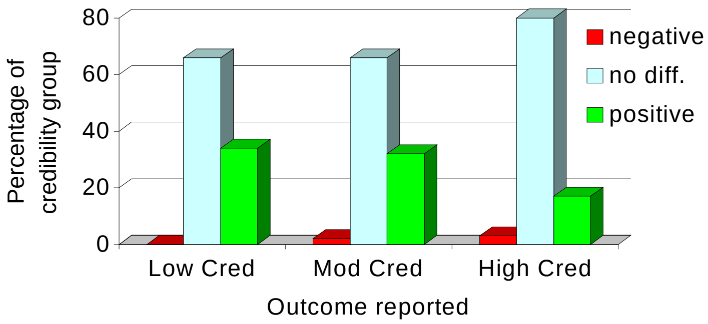


Figure 2.3 Study outcomes according to level of control face-validity.

Admittedly, it may not be practically possible to devise and implement an ideal control method for meditation trials, nevertheless it is important to select a strategy that approximates that ideal. The bare minimum criteria for a control process in meditation research should therefore be:

- First, high face validity as a therapeutic/stress management intervention in its own right. It should actually appear to be a credible meditation technique if that is the expectation of participants.

- Second, a process that involves relaxation and reduction of somatic arousal since this is the nearest conventionally understood phenomenon that meditation resembles and from which it needs to be distinguished.

Given these considerations, two strategies with high face validity are worth discussing in further detail.

#### 2.3.6.2 Sham meditation

Sham meditation involves designing control strategies that overtly resemble the intervention, but which do not actually trigger the effects purported to be specifically associated with meditation. Considering the data that we have just examined above, the diversity, and apparent impotence, of many meditative practices makes the construction of sham meditation quite feasible since researchers can develop rationales to justify almost any method that approximates the expectations of trial participants. For instance, Smith's RCT compared TM to an imitation exercise designed to closely mimic the entire technique, except for the proprietary mantra. Forty four participants practiced one of the 2 techniques for 24 weeks, with the same instructions for frequency and duration only to find that no difference between the 2 methods was detectable[16]. This study used well validated self-reporting measures shown in other studies to be quite sensitive to the effects of meditative practices. Similarly Dua compared a form of meditation that he developed to a "negative thought reduction" method as well as to a "negative thought enhancement placebo" for the management of anger in a small RCT and found no differences between the practices in any of the outcome measures at the end of the treatment period[49]. On the other hand, Wolf compared a meditation based on a traditional Sanskrit mantra (the *maha* mantra) with a pseudo mantra and observed substantial differences in post treatment outcomes[50]. In smaller trials, Rai observed a number of significant differences when he compared *Sahaja Yoga* meditation to "mimicking exercises" in the treatment of asthma[51], hypertension and stress[52, 53]. Sham meditation procedures necessarily involve deception of participants and the ethicality of this in clinical trials is open to dispute. Further, this kind of strategy can be logistically challenging and there is always a risk that the deception might be uncovered, thereby immediately invalidating the entire study.

The fact that some techniques elicit detectable effects when compared to sham procedures while others do not implies that some meditation techniques may not have specific effects whereas others may well have such effects. This logically suggests the possibility that the genre is not homogenous and that the use of meditation versus sham studies offers a method by which specifically effective techniques may be separated from those that are not.

#### 2.3.6.3 Head-to-head comparison

The second is a head-to-head comparison where two different approaches to meditation are compared. They are easier to conduct since elaborate deception strategies are not required, have inherent authenticity and ethical problems are much less likely. Head-to-head trials are important and valuable in the current context because they allow comparison of different definitions, paradigms and approaches to meditation. They are especially useful given that there is no consensus even on what exactly meditation is. A disadvantage of such comparisons is that they may not necessarily allow for a clear distinction between meditation-specific and non-specific effects.

In the RCTs developed for this thesis, elements of both head-to-head and sham comparisons were adopted with an emphasis on developing a high face-validity control method.

Some might argue that controlling for non-specific effects is an academic exercise with little real-world relevance. This is supposedly because factors such as the placebo effect, expectancy of relief and demand characteristics are a critical component of most health interventions when administered to patients in the field. Thus trials directed at assessing the ecological ("real-world") relevance and validity of an intervention have no need to control for factors which will be operating in conjunction with the intervention effect anyway[32]. Authors of such reports add that studies with these kinds of controls reflect real-world scenarios since study participants offered either meditation or the "usual care" (i.e. usually nothing) reflect the reality of their environment. This line of argument assumes that the only value of proper controls is its ability to help answer theoretical questions about meditation, but that such controls fail to allow meditation to demonstrate its "practical relevance".

Yet commercial purveyors of meditation frequently claim that their often expensive proprietary techniques are uniquely effective in order to justify expensive fees. Moreover, many meditation techniques can be arduous and culturally challenging. It is important to determine whether it is justifiable to demand these significant costs and efforts or whether the same effects might be elicited by simpler strategies that are similarly rich in non-specific effects but possibly cheaper and easier to implement. By controlling for non-specific effects, it is possible not only to provide important theoretical information about whether meditation has any unique effects, but also whether it is an economically justifiable option, whether it offers any more of an advantage over accepted strategies and whether the claims of meditation enthusiasts have any basis.

### 2.3.7 Author affiliation

Recent articles in high impact health science journals have highlighted the need to separate the influence of commercial interests from the clinical trial publication process, and there is no reason why meditation research should not be subject to the same guidelines. Those methods that involve a commercial dimension such as TM, the *Mindfulness* based stress reduction programme (MBSR) and the *Relaxation Response* (RR), feature a large proportion of research by authors whose tenure or whose academic unit appears to benefit from either income or kudos associated with positive research into their techniques.

Also important is the fact that much research on meditation has been conducted by enthusiastic supporters of the practice. However, there are both good arguments and strong evidence to indicate that allegiance to a specific therapy can have a systematic impact on the findings of trials[54].

Approximately 52 studies involved authors whose affiliations might potentially impact on the study outcomes in this way. Much of the research by these authors is associated with favourable results. For instance, despite the fact that there are only 15 RCTs of MBSR, only 3 of which employed high face validity controls (none of which report any convincing findings in favour of the MBSR), it is one of the best-known and respected meditation techniques in the USA.

Another example is TM, the proponents of which claim in excess of several hundred clinical trials as proof of its effectiveness. However, the most favourable reports have emanated from researchers affiliated with the Maharishi University of Management, an institution more or less owned and allied with the TM organization and named after the technique's founder.

In 24 of the 118 studies selected for this review, it was clearly stated that one of the authors instructed the intervention group. A further 15 studies involved authors who had developed the meditation technique being examined.

At least another 18 trials featured authors who were employed by or who themselves had established institutions reliant on income or credibility associated with the meditation technique. For example, 14 out of 25 studies on TM were authored by researchers affiliated with the Maharishi University of Management, Maharishi Ayurveda or some other part of the TM organisation (12 were employed, 4 were TM trainers). Of those studies by authors with these affiliations 78% of outcomes are reported as significantly positive and in favour of the technique whereas in those studies by authors with no stated affiliations with TM, only 23% of the outcomes are reported as significantly positive and in favour of the technique while 73% of outcomes exhibit no significant changes.

Similarly, Jon Kabat-Zinn, the founder of MBSR, has been an author in 2 of the 15 studies conducted on the MBSR. Five studies on *Mindfulness* involved authors who also trained the participants. In 4 studies the author claimed to have played some part in developing the meditation examined.

Of the 13 trials of RR, 6 were conducted in association with the MindBody medical institute, from which the technique originated and which could have benefited from income generated by commercialization of that technique. The technique's developer and major proponent, Herbert Benson, was an author in 3 trials. In 4 studies the author trained the intervention group.

Conflict of interest issues in this field are of considerable concern. They may be effectively addressed by more independently funded clinical trials conducted by researchers who are open-minded but not dependent on the financial ramifications or effects on reputation (except perhaps for their scientific validity) of the outcomes of their trials. Until such independent support becomes systematically and widely available however it seems inevitable that it will be the enthusiasts for meditation that will drive research.

### 2.3.8 Measures

A wide variety of outcome measures employed in these RCTs can be broadly categorized as follows.

#### 2.3.8.1 Subjective measures

These were the most popular, used in approximately 200 instances (see Table 2.4). The most common were measures of anxiety (such as the STAI), measures of wellbeing and functional health (such as the SCL90R and the SF-36), measures of mood (such as the POMS and the PANAS) and measures of stress. They are primarily psycho-behavioural in nature.

The inherent limitations of self-reported data are well recognized and yet the experiences that they are designed to tap are fundamentally impossible to assess with objective instruments. Therefore despite their limitations, self-report questionnaires such as the STAI, the SCL90R and other quality of life measures have a well-defined role in research and are increasingly recognized as clinically valuable indicators.

Table 2.4 Number of studies by subjective self report measure used.

| Self report measure | No. of studies |
|---|---|
| State Trait Anxiety Inventory | 33 |
| Other Subjective Measure | 33 |
| Stress Measures | 31 |
| Positive Affect and Negative Affect Scale & Other Mood Measures | 22 |
| Short Form 36 & Quality of Life or Wellbeing | 21 |
| Beck Depression Inventory & Other kinds of Depression Measures | 21 |
| Hospital Anxiety and Depression Scale & Other Anxiety Measures | 17 |
| Disease Specific Quality of Life or Symptom Scale | 15 |
| Symptom Check List 90 Revised | 14 |
| Profile of Mood States | 9 |
| Spiritual/ Self Actualization | 9 |
| Symptom Diary | 8 |

#### 2.3.8.2 Objective Measures

These were used in approximately 150 instances (see Table 2.5). The most common were physiological measures of autonomic activity (BP, HR, electrodermal activity, electromyogram, skin temperature, respiratory rate) and effects on aspects of brain and mental function (cognitive function, academic performance and EEG).

Objective physiological measures of arousal such as BP, HR and skin temperature, in some ways offer much more reliable information and are the commonest of the objective biological measures used in RCTs of meditation. Changes in measures of physiological arousal generally correlate with subjective measures of stress but they are very limited in their ability to predict behavioural or clinical outcomes.

Table 2.5 Number of studies by objective measure used.

| Objective measures | No. of studies |
|---|---|
| Autonomic Arousal (EDA, EMG, ST, RR, HR, BP) | 85 |
| Other objective | 19 |
| Cognitive function or academic performance | 13 |
| Exercise tolerance | 10 |
| Hypertensive BP | 9 |
| Endocrine | 8 |
| Cardio-metabolic risk factors other than BP | 6 |
| EEG | 6 |
| Medication consumption | 5 |
| Immunological | 4 |
| Other physiological | 3 |

#### 2.3.8.3 Third party observers

Third party observers were used in 15 studies to rate participants on a wide variety of measures. Most were clinicians reporting on clinical outcomes.

#### 2.3.8.4 Timing

Timing of assessments is also important since both psychological tests and physiological tests can be influenced by acute effects of meditation. In one trial it was specifically reported that post assessments that were administered soon after a meditation session, despite the fact that its aim was to assess chronic rather than acute effects of meditation. Five trials were designed to assess the acute effects of a single meditation session.

The breadth of subjective and objective measures that have been used in the RCTs included in the present review is impressive, with a total of 50 distinct measures employed in almost 100 RCTs. Some of these measures are particularly sensitive to moment-to-moment changes in subjective experience or physiological activity and yet it appears that none consistently change specifically in response to meditation. This might be logically explained in two ways:

- either meditation has no consistent specific effect

  or

- those measures so far used in RCTs are not sufficiently sensitive to the specific effects of meditation.

Given the number and variety of measures employed it is doubtful that the latter explanation is valid.

**2.3.9 Sample size**

Sample size is obviously a key factor in determining the validity and generality of trial outcomes. It needs to be determined carefully to ensure that the research time, effort and support costs invested in any clinical trial are not wasted. Ideally, clinical trials should be large enough to detect reliably the smallest possible differences in the primary outcome with treatment that are considered clinically worthwhile. This review found that it was common for studies to be "underpowered", failing to detect even large treatment effects because of inadequate sample size suggesting that resources may have been wasted for want of a slightly larger sample. Some ethics committees may object to recruiting patients into a study that does not have a large enough sample size for the trial to deliver meaningful information[55]. Despite the importance of appropriate sample size, only 12 studies reported the use of a sample size calculation.

It is a widely accepted rule of thumb that trials with 30 or less participants per treatment arm are unsuited to conventional statistical analysis. In fact trials with less than 15 participants per treatment arm, while useful for generating hypotheses for further research, are not at all reliable for making conclusive statements. In the present review, 78 studies used 30 participants or less per treatment arm (see Table 2.6). In fact 17 studies used 10 or less participants per treatment arm, making any kind of analysis futile (although this did not stop the investigators from conducting statistical analyses), whereas only 42 studies used more than 30 participants per treatment arm.

Table 2.6 Number of participants per treatment arm.

| No. of participants per treatment arm | No. of studies |
|---|---|
| 10 or less | 17 |
| 11–20 | 43 |
| 21–30 | 18 |
| 31–40 | 11 |
| 41 or more | 31 |

### 2.3.10 Drop-out rates

Drop-outs were reported in 79 studies, excluding studies that involved a single session of meditation and therefore failed to provide participants with an opportunity to drop-out prior to post intervention assessment. The drop-out rate varied from 0% to 55% with a mean of 18% (SD 14.75%). The mean dropout rate of 18% is somewhat high when compared to pharmaceutical trials but can be explained by the fact that meditation trials involve arduous demands on the participants such as travel to classes, daily practice, disruptions to routines and other lifestyle modification requirements. In some ways, this also represents differences between the cultures in which meditation evolved as compared to the cultures in which meditation is now being adopted.

In psychotherapy RCTs, drop-out rates appear to be considerably less. For example in a meta-analysis of 81 treatment studies, with a median 14.7 hours of treatment over 15 weeks (comparable to the meditation RCTs in this review), mean drop-out rate at post-intervention assessment was 4.7%[56]. The superior retention rates of psychotherapy trials compared to that of meditation RCTs may relate to the higher credibility of psychotherapy and orthodox psychiatry or perhaps to the possibility that patients in psychotherapy trials are more seriously ill and hence more motivated than participants in meditation trials.

On the other hand, comparing meditation to psychotherapy clinics reveals that meditation trial drop-out rates are relatively favourable when compared to those in psychotherapy practice. Many large studies of psychotherapy clinics show that the median patient drops out by the fifth session (or 5 hours of therapy) and most are lost by the tenth session, following a characteristic decay curve[57]. Garfield reports a similar pattern, with 50% of the patient cohort dropping out somewhere between the fifth and eighth hour of therapy[58]. Sledge describes drop-out rates of approximately 67% in brief psychotherapy, which were reduced by approximately half when the length of therapy was specified at the start of treatment[59]. In these studies demographic or clinical factors were insufficient explanatory factors. Admittedly, some of this may be due to selection and treatment criteria but even clinics with rigorous intake and treatment protocols appear to achieve similar drop-out rates, at about 17%[60], to those seen in this review of meditation RCTs.

### 2.3.11 Intervention period

Intervention periods varied widely. They ranged from a single session to 60 weeks. The 3 most common intervention periods were 8 weeks (25 studies), 12 weeks (14 studies) , and 24 weeks (9 studies). In 8 studies there were either single sessions of meditation or training that involved less than one week. These relatively short periods contrast with the ancient tradition of meditation which states that its benefits may take many years of practice before becoming tangible. Despite this, the demands of modern clinical trials require results in days or weeks. Therefore a balance must be achieved between the amount of time needed for the effects of meditation to become measurable versus the likelihood that participants will become non-compliant and researchers run out of resources. Researchers need to carefully select techniques that are likely to elicit detectable effects within relatively short timeframes. Given these considerations, perhaps it is not surprising that those trials that involved single sessions of meditation in which its acute effects on physiology were measured on naïve participants, showed no effects at all.

Follow-up data is important as it gives an indication of how durable the effects of meditation might be. Unlike modern Western therapeutic thinking however, meditation was not originally designed to be used as a course of treatment so much as to be part of an ongoing lifestyle thus implying that the benefits of meditation are likely to persist in the follow-up phase only so long as the person chooses to meditate regularly. Meditation instructional programs are usually relatively intense and it is therefore worthwhile determining whether changes brought on by the instructional program can be maintained when participants are left to continue unsupervised with whatever skills they have acquired in the more formal phase of their training. Given that consistent evidence for a specific effect is lacking even within the intervention phase of the studies in this review, it is even more unlikely that evidence for an effect will be detectable in the follow-up phases. Of the entire sample of studies in this review, 76 studies did not include any follow-up assessment strategies.

It might also be argued that, since researchers tend to be hampered by lack of resources, the primary question as to whether meditation has any specific effects ought to take priority over questions about the durability of its effects, if there are any. It is therefore understandable that many trials have not included follow-up assessments in their design. For this reason, it was decided that more in depth analysis of follow-up data would be of little value to the primary questions set out at the beginning of this review.

### 2.3.12 Compliance

Like any other evaluation of therapeutics, the detectable effect of the intervention will be determined by the degree to which the participant complies with the treatment. This is particularly important in meditation research because meditation requires considerable active involvement and commitment. There are several ways to assess compliance, including attendance rates at supervised treatment sessions, home-practice diaries and subjective experience reports. In this review, of the 99 studies that assessed the effects of repeated practice of meditation, 62 assessed day-to-day compliance, usually by using a home practice diary.

Compliance may also be assessed using a proxy measure such as drop-out rates.

### 2.3.13 Analysis strategy

#### 2.3.13.1 Intention-to-treat

Despite using randomization to ensure that factors which may affect trial outcomes are balanced between treatment arms, there can be no guarantee that participants who drop-out or are non-compliant also have the same balance of potentially influential factors. Thus any analysis that excludes drop-outs and non-compliant participants may introduce a bias into treatment comparisons. Intention-to-treat (ITT) analysis is a strategy designed to overcome this issue[61]. A definition of ITT is given by Bubbar:

> Intention-to-treat analysis compares study groups in terms of the treatment to which they were randomly allocated, regardless of the treatment they actually received. This preserves randomization and minimizes bias. Intention-to-treat analysis provides a conservative estimate of treatment effect; however, the underestimation can be substantial when noncompliance is high. As such, noncompliance should be kept to a minimum through the study design...intention-to-treat analysis has an important role to play in the analysis of data from randomized clinical trials as it minimizes bias and provides a better estimate of the true treatment effect.[62]

Furthermore ITT, by giving a conservative estimate of the treatment effect compared to what may have occurred if no drop-outs occurred and participants were fully compliant, can be used to develop a more realistic impression of how an intervention will perform in clinical practice. In other words ITT can be seen as a test of a treatment policy or strategy. The strength of ITT can be undermined when participants are lost to follow-up and as a result missing data must be approximated.

Disadvantages of ITT relate to the fact that treatment effects may be diluted and therefore go undetected. Similarly in trials where two treatments are compared, ITT analysis may incorrectly cause the two treatments to seem equally effective.

Alternatives to ITT include "per protocol" and "treatment received"; however these approaches are also associated with substantial risk of introducing bias into the outcomes[62].

In this review, only 24 studies reported outcomes using ITT analysis. The remaining trials used "per protocol" data. Only 23 studies (10 used ITT) compared baseline data of the "drop-out" cohort with the "completer" cohort, of which 6 reported some significant differences between the two groups. Of the 13 studies that did not use ITT but which compared drop-outs with completers, 4 reported at least some significant differences between the two groups thereby demonstrating that the risk of bias as a result of non-ITT analysis, is of considerable practical significance. The fact that the drop-out rates in meditation studies are generally high adds further importance to the use of ITT in meditation research.

#### 2.3.13.2 Appropriate statistical tests

The RCT methodology inherently requires statistical analysis methods that compare treatment groups and take into account the use of repeated measures. Despite this, 26 studies report using univariate ANOVA/ANCOVA/MANOVA/MANCOVA of pre- and post- scores (see Table 2.7). Another 14 studies provided reports that were too unclear or confusing to be confidently understood, 2 did not describe the analysis strategy at all and 2 failed to make any comparisons between the intervention arms of the study (i.e. they only reported on within-group changes and imputed between-groups differences incorrectly) (see Table 2.8). In other words 63 studies used appropriate statistical methods exclusively. Five studies used a mix of appropriate and inappropriate methods and 41 studies used methods that appeared to be entirely inappropriate to the study design.

Table 2.7 Number of studies using various appropriate statistical analyses.

| Appropriate tests | No. of studies |
|---|---|
| Repeated Measures ANOVA | 34 |
| Paired T Test of change score | 13 |
| Repeated Measures MANOVA | 7 |
| ANOVA change score | 6 |
| Repeated Measures ANCOVA | 8 |
| Repeated Measures Non Parametric Tests | 4 |
| ANCOVA change score | 6 |
| MANOVA change score | 2 |
| Repeated Measures MANCOVA | 7 |
| Regression | 1 |

Table 2.8 Number of studies using various inappropriate statistical analyses.

| Inappropriate tests | No. of studies |
|---|---|
| Univariate ANOVA | 19 |
| Unclear or confusing description | 10 |
| Univariate ANCOVA | 15 |
| Other inappropriate methods | 7 |
| Not reported | 4 |
| No between group comparisons | 3 |
| Univariate MANOVA | 1 |
| Univariate MANCOVA | 1 |

Moreover, only 4 studies reported on whether data was normally distributed. Despite the fact that all studies used multiple measures, only 15 reported using Bonferroni or some other correction for use of multiple comparison tests.

Consequently, even ignoring questions about face-validity of the control method, minor violations of the randomization process, sample size or choice of outcome measures, a substantial proportion of studies made conclusions that, after close scrutiny of the reported analysis and results, were unsupported by the data.

#### 2.3.13.3 Assessing analysis, results and conclusions

Alerted to the fact that so many studies appear to have used inappropriate statistical methods, an assessment was made of whether authors' conclusions were supported by the analysis and results of the data. It was found that in 67 studies, the conclusion was not supported. Logically, not all of these instances relate to incorrect analysis. In fact in those studies where appropriate analysis strategies were used, the authors overstated the strength of the results in other ways. This is a significant consideration given that many time-pressured journal readers will selectively read, and quote, only sections of any publication, especially the conclusion.

### 2.3.14 The Jadad score

The Jadad scoring system[63] is a widely used method of rating RCTs for basic methodological rigour. However it seems to be inadequately structured to meaningfully discern the methodological standard of meditation trials. For instance, while all trials selected were randomized, only a minority described randomization methods and none used the term "double blind". The blinding process in meditation trials is complex since it involves blinding of participants, raters, instructors, statisticians and other investigators. It also demands that the comparator intervention is properly able to control for non-specific effects. Many trials feature some of these steps and others actually feature them all. And yet the Jadad score only applies one point for this crucial but complex and multifaceted factor. Similarly, very few trials described drop-outs.

The Jadad score of the studies in this review mostly ranged between 0 and 2. Trials with high scores did not seem to be much better designed than trials with lower scores. Thus the Jadad system does not usefully differentiate between trials with a methodology of a sufficient standard to discern effects specific to meditation, and those that do not have such a methodology. Despite evaluating other methodological rating systems none were appropriately orientated to be useful in discerning meditation research.

### 2.3.15 Methodological quality

Before attempting to answer the question about whether the data in this review provides any evidence for a specific effect, it is evident that the quality of the data itself must be assessed. The heterogeneous quality of the RCTs indeed raises the question as to whether there are any trials of sufficient methodological rigour to generate outcomes that are sufficiently reliable to answer this important question.

Using the database to filter the RCTs according to various important methodological criteria produced the following results:

- of the initial 133 RCTs, 25 had to be excluded for violations of randomization
- a further 50 studies were excluded because their low to moderate face-validity control methods were unlikely to control for non-specific effects
- another 41 studies were excluded because they used less than 30 participants per treatment arm and thus the reliability of their statistical analysis was limited

- twelve studies were excluded because they used inappropriate analysis strategies

- only two RCTs remained, each reporting a mix of favourable and unfavourable outcomes.

*Therefore, taking meditation as a single genre, the evidence, or more accurately the quality of the evidence for a specific effect is weak.* More meaningful insights may be gained by more specific assessment of subgroups of RCTS according to meditation technique, control method, primary outcome measure or definition of method.

### 2.3.16 Meditation techniques

The commonest single technique to have been subjected to RCT evaluation was TM — the results of 24 RCTs having been published in English-speaking, peer-reviewed journals. This is followed by the 19 RCTs for *Mindfulness* related techniques, and 15 for *Relaxation Response*. This data is presented in Table 2.9.

Table 2.9 Numbers of studies using various different mediation techniques.

| Meditation technique | No. of studies |
|---|---|
| Miscellaneous | 28 |
| Transcendental Meditation | 24 |
| Multimodal | 28 |
| *Mindfulness* related techniques | 19 |
| *Relaxation Response* | 15 |
| Clinically Standardized Meditation | 7 |
| Not specified | 4 |
| *Sahaja Yoga* | 2 |

Twenty eight trials used a "multimodal" approach in which meditation was used as part of a "blunderbuss" of interventions woven into a single coordinated program. Most of these programs involved other practices aimed at reducing stress such as yoga postures, exercise, breathing techniques, or group support. Such approaches may be more clinically effective but the adjunctive use of non-meditative techniques obscures any effect that may be specifically attributed to the meditation component. They are therefore not useful in trying to understand the nature of meditation per se. Similarly, examining the 16 trials that were more or less based on Kabat Zinn's Mind Body Stress Reduction Program (MBSR) clearly indicates that this interventions is only one component of a larger collection of practices including *hatha* yoga, simple cognitive therapy and breathing exercises. Therefore, although the MBSR is frequently equated with *Mindfulness*, for scientific purposes it would be more appropriately relegated to the multi-modal category.

A miscellany of methods was used in 28 trials which included *mantra* meditation (3 trials), *kundalini* meditation (2 trials) , yoga meditation, ACEM, NARM, Zen, Buddhist, breathing, actualism and autogenic meditation. No technique was specified in 4 of the studies.

**2.3.17 Meditation and non-specific effects**

An examination of the reported outcomes of studies that compared meditation to low face-validity control showed that while differences in certain measures in favour of meditation were reported in 33% of comparisons, 61% demonstrated no differences. The fact that in this latter group of studies meditation was unable to generate a difference despite the fact that the control method was of low face-validity suggests that in many circumstances meditation may not even generate a non-specific effect!

In contrast, in studies that used high face-validity controls (i.e. strategies that appeared adequately to control for non-specific/generic effects of stress management interventions), there were only 19% of comparisons reported differences in favour of meditation, whereas 77% reported no favourable differences.

The influence of plausibility ("face validity") of the control method clearly has a profound effect on the pattern of outcome reported in the study. More importantly, it clearly suggests that in the majority of cases the effects of meditation are attributable solely to non-specific effects.

Table 2.10 Numbers of differences by comparison technique.

| Comparison technique | No. of studies | Positive differences | No differences |
|---|---|---|---|
| Educational materials, unstructured | 8 | 47% | 53% |
| Rest/napping | 9 | 42% | 58% |
| Waiting list/ no treatment | 58 | 33% | 67% |
| Educational classes | 16 | 32% | 67% |
| Standard treatment | 18 | 30% | 67% |
| Relaxation methods | 22 | 15% | 79% |
| Biofeedback | 7 | 5% | 95% |
| Exercise | 10 | 3% | 97% |

### 2.3.18 Meditation as a single genre versus relaxation

Progressive muscle relaxation (PMR) or similar structured relaxation exercises, was compared to meditation in 22 studies (see Table 2.10). Of these, 15% of comparisons reported effects in favour of meditation, whereas 79% reported no difference suggesting that it is generally equi-effective to meditation.

### 2.3.19 Meditation and rest or napping

Rest or napping was compared to meditation in 8 studies (see Table 2.10). In 42% of comparisons meditation was significantly more effective whereas in the remaining 58% the 2 interventions were equally effective.

### 2.3.20 Meditation and biofeedback

In 7 studies, biofeedback was compared and only one of these reported a single significant difference in favour of meditation (see Table 2.10). Whereas in 95% of comparisons no differences between meditation and biofeedback were evident. Paradoxically, 2 of the comparisons involved the *addition* of biofeedback to the meditation regime and yet detectable differences were not observed between meditation alone and biofeedback added to meditation.

### 2.3.21 Meditation and exercise

Exercise was compared to meditation in 10 studies. In all but one comparison there were no significant differences between the two interventions (see Table 2.10).

### 2.3.22 Meditation and sham meditation

Sham, placebo or imitation strategies were compared to genuine meditation in 9 studies. One demonstrated a strong positive effect when a poorly specified meditation (*maha* mantra meditation) was compared to a sham meditation and one reported a moderately positive effect when comparing a non-specific meditation to a placebo strategy. Five comparisons reported no difference between meditation and the sham procedure (2 trials of TM and 3 trials of non-specific meditation).

### 2.3.23 Comparisons of different meditation techniques

Comparisons between different meditation techniques featured in 12 trials. Of these, 5 comparisons reported no differences between techniques (TM versus either *shavasana*, TM versus *Relaxation Response*, 2 non-specific forms of meditation versus quasi-meditative practices and CSM versus *Relaxation Response*) while 2 reported strong differences (*kundalini* yoga vs a combination of *Relaxation Response* and *Mindfulness*, however the author developed the *kundalini* yoga technique) and 1 reported moderate differences (TM versus *Mindfulness*, however the author was affiliated with a TM-owned institution).

### 2.3.24 The evidence base for specific techniques

2.3.24.1 Evidence for TM

Of the 24 studies of TM, 22 were clinical trials and 2 were physiological trials assessing effects after brief training giving 37 comparisons. The author was the trainer in one study, while in 5 studies the author was employed by an institution that had formal affiliations with the TM organization. TM was compared to low credibility controls in 19 comparisons, to moderate credibility controls in 4 instances and to high credibility controls in 14 instances. Sample size ranged from 20 to 250 participants, sample size per treatment arm ranged from 10 to 78. Drop-out rates varied from 0% to 55%. In 13 studies the statistical methods were inappropriate or not clearly described and in 16 studies the author's conclusions were not supported by the analysis and results.

Of the more methodologically rigorous studies, 12 used high credibility control methods and of these in turn, 6 used 41 or more participants per treatment arm, but only one appears to have used appropriate statistical tests. In the last mentioned three-arm study, the main investigators were employed at an institution with formal affiliations to the TM organization. While the sample size was 147, no sample size calculation was given and the drop-out rate was 23.9%. The use of ITT, a fully described randomization method and a comparison of baseline measures, produced no statistical differences between groups.

With regard to TM's claim of "508 scientific studies"[64], only 24 (3%) of these were RCTs and of these, at least 6 were published by lead-authors employed by TM-linked institutions, primarily the Maharishi University of Management. Such links naturally raise questions about conflicts of interest and objectivity in the reporting of results, particularly in the light of the strongly commercialized nature of the TM technique. Control methods in the TM sponsored research were also mostly inadequate, with the commonest strategy being unstructured education. Of the 12 RCTs that are more likely to have been conducted in independent institutions 5 involved multiple comparisons resulting in a total of 17 comparisons. Of these 17, 11 used low face-validity control methods involving for example, either "standard treatment", "no treatment" or perfunctory and poorly structured strategies such as "self education" or "referral to community resources" and therefore failed adequately to control for non-specific effects. Perhaps unsurprisingly these trials each reported a number of significant effects in favour of TM. What is surprising is that even some of these trials reported only minor (but statistically significant) differences between TM and the inactive comparator, suggesting a weak effect. Of the 6 that used control methods that might have adequately excluded both placebo effects and simple relaxation, 4 reported no significant differences and 3 reported some significant difference. Two of the positive trials controlled somewhat for the simple but non-specific effects of rest, placebo and expectancy, but did not clearly adjust for the credibility and expectancy specifically associated with meditation. One trial involving comparisons of TM with another form of meditation conducted by Puente in 1981[65] offered some true control by comparing the physiological effects of TM, *Relaxation Response* and no treatment, and also provided an opportunity to test its claim as "the single most effective meditation technique"[64]**.** However, no significant differences were found in this one and only trial that satisfies all the criteria for independent scientific investigation.

By way of contrast, the only TM sponsored trial comparing 2 forms of meditation reported a positive effect in favour of meditation; the other 4 TM sponsored trials in which it was compared to relaxation-style control strategies likely to generate similar levels of expectancy, placebo and simple rest, all reported significant differences in favour of TM. Such distinctions between independent and sponsored research emphasise the need for further independent research into TM. Currently definitive, independent evidence for TM at best weak and in all likelihood is entirely absent.

2.3.24.2 Evidence for RR

The author was the trainer in 4 of the 15 studies on *Relaxation Response* which have been conducted, and in another 3 the author was in fact the developer of the technique. Twelve were clinical trials and one was a physiological trial. *Relaxation Response* was compared to low credibility controls in 9 instances, to moderate credibility controls in 7 instances and to high credibility controls in 7 instances. Sample size ranged from 15 to 387 participants, while sample size per arm ranged from 8 to 97. The drop-out rate varied from 0% to 54%. In 5 studies the statistical methods were inappropriate or not clearly described and in 9 the author's conclusions were not supported by the analysis and results.

Of the more methodologically rigorous studies, 7 used high credibility control methods and of these, only one study used 31 or more participants per treatment arm. Unfortunately inappropriate statistical tests (see above) were used, rendering its outcomes completely unreliable.

Closer examination revealed that trials using low credibility controls reported 4 comparisons with moderate to strong effects in favour of *Relaxation Response* and 2 comparisons with minimal to no favourable effects. In contrast trials with high credibility controls generated one comparison that reported moderately favourable effects, 2 comparisons with negligible to no effects and 2 in which the comparator was significantly more effective than the meditation technique. The single positive comparison was reported by authors who were both linked to and employed by the institution that developed and now markets RR-related methods. Moreover the outcome measures upon which the reports were based were self-report scores developed for that trial but had not been statistically, clinically or ecologically validated.

2.3.24.3 Evidence for *Mindfulnesss* and the MBSR

There have been 17 studies (15 using the MBSR and 2 using *Mindfulness* alone) conducted in these fields. In 3 studies, the author was the trainer and in 4 studies an author was in fact the developer of the technique. There were 14 clinical trials and one was a physiological trial. Low credibility controls in 14 instances, moderate credibility controls in 2 instances and high credibility controls in 4 instances. Sample size ranged from 17 to 165 participants , sample size per arm ranging from 8 to 72 The drop-out rate varied from 0% to 37%. In 6 studies (4 for MBSR-based *Mindfulness*) the statistical methods were inappropriate or not clearly described and in 7 (5 for MBSR-based *Mindfulness*) studies the author's conclusions were not supported by the analysis and results.

Of the studies specifically focused on the MBSR, only 3 studies used a high credibility control method. Again, there was insufficient good quality evidence to indicate whether *Mindfulness* has a specific effect.

Jain[66] compared MBSR-based *Mindfulness* to relaxation and a WL control in an RCT design to assess their effects on distress and mood. At the end of the intervention, the 2 active strategies were shown to be equivalently effective in reducing distress and improving positive states of mind. MBSR-based *Mindfulness* however, was associated with significantly less ruminative and distractive thought compared to relaxation, Although only a single study, it indicates that *Mindfulness* is as effective as relaxation but that it may achieve at least part of its effect by altering negative cognitions. However it also suggests that the clinical effect of *Mindfulness*, although different, is still no greater than the non-specific effects generated by relaxation-like methods. Moritz[25] compared a spirituality based education programme (SBEP, combining education and visualisation exercises) to MBSR-based *Mindfulness* and a WL control. At the end of the 8 week intervention analysis showed that the SBEP was almost twice as effective as the MBSR-based *Mindfulness* intervention at improving mood and mental health scores thereby suggesting that MBSR is less effective than a combination of education and visualisation. Koszycki[67] compared the MBSR to cognitive based group behaviour therapy in order to compare their relative effectiveness for the management of social anxiety disorder. At the end of the 8 week intervention period, the behaviour therapy strategy was significantly more effective than the MBSR on the most clinically important measures, and similarly effective on the remaining measures. Taken together the general picture does not support the idea that either *Mindfulness* or the MBSR has much in the way of specific effects.

A comprehensive methodologicall characterisation of each RCT assessed in this review is included in Appendix 2.

## 2.4 Meta-analytic review

As discussed above, research into the efficacy of psychological therapies is considerably more difficult than pharmaceutical trials[56]. Andrews described the then current understanding of psychotherapy in 1981:

> When reviewing a large set of controlled trials, therapists, patients, treatments, and outcome measures vary so much that the resulting detail is often too much for the human mind to encompass. What commonly happens is that the reviewer seeks to bring

> order into the chaos by progressively discarding or discontinuing studies on methodological grounds until he has a small and manageable set of studies that he believes represent the true state of affairs. Valuable data therefore are often discarded and selection biases may confound the result. A technique to synthesize existing knowledge about psychotherapy is desperately needed….[56]

These observations from 27 years ago about research into psychotherapy might equally apply to the current state of research into the effects of meditation — virtually all studies exhibit significant methodological flaws preventing confident conclusions from being made. Applying hard and fast rules of methodological rigour, based on guidelines such as the CONSORT agreement or Jadad score, clearly results in the majority of meditation RCTs being excluded from consideration. While this is in itself an indicator of the quality of the extant data, throwing the baby out with the bathwater denies us the opportunity of examining the available information for insights that could otherwise be helpful in at least developing a reasonable impression about meditation's potential effects. Or in Tukey's famous words, "It is better to have an approximate answer to the right questions rather than an exact answer to the wrong question"[68].

Indeed a meta-analytic approach, using effect sizes in combination with regression analyses can be used to partially overcome a number of the shortcomings described above and help develop the important approximate answer to the right question. The rationale behind the meta-analytic approach is that outcome measure scores will range in severity but be distributed about the mean score. After treatment the group receiving the active intervention should have changed beyond that of the comparator group. This difference can be determined by measuring the distance between the distributions of the outcome scores of the 2 groups assessed at the same time. When this difference is expressed in standard deviation units it is called the *effect size*. The advantage of using effect size is that it is independent of any specific metric or scaling properties of the outcome measure involved. Thus effect size derived from different outcome measures can be aggregated and compared statistically[69, 70].

Further to this, studies from this review were assessed for the necessary data (mean scores and standard deviations at the relevant time-points, or their non-parametric equivalents). Selection bias was reduced by using all RCTs that provided sufficient data to determine effect size. Of the *133* studies identified, 15 were excluded because of problems with randomization. A further 66 were excluded because they provided insufficient data for calculation of the relevant effect sizes. Studies were classified in several different ways, including meditation technique, clinical condition and outcome measures (and the broader constructs that they assessed such as stress, anxiety and depression). Multiple outcome measures were averaged to give a mean effect size for each construct to which they were related in order to ensure that each treated group was only represented once in the analysis for each symptom construct.

Effect sizes were calculated in accordance with Cohen's *d*[71]. Pooled standard deviations were used in the calculation[72]. Pre- and post-treatment scores of each treatment arm rather than pre- and post-treatment scores of the difference between treatment arms were used because of the significant heterogeneity of control strategies employed in various trials and hence their varying ability to generate non-specific effects.

Due to the limited number of studies that reported sufficient data to enable calculation of effect size, it was not possible to perform meaningful correlations and regression analyses. Nevertheless a number of useful observations could still be made.

First, because of the relatively small number of studies available for analysis, the many different meditation techniques were grouped into 5 thematically related categories. These were:

1. *Relaxation Response* and studies describing the intervention as based on it.

2. The MBSR and studies describing the intervention as based on it.

3. TM and studies describing the intervention as based on it.

4. Multimodal interventions of which meditation is one part, such as yoga, lifestyle strategies etc.

5. Miscellaneous, where only a few studies had been conducted on a particular technique and/or when a technique did not easily fall into one of the previous categories.

The mean effect sizes for the various categories varied widely however the degree of variation around the mean was so broad that comparison of means may not be meaningful. Median effect sizes for each category did not seem to differ significantly. This is an interesting observation given the diverse definitions, constructs and claims associated with each technique. It explains much of the homogeneity in outcomes, despite the heterogeneity of interventions and philosophies. See Table 2.11 below.

Table 2.11 Effect sizes for categories of meditation technique.

| Category of meditation technique | n | Mean ES | SD | Median ES |
|---|---|---|---|---|
| **Miscellaneous** (Zen, ACEM, Kundalini, CSM not-specified, other) | 15 | 0.61 | 1.39 | 0.36 |
| **Multimodal** | 12 | 0.62 | 0.89 | 0.48 |
| **Transcendental Meditation** (and methods based on it) | 10 | 0.48 | 0.43 | 0.33 |
| ***Mindfulness* Based Stress Reduction Programme** (and strategies based on it) | 6 | 0.48 | 0.35 | 0.47 |
| ***Relaxation Response*** (and methods based on it) | 6 | 0.58 | 0.48 | 0.43 |

Note: n = number of studies categorized, ES = effect size, SD = standard deviation

Second, when assessing the impact of meditation as a single category on outcome measures a slightly greater effect size for behavioural as compared to biological measures was evident. Within the subjective measure category, anxiety and stress-related measures were associated with the greatest effect sizes, whereas mood measures were associated with the least. See Table 2.12.

Importantly, the relative effect sizes of various control strategies were evaluated. As expected, the low face-validity category of control strategies had minimal effect sizes, whereas moderate face-validity and high face-validity strategies had effect sizes near to or similar to the meditation techniques against which they were being compared (see Table 2.13). As the various control strategies were allocated to their respective credibility categories based only on their description given in the study, the fact that their respective effect sizes stratified into similar groups provides practical support for salience of this taxonomy and the ideas that underlie its development (see Table 2.14).

Comparing the mean effect size of meditation as a single genre (M = 0.57, SD = 0.87) to the mean effect size for control strategies as a single genre (M = 0.45, SD = 1.58) using independent samples *t*-tests demonstrated no significant difference between the two groups ($t = 1.18$, df = 730).

To explore the possibility that a single subclass of meditation might be more effective than another the subclass with the highest mean effect size (“multimodal”) was compared to the subclass with the lowest mean effect size (TM) using independent *t* -tests. They were not significantly different ($t = 1.33$, df = 188).

To explore the possibility that a single technique of meditation might be more effective than another, the most frequently used techniques with data available were compared. In the database, there were 8 studies on TM (Mean effect size = 0.50, SD = 0.45), 5 on the

*Relaxation Response* (mean effect size = 0.58, SD = 0.48), and 6 on the MBSR (mean effect size = 0.48, SD = 0.21). There were 10 studies using multimodal strategies (mean effect size = 0.62, SD = 0.89) however given that the interventions in this class used a mix of meditative and non-meditative strategies it is unclear which components of the intervention are generating the measured effect. No significant differences between the effect sizes of any of these techniques were evident using independent *t*-tests and correcting for multiple comparisons.

To explore the possibility that a single subclass of control strategy might be more effective, “high face validity” was compared to “low face validity” and “moderate face validity” using independent *t*-tests, adjusting for multiple comparisons. “high face validity” was significantly different to “low face validity” ($t$ = 2.61, df = 230, $p < 0.05$). When comparing “moderate face validity” to “high face validity” there was a significant difference ($t$ = 2.38, df = 230, $p < 0.05$). When comparing “moderate face validity” to “low face validity” there was no significant difference ($t$ = 1.52, df = 256, $p < 0.05$).

Finally, when comparing meditation as a single genre with “high face validity” controls there was a significant difference ($t$ = 2.01, df = 466, $p<0.05$) suggesting that in actual fact, meditation as a single genre somehow generates a lower effect than strategies that probably only generate non-specific effects!

Furthermore, the fact that the median effect size associated with meditation is not significantly different to that of the median effect size of high credibility controls against which it is compared, can be interpreted as supporting the idea that many methods of meditation more or less rely on non-specific effects for their respective clinical and biological impacts.

Table 2.12 Effect sizes for meditation by categories of measure.

| Category of measure | n | Mean ES | SD | Median ES |
|---|---|---|---|---|
| **Anxiety and Stress** (STAI, other anxiety and other stress) | 13 | 0.90 | 0.79 | 0.70 |
| **Disease Specific QOL, and Symptoms** | 5 | 1.60 | 3.44 | 0.56 |
| **Depression** (BDI, HADS, other depression) | 3 | 0.56 | 0.16 | 0.55 |
| **Non-specific QOL** (SCL90R, SF36, other general QOL or wellbeing) | 3 | 0.49 | 0.37 | 0.44 |
| **Mood** (POMS, PANAS, other mood) | 6 | 0.52 | 0.58 | 0.36 |
| **Autonomic Measures** (Physiological BP, stressor BP, HR, ST, EDA, EMG, RR) | 7 | 0.41 | 0.86 | 0.22 |
| **All Physiological** | 22 | 0.49 | 0.45 | 0.35 |
| **All Psychobehavioural** | 33 | 0.40 | 0.34 | 0.31 |

Note: n = number of studies categorized, ES = effect size, SD = standard deviation

Furthermore, the fact that the median effect size associated with meditation is not significantly different to that of the median effect size of high credibility controls against which it is compared, can be interpreted as supporting the idea that many methods of meditation more or less rely on non-specific effects for their respective clinical and biological impacts.

Table 2.13 Effect sizes of high face validity controls by category of measure.

| Category of measure | n | Mean ES | SD | Median ES |
|---|---|---|---|---|
| **Anxiety and Stress** (STAI, BDI, HADS, other anxiety and other depression) | 15 | 0.80 | 0.78 | 0.62 |
| **Mood and Stress** (POMS, PANAS, other mood, other stress) | 7 | 0.58 | 0.58 | 0.43 |
| **Disease Specific & General QOL, Wellbeing** (SCL90R, SF36, disease specific symptoms/QOL, general QOL or wellbeing) | 8 | 0.66 | 1.40 | 0.45 |
| **Autonomic Measures** (Physiological BP, stressor BP, HR, ST, EDA, EMG, RR) | 7 | 0.41 | 0.86 | 0.22 |
| **All Physiological** | 22 | 0.49 | 0.45 | 0.35 |
| **All Psychobehavioural** | 33 | 0.40 | 0.34 | 0.31 |

Note: n = number of studies categorized, ES = effect size, SD = standard deviation

The effects of meditation on anxiety and stress are comparable to effect sizes described in conventional meta-analyses of psychotherapy field studies[73]. For example Andrews' review of psychotherapy for neurotic patients reported a mean effect size of 0.74 for verbal psychotherapy and 0.97 for behavioural psychotherapy vis-a-vis a mean effect size of 0.55 for placebo[56]. It should be noted however that the meditation studies focused on participants with non-pathological anxiety states, raising the possibility that the potential impact of meditation may be limited by a "ceiling effect" due the recruited sample's relatively mild symotomatology and hence minimal scope for clinical improvement.

Table 2.14 Effect size of control strategies by category of face validity.

| Category of measure | n | Mean ES | SD | Median ES |
|---|---|---|---|---|
| **Low Face Validity** | | | | |
| Waiting list, Standard treatment. No treatment, Community resources, unstructured reading, Structured reading, Unstructured educational materials | 37 | 0.24 | 0.35 | 0.17 |
| **Moderate Face Validity** | | | | |
| Educational classes, Exercise Journal writing, Listening to music | 12 | 0.31 | 0.30 | 0.22 |
| **High Face Validity** | | | | |
| Relaxation, rest, napping, Hypnosis, biofeedback, Visualisation, breathing, Behaviour therapy, stress, management, group therapy, Pseudo, quasi, anti-meditation | 28 | 0.91 | 2.89 | 0.49 |

Note: n = number of studies categorized, ES = effect size, SD = standard deviation

## 2.5 Conclusions

First, there is insufficient evidence to support the idea that meditation, as conceived and tested by scientific researchers in the West, is any more effective than simple relaxation or rest.

Second, the use of high face-validity control groups is critical in meditation research because of the need to exclude the important confounding effects of non-specific factors that relate to plausibility of the intervention (such as placebo, expectancy, or therapeutic contact).

Third, there is at the moment no systematic comparison of different conceptualizations of meditation. Only Carrington has compared two kinds of meditation in the context of work stress and found that there were no major differences between the two[36]. It should be noted however that the different meditations in her trial both belong in the same "relaxation meditation" category.

These observations could lead to three possible conclusions:

1. *Meditation is in fact no more effective than other approaches to rest and relaxation*. Yet that meditative traditions have existed for thousands of years and at least in India, are widely perceived to have specific and unique features. In other words history and culture do not agree with the idea that meditation is simply a method of mundane relaxation. While this "test of history" does not provide proof of efficacy, it does encourage the undertaking of a thorough examination of the phenomenon before it is discarded as mere folklore and superstition.

2. *The measures which have so far been used to assess the effects of meditation are not sensitive to the specific effects of meditation*. The wide variety of outcome measures used means that if the specific effects of meditation are not detectable, then the effects are either too small or too esoteric for mundane study. Yet classical descriptions of meditation suggest that despite the metaphysical basis of meditation, its effects do manifest themselves in mundane dimensions such as health and behaviour, implying that at least some of the many measures available to researchers should be able to detect a differential effect. Again, while this might be satisfactorily applied to the genre as a whole, there appear to be isolated exceptions which suggests that certain as yet undetermined categories may be able to generate specific effects. Yet our analysis of the aggregated data has not yet yielded a pattern with sufficient clarity to identify the features of that category.

3. *The methods that have been labelled as "meditation" in the trials do not consistently reflect the true nature of meditation.* This is the most interesting and

> important issue and therefore merits considerable discussion. The functional and conceptual definition determines the nature of the intervention, which in turn influences the choice of the control method that ought to be used and therefore the validity and generality of the findings. Yet defining meditation has proven to be a difficult challenge for modern researchers. While early empirical reports seemed to show that measurable distinctions between meditation and rest or simple relaxation existed, rigorous trials did not support these perceptions[74]. As a result, much of the research work on meditation has been based on the assumption that meditation techniques are much the same despite minor external and superficial differences. Indeed Western researchers have proposed that most meditative processes are physiologically similar to simple rest and relaxation[75] and the high quality physiological trial data seems to support this[76]. These perceptions have thus given rise to an assumption of "psycho-physiological uniformity"

This last idea, it is contended, is the key to the problem because in fact, both Western meditation enthusiasts and Western scientists, despite their opposing views, have failed to apprehend a key factor that underlies the ancient tradition of meditation: The idea that meditation necessarily involves the experience of *mental silence*. This importance of this crucial idea will be thoroughly explored in the next section of this thesis.

Table 2.15 Summary of characteristics of 118 meditation studies selected for review.

| Author | Year | n | Drop outs | Intervention Period (weeks) | Instructional Sessions (no.) | Follow-up (weeks) | Meditation Technique† | Control Method †† | Condition Assessed ††† | Main Participant Type |
|---|---|---|---|---|---|---|---|---|---|---|
| Alexander[77] | 1989 | 73 | 25 | 12 | 18 | 84 | TM, MBSR | RM, WL | wellbeing, QOL, FH, ageing, other | elderly |
| Anderson[37] | 1999 | 91 | 0 | 5 | 5 | 9 | MMTM | WL | stress/adjustment, anxiety | worker |
| Astin[32] | 1997 | 28 | 9 | 8 | 8 | - | MBSR | WL | self actualisation, stress/adjustment | uni student |
| Astin[78] | 2003 | 128 | 50 | 8 | 8 | 16 | MuMo | EC | depression, pain | female |
| Bahrke[79] | 1978 | 75 | 0 | 1 | 1 | - | RR | EX, RE | anxiety, physiological effects | male |
| Barnes[80] | 2001 | 35 | 2 | 8 | 40 | - | TM | EC | hypertension | children |
| Barnes[3] | 2004 | 156 | 56 | 16 | 80 | 16 | TM | UEM | hypertension | African American |
| Barnes[669] | 2004 | 89 | 16 | 12 | 60 | - | MBSR | EC | hypertension | children |
| Barnhofer[670] | 2007 | 34 | 12 | 8 | 8 | - | MBSR | ST | depression | other |
| Benson[75] | 1978 | 69 | 37 | 8 | 1 | - | RR | HY | anxiety | outpatient |
| Berger[81] | 1988 | 387 | 82 | 12 | 10 | - | RR | EX, EC, WL | stress/adjustment | uni student |
| Bormann[82] | 2006 | 93 | 27 | 10 | 6 | 12 | Mantra | EC | chronic illness (HIV, epi, ibs, asthma) | outpatient |
| Boswell[83] | 1979 | 80 | 0 | 2 | 0 | - | MMTM | PQ; RM; NT | anxiety, physiological effects | uni student |
| Brazier[84] | 2006 | 62 | 15 | 3 | 12 | 6, 12 | MuMo | ST | chronic illness (HIV, epi, ibs, asthma) | outpatient |
| Bruning[85] | 1987 | 86 | 21 | 10 | 184 | - | CSM | EX, EC | work stress | worker |
| Carlson[86] | 1988 | 36 | ‡ | 2 | 6 | - | Other | RM, WL | stress/adjustment | uni student |
| Carrington[87] | 1980 | 154 | 6 | 6 | 0 | 22 | RR, CSM | RM, WL | work stress | worker |
| Carson[671] | 2005 | 43 | 0 | 8 | 8 | 12 | Other | ST | pain | outpatient |
| Castillo-Richmond[88] | 2000 | 138 | 78 | 24 | 24 | 36 | TM | UR | cardiometabolic risk, heart disease not HT | African American |
| Cohen[89] | 2004 | 39 | 9 | 7 | 7 | 1,4,12 | Other | WL | wellbeing, QOL, FH, oncology | oncology patient |
| Couture[90] | 1994 | 40 | 0 | 2 | 10 | - | RRB,MuMo | BFB, NT | athletic performance | athlete |

| Author | Year | n | Drop outs | Intervention Period (weeks) | Instructional Sessions (no.) | Follow-up (weeks) | Meditation Technique† | Control Method †† | Condition Assessed ††† | Main Participant Type |
|---|---|---|---|---|---|---|---|---|---|---|
| Credido[91] | 1982 | 30 | 3 | 6 | 7 | - | CSM | BFB, RE | physiological effects | female |
| Curiati[92] | 2005 | 19 | 4 | 14 | 12 | - | MuMo | UEM | cardiometabolic risk, heart disease not HT, chronic illness (HIV, epi, ibs, asthma) | elderly |
| Davidson[93] | 2003 | 48 | 7 | 8 | 9 | 16 | MBSR | WL | physiological effects | worker |
| Deberry[94] | 1982 | 36 | 0 | 10 | 10 | 10 | MuMo | WL | anxiety, depression | elderly |
| Deckro[95] | 2002 | 128 | 38 | 6 | 6 | - | MuMo | WL | stress/adjustment, anxiety | uni student |
| Delmonte[96] | 1985 | 40 | 0 | 2 | 14 | - | MMTM | RE | physiological effects | health pro |
| Dillbeck[97] | 1977 | 33 | 0 | 2 | 4 | - | TM | SM | anxiety | uni student |
| Ditto[674] | 2006 | 32 | 0 | 4 | 2 | - | Mind | RM, WL | physiological effects | uni student |
| Dua[49] | 1992 | 32 | 3 | 4 | 6 | 6 | Other | PQ, BT, WL | other | uni student |
| Edelman[98] | 2006 | 154 | 32 | 40 | 28 | - | MuMo | ST | cardiometabolic risk,heart disease not HT | no morbidity |
| Elder[99] | 2006 | 60 | 5 | 12 | ‡ | 12 | TM | UEM | cardiometabolic risk, heart disease not HT | outpatient |
| English[100] | 1983 | 36 | 1 | 5 | 4 | - | RR | RM, WL | physiological effects | no morbidity |
| Fee[101] | 1978 | 54 | 0 | ‡ | 5 | - | Other | BFB,RM,NT,BT | physiological effects | uni student |
| Fiedler[102] | 1989 | 66 | 9 | 7 | 9 | - | MuMo | WL | work stress, stress/adjustment | worker |
| Fields[103] | 2002 | 57 | 11 | 52 | 13 | - | MuMo | EX, ST | cardiometabolic risk, heart disease not HT | outpatient |
| Galvin[104] | 2006 | 15 | 0 | 5 | 5 | - | RR | ST | academic/school performance | elderly |
| Gaston[105] | 1991 | 18 | 6 | 20 | 12 | - | Other, MuMo | WL | chronic illness (HIV, epi, ibs, asthma) | outpatient |
| Griffiths[106] | 1981 | 50 | ‡ | 3 | 6 | - | NS | BFB, NT | anxiety, Other | uni student |
| Haffner[107] | 1982 | 21 | 1 | 8 | 8 | 12 | MuMo | NT | hypertension | outpatient |
| Hager[108] | 1978 | 30 | 13 | 4 | 1 | - | RR | BFB | hypertension | outpatient |
| Hall[109] | 1991 | 30 | 0 | 7 | ‡ | - | TM | RM, NT | other | uni student |
| Harinath[110] | 2004 | 30 | 0 | 12 | 84 | - | MuMo | EX | physiological effects, athletic performance | worker |

| Author | Year | n | Drop outs | Intervention Period (weeks) | Instructional Sessions (no.) | Follow-up (weeks) | Meditation Technique† | Control Method †† | Condition Assessed ††† | Main Participant Type |
|---|---|---|---|---|---|---|---|---|---|---|
| Hiderley[111] | 2004 | 31 | 0 | 8 | ‡ | - | Other | UR | oncology | oncology patient |
| Irvin[112] | 1996 | 45 | 12 | 7 | 1 | - | RR | EC, ST | other | female |
| Jain[66] | 2007 | 104 | 23 | 4 | 4 | - | MBSR | RM, WL | physiological effects | uni student |
| Janowiak[113] | 1994 | 62 | ‡ | 8 | 7 | - | CSM | Bre, NT | stress/adjustment, self-actualisation | uni student |
| Jayadevappa[114] | 2007 | 23 | 0 | 37 | 34 | - | TM | EC | cardiometabolic risk, heart disease not HT | outpatient |
| Kabat-Zinn[115] | 1998 | 37 | 18 | 13 | 0 | - | MBSR | ST | chronic illness (HIV, epi, ibs, asthma) | outpatient |
| Keefer[116] | 2001 | 16 | 3 | 6 | 6 | 12 | RR | WL | chronic illness (HIV, epi, ibs, asthma) | outpatient |
| Kember[117] | 1985 | 20 | 4 | 24 | 1 | - | TM | ST | academic/school performance | uni student |
| Kindlon[118] | 1983 | 35 | ‡ | 11 | 13 | - | Other | RE | anxiety, academic/school performance | uni student |
| Kingston[119] | 2007 | 45 | 3 | 3 | 6 | - | MuMo | Vis | physiological effects, wellbeing, QOL, FH | uni student |
| Kirkland[120] | 1980 | 60 | 10 | 2 | 5 | - | RR | RM, WL, EC | anxiety, academic/school performance | uni student |
| Kirsch[121] | 1979 | 38 | 0 | 3 | 0 | - | RR | BT | anxiety | uni student |
| Klein[122] | 1985 | 74 | 32 | 12 | 12 | 36 | Other | GT, EX | depression | general pop'n |
| Koszyki[67] | 2007 | 53 | 13 | 8 | 9 | - | MBSR | BT | anxiety | other |
| Kumar[123] | 2002 | 67 | 0 | 7 | 1 | - | KM | WL | other | school student |
| Labrador[124] | 2007 | 103 | 19 | 16 | 23 | - | TM | EC | cardiometabolic risk, heart disease not HT, stress/adjustment | outpatient |
| Lee[125] | 2006 | 46 | 5 | 8 | 8 | - | MuMo | EC | anxiety | outpatient |
| Lehrer[126] | 1983 | 61 | 11 | 5 | 5 | 24 | CSM | RM, WL | stress/adjustment | outpatient |
| Linden[127] | 1973 | 90 | 0 | 18 | 15 | - | Other | EC, NT | academic/school performance | children |
| Malcolm[128] | 2007 | - | - | - | - | - | MBSR | WL | - | - |
| Mandle[129] | 1990 | 45 | 0 | 1 | 0 | - | RR | RE, NT | anxiety, pain, physiological effects | inpatient |
| Mccarberg[130] | 1999 | 353 | 108 | 24 | 8 | 24 | MuMo | UR | pain | inpatient |

| Author | Year | n | Drop outs | Intervention Period (weeks) | Instructional Sessions (no.) | Follow-up (weeks) | Meditation Technique† | Control Method †† | Condition Assessed ††† | Main Participant Type |
|---|---|---|---|---|---|---|---|---|---|---|
| Mccomb[131] | 2004 | 20 | 2 | 8 | 8 | - | MBSR | WL | hypertension, cardiometabolic risk, heart disease not HT, wellbeing, QOL, FH | female |
| Mcmillan[132] | 2002 | 145 | 15 | 4 | 5 | 48 | Mind | EX, ST | other | inpatient |
| Moadel | 2007 | 128 | 36 | 12 | 12 | - | MuMo | ST | oncology | oncology patient |
| Moritz[25] | 2003 | 165 | 18 | 8 | 8 | 4 | MBSR | Vis, WL | stress/adjustment, wellbeing, QOL, FH | general pop'n |
| Murphy[133] | 1986 | 60 | 17 | 8 | 24 | 6 | CSM | EX, NT | substance abuse | uni student |
| Oken[134] | 2004 | 69 | 12 | 24 | 24 | - | MuMo | EX, WL | chronic illness (HIV, epi, ibs, asthma) | outpatient |
| Oktedalen[135] | 2001 | 29 | ‡ | 24 | ‡ | - | ACEM | ST | physiological effects, athletic performance | athlete |
| Oman[136] | 2006 | 61 | 3 | 8 | 8 | 8,19 | Other | WL | stress/adjustment | health pro |
| Ottens[137] | 1975 | 57 | 3 | 10 | 10 | - | TM | BT,WL | substance abuse | uni student |
| Panjwani[138] | 2000 | 32 | 0 | 24 | 36 | - | SYM | PQ, WL | chronic illness (HIV, epi, ibs, asthma) | outpatient |
| Parker[139] | 1978 | 30 | 0 | 3 | 9 | - | RR | RM, RE | substance abuse | male |
| Patel[140] | 1981 | 204 | 12 | 8 | 8 | 208 | MuMo | UEM | hypertension, cardiometabolic risk, heart disease not HT | worker |
| Puente[141] | 1980 | 60 | 3 | 3 | 7 | - | TM | BT, WL, RM | stress/adjustment | general pop'n |
| Puente[65] | 1981 | 47 | 3 | 1 | 6 | - | TM, RR | ST | physiological effects | general pop'n |
| Puryear[142] | 1976 | 218 | 59 | 4 | 0 | - | Other | ST | anxiety | no morbidity |
| Rausch[683] | 2006 | 387 | 0 | 1 | 2 | - | CSM | RM, RE | - | uni student |
| Sawada[38] | 1988 | 24 | 6 | 1 | 2 | - | Other | RM | physiological effects | health pro. |
| Schneider[143] | 1995 | 127 | 16 | 12 | 9 | 12 | TM | RM, EC | hypertension | African American |
| Schneider[144] | 2005 | 197 | 47 | 12 | 6 | 52 | TM | RM, UEM | hypertension, cardiometabolic risk, heart disease not HT | outpatient |
| Seer[145] | 1980 | 41 | 3 | 5 | 5 | 12 | MMTM | PQ, NT | hypertension | outpatient |

| Author | Year | n | Drop outs | Intervention Period (weeks) | Instructional Sessions (no.) | Follow-up (weeks) | Meditation Technique† | Control Method †† | Condition Assessed ††† | Main Participant Type |
|---|---|---|---|---|---|---|---|---|---|---|
| Sephton[146] | 2007 | 91 | 23 | 8 | 8 | 8 | MBSR | WL | pain, depression | female |
| Shannahoff-Khal[147] | 1999 | 21 | 7 | 12 | 48 | 60 | KM | - | other | outpatient |
| Shapiro[148] | 1998 | 78 | 5 | 8 | 7 | - | MBSR | WL | stress/adjustment | uni student |
| Sharma[149] | 2006 | 30 | 0 | 8 | 24 | - | SYM | WL | depression | outpatient |
| Sheppard[150] | 1997 | 44 | 12 | 12 | 24 | 140 | TM | SM | work stress | worker |
| Smith[151] | 1976 | 139 | 61 | 24 | 12 | - | TM | PQ, WL | anxiety | uni student |
| So[152] | 2000 | 99 | 0 | 52 | 250 | - | TM | ST | academic/school performance | school student |
| Solberg[153] | 1996 | 25 | 0 | 7 | 7 | 52 | ACEM | NT, ST | athletic performance | athlete |
| Solberg[154] | 2000 | 39 | 8 | 24 | 7 | - | ACEM | BFB, UEM | athletic performance | athlete |
| Speca[155] | 2003 | 109 | 6 | 7 | 7 | 24 | MBSR | WL | oncology | oncology patient |
| Targ[156] | 2002 | 181 | 51 | 12 | 24 | - | MuMo | EC | oncology | oncology patient |
| Taub[157] | 1994 | 250 | 132 | 24 | 47 | 52 | TM | BFB, O, ST | substance abuse | male |
| Taylor[158] | 1995 | 10 | 0 | 10 | 20 | 4 | MuMo | NT | chronic illness (HIV, epi, ibs, asthma) | inpatient |
| Teasdale[159] | 2000 | 145 | 13 | 60 | 12 | 52 | MBSR | NT | depression | outpatient |
| Tlozcynski[160] | 1997 | 7 | 0 | 3 | 1 | - | NS | HY | other | uni student |
| Tlozcynski[161] | 1998 | 75 | 13 | 6 | 1 | 3 | Zen | RM, WL | stress/adjustment | uni student |
| Tsai[162] | 1996 | 137 | ‡ | 1 | 3 | 3 | MuMo | EC | work stress | health pro |
| Vedanthan[163] | 1998 | 17 | 0 | 16 | 48 | - | MuMo | WL | chronic illness (HIV, epi, ibs, asthma) | uni student |
| Wachholtz[689] | 2004 | 84 | 16 | 2 | 1 | - | Other | RM | physiological effects | uni student |
| Weinstein[164] | 1992 | 76 | 24 | 5 | 1 | - | NS | RM | anxiety | uni student |
| Weissbecker[165] | 2002 | 91 | 23 | 8 | 9 | - | MBSR | WL | pain | female |
| Wenk-Sormaz[166] | 2005 | 132 | 12 | 2 | 2 | - | Zen | RE, EC | other | uni student |

| Author | Year | n | Drop outs | Intervention Period (weeks) | Instructional Sessions (no.) | Follow-up (weeks) | Meditation Technique† | Control Method †† | Condition Assessed ††† | Main Participant Type |
|---|---|---|---|---|---|---|---|---|---|---|
| Wenneberg[167] | 1997 | 66 | 27 | 16 | 6 | - | TM | UR | physiological effects | male |
| Williams[168] | 2001 | 103 | 28 | 8 | 9 | 12 | Other | UR | work stress | general pop'n |
| Williams[169] | 2005 | 58 | 17 | 8 | 2 | 60 | MuMo, other | O, NT | chronic illness (HIV, epi, ibs, asthma) | inpatient |
| Wilson[170] | 1975 | 25 | 4 | 12 | 1 | 12 | TM | UEM | chronic illness (HIV, epi, ibs, asthma) | outpatient |
| Wolf[50] | 2003 | 93 | 32 | 4 | 1 | 4 | Mantra | NT, PQ | other | general pop'n |
| Woolfolk[171] | 1976 | 32 | 8 | 4 | 4 | 6 | Zen | RM, WL | other | general pop'n |
| Woolfolk[172] | 1981 | 60 | 0 | 1 | 1 | - | Mantra, other | - | physiological effects | uni student |
| Wood[173] | 1986 | 32 | 3 | 1 | 0 | - | TM | RE | physiological effects | uni student |
| Yen[174] | 1996 | 392 | 93 | 8 | 8 | - | MuMo | O, NT, UEM | hypertension | outpatient |
| Yuille[175] | 1980 | 136 | 34 | 12 | 4 | - | TM | PQ, EX, NT | academic/school performance | uni student |
| Zuroff[176] | 1978 | 61 | 1 | 9 | 6 | 1-4 | TM | NT, RM | anxiety, stress/adjustment, substance abuse | uni student |

† **Techniques: ACEM** = ACEM meditation, **CSM** = clinically standardized meditation, **KM** = *Kundalini* Meditation, **MBSR** = mindfulness-based stress-reduction and similar, **Mind** = mindfulness only, **MMTM** = mantra meditation TM based, **MuMo** = multimodal, **NS** = not specified, **RR** = relaxation response, **RRB** = relaxation response based, **ST** = Standard treatment, **SYM** = Sahaja Yoga meditation, **TM** = Transcendental meditation

†† **Control methods: BFB** = biofeedback, **Bre** = breathing, **BT** = behavioural therapy, **EC** = educational classes, **EX** = exercise, **GT** = group therapy, **HY** = hypnosis, **NT** = no treatment, **O** = other, **PQ** = pseudo, quasi-, anti-meditation, **RE** = rest/napping, **RM** = relaxation method, **SM** = stress management, **SR** = structured reading, **ST** = standard treatment, **UEM** = educational materials- unstructured, **UR** = community resources/unstructured reading, **Vis** = visualisation, **WL** = waiting list.

††† **Conditions Abbreviated: FH** = functional health, **HT** = hypertension

‡ unclear data reported.

# Chapter 3. Cultural Background to Meditation

> …all meditative techniques [are] culturally embedded. This means that any specific technique cannot be understood unless it is considered in the context of some particular spiritual tradition, situated in a specific historical time period, or codified in a specific text according to the philosophy of some particular individual[177].

## 3.1 Overview

The Western scientific and health community of scientists and clinicians has generated in excess of 3,000 peer-reviewed articles on or referring to meditation (as featured in the major bibliographic databases such as MEDLINE and PsycINFO). Figure 3.1 illustrates the accumulation rate of journal articles that feature information on meditation in MEDLINE alone. However, despite this impressive accumulation of publications, Figure 3.2 shows the number of RCTs of meditation published per year—studies that would be regarded as serious explorations of meditation's effects—and this reveals a different story. The maximum yearly output was in 2000–2001 when 12 RCTs were reported in MEDLINE. In the same time period 106 RCTs for fluoxetine, as an example of a mainstream medication, and 98 RCTs for acupuncture, as an example of a complementary medicine, were published. The rate of publication of RCTs on meditation is poor in comparison to other therapeutic modalities in either the mental health or complementary and alternative medicine genres. Thus although meditation is often a topic of superficial discussion amongst scientists and clinicians, it is rarely the subject of in-depth scientific examination. An important fact is that reviews of the RCT database consistently fail to provide reliable proof that meditation has any specific health benefits[10].

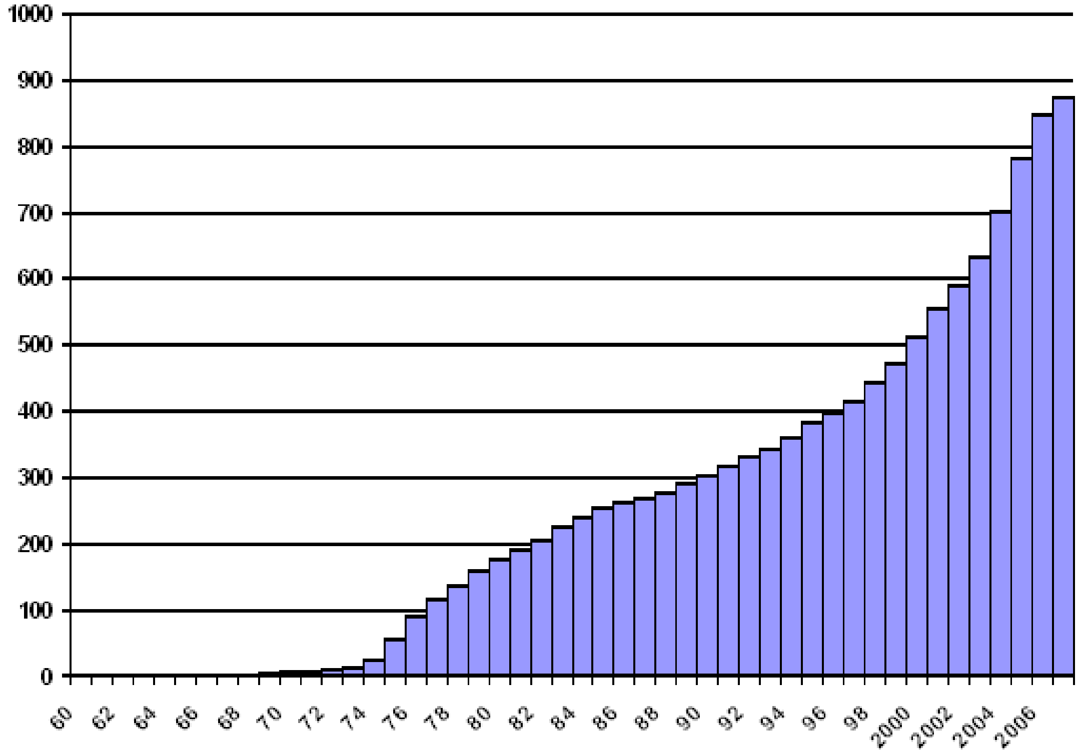


Figure 3.1 Number of citations in MEDLINE per year with "meditation" keyword.

In Section 3.2.1, below, I suggest that the reason for this imbalance between superficial vis-á-vis in-depth examination may be because both health practitioners and health consumers in the West have found in meditation ideas and practices that are philosophically attractive but difficult to scientifically justify. For the purposes of this thesis, the West is understood culturally and sociologically as including Europe, North America, Australia, New Zealand and any culture that has adopted their ideas as part if their self identity[178].

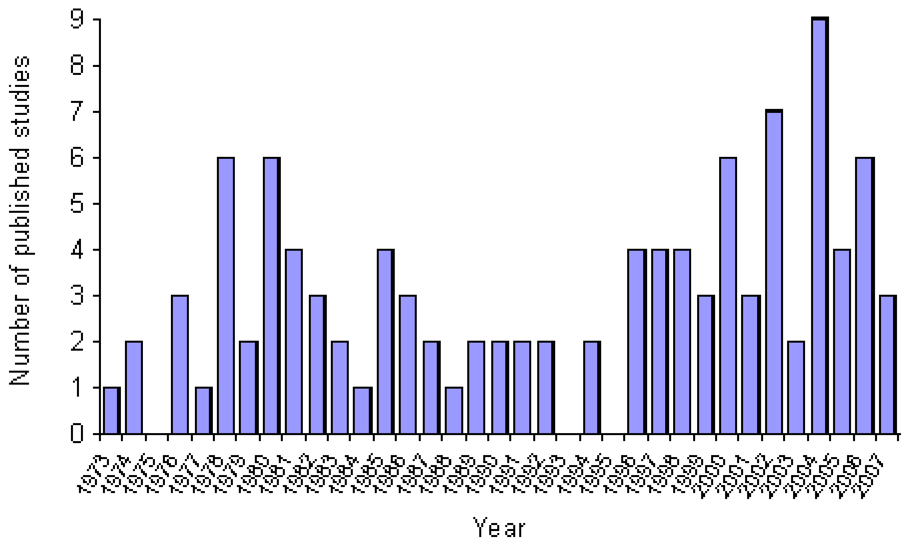


Figure 3.2 Number of meditation studies published per year in MEDLINE database.

One of the central themes of this thesis is that the failure of the proponents of meditation in the West to produce conclusive data on its specific efficacy in the health sphere, has been due to understandings having been largely confined to Westernised versions of the practice. Such understandings have meant that the original ideas about meditation as developed in South Asia and particularly on the Indian sub-continent, have been substituted by more culturally accessible but less effective Western concepts. Thus, the hypothesis being proposed in this thesis is that any solution to the current scientific impasse needs to involve a re-examination of the cultural contexts in which meditation is practiced. Of particular importance in this regard are South Asian cultural themes embodied in ideas such as *yoga, moksha*, and *sahaja.* It is argued that Western conceptualizations and definitions of meditation need to be reshaped to more accurately reflect the original meaning of the practice, particularly the experience of *mental silence*.

## 3.2 Popularity of meditation in the West

The rise of Western "pop culture" and "alternative lifestyles" in the 1960s, was a crucial social change that led many Western consumers to dabble with spiritual ideas and practices, especially meditation. Symbolizing this development was the Beatles' much-publicised trip to a meditation retreat in Rishikesh, India. The fact that the Beatles left the retreat in disappointment and acrimony not long after their arrival[179], serves to illustrate the other side of this social phenomenon; that the ancient tradition has been misused by entrepreneurs and cultic organizations who have exploited Westerners' naiveté and ignorance of the historical, philosophical and cultural context from which meditation emerged.

Meditation is widely perceived in the West as an effective method of reducing stress, and enhancing wellbeing. In Australia, a survey conducted by Kaldor of a randomly selected but representative sample drawn from the state of Western Australia (n=1,033) found that 11% of respondents had practiced meditation at least once[2]. The Australian Community Survey (ACS), conducted by the National Church Life Survey[180, 181] found that 1.5 million Australians had tried meditation within 12 months of the time of the survey and that while 29% of those surveyed found prayer to be a source of peace and wellbeing, 24% had used meditation to achieve the same effect! Only 21% reported church attendance as a source of peace or wellbeing. In fact the ACS reports that although only about 20% of Australians attend church monthly or more often "around 33% of Australians pray or meditate at least weekly"[180, 181].

This situation in Australia reflects trends in other Western countries. In 2002 a National Health Interview Survey (NHIS), undertaken by the Centers [sic] for Disease Control and Prevention (CDC) in the United States administered to 31,000 representative adults, demonstrated that 8% of respondents had practiced meditation at some time[3]. That biomedically trained physicians in Australia were also advising patients about the therapeutic effects of meditation, was demonstrated when Pirrotta conducted a survey of Australian GPs in 2000[1]. She found that almost 80% of respondents had recommended meditation to patients at some time during the course of their practice, even though less than 35% had any formal training or education in the field[1]. This reflects, on the one hand, the growing legitimacy of what was once regarded as a fringe concept and on the other, the paucity of quality education in the field. More recent surveys about the status of meditation in the perception of general practitioners have produced revealing results. For instance, a survey of GPs reported by Cohen et al. in 2005[182]found that:

- 82% regarded meditation as moderately or highly effective with low risk for harm, whereas only 3% regarded it as occasionally or frequently harmful
- 23% were either self taught or had only attended an introductory workshop on meditation, while a mere 3% had formal training such as part of a certificate, diploma or degree
- 51% said they would like to receive some form of training or had already done so over the previous 12 months for personal use
- 40% affirmed that they had either used it over the previous 12 months or would consider using it in their practice
- 65% said they would actively encourage any patient who raised the topic to practice meditation
- 9% had suggested the use of meditation at least once per week or more, while 56% had suggested it at least once per month.

While there is no hard data, it seems reasonable to assume that endorsement of meditation practice by a good proportion of physicians is likely to be seen as tacit approval by consumers.

## 3.3 Meditation and alternative health

The burgeoning legitimacy of meditation reflects a larger social trend in favour of alternative health practices. Complementary and alternative medicine (CAM) has been defined by Pirotta et al. as a:

> …group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine[1].

The CDC survey cited above showed that 36% of US adults aged 18 years and over were using some form of CAM at the time. When prayer specifically for health reasons was included in the definition of CAM, the number of adults using some form of CAM over the previous year rose to 62%. Other studies indicate that visits to alternative therapists outstripped those to mainstream doctors[183].

The reasons that consumers cited for this significant defection from the mainstream biomedical paradigm appeared to reflect increasing disillusionment with what may be termed "scientism" and increasing enthusiasm about ideas that promoted more holistic, even spiritual understandings of health, wellbeing and “individual purpose”. Bakx proposed that many had concluded that modernity, as embodied in science and biomedicine, was a failed social experiment[184]. If his conclusions were valid, there appeared to be a general searching for a post-modern philosophy in which nature (and the cosmos) was perceived as benevolent and individuals were able to take control of their own health and personal development. Another key survey by Richardson in 2004 suggested that while mainstream healthcare focused on the exclusion of major disease and the development of lifesaving technologies, consumers were becoming increasingly interested in an experience of positive health and wellbeing[185]. Astin postulated that alternative medicine seems to offer clearly defined (although not necessarily verifiable) methods by which consumers could cultivate such experiences. This trend appears to be driven by well-educated affluent consumers, and suggests that the movement away from medical orthodoxy is being driven by educated choices rather than ignorance or gullibility[186].

Within this context, the yogic idea that one's state of mind, if not one's level of consciousness, is a major determinant of one's general health conveniently combines a number of fashionable notions from popular psychology, alternative medicine and New Age spirituality. Thus it is not surprising that many relatively well educated and discerning Western consumers are attracted by the promise of yoga or meditation as therapeutic tools.

Seemingly, as a result of these influences the mass media, organizations and a plethora of self-described "experts" are promoting meditation as a universal panacea. For instance, in 2002 *Time* magazine ran a feature issue on meditation, in which the question was posed as to why it was becoming so popular. The answer was given in a subheading: "Because it works"[187]. Commercialized meditation techniques frequently promote themselves as "cure-alls". A notable example is the Transcendental Meditation organization which promotes its proprietary technique as:

> the single most effective meditation technique available for gaining deep relaxation, eliminating stress, promoting health, increasing creativity and intelligence, and attaining inner happiness and fulfilment…

The organization goes on to claim that:

> The effectiveness of the Transcendental Meditation program has been validated by over 500 scientific studies at more than 200 independent research institutions in 30 countries[64].

It is worth noting that basic instruction in the TM technique costs in excess of AU$1,200[8]. Despite these claims, when Canter reviewed the experimental data relating to TM's effect on blood pressure (BP) and hypertension (HT) (parameters associated with the most frequent and impressive reports on TM in the medical literature) he found that of the many positive trials boasted by the organization's promotional material, only six had used a randomized control design and that all of these featured authors with clear financial affiliations with the TM organization. Of these, none generated convincing outcomes although they all reported minor positive outcomes[188]. Clearly, objective evaluation of the extant data reveals a different picture to that depicted in mass media and advertising. This raises the question of whether the promotion of meditation as a universal panacea is realistic, reasonable or indeed ethical.

### 3.3.1 Decline of institutional Christianity and the rise of New Age religion

In his study of 1,599 members of the baby-boomer generation conducted in the US in the early 1990s, the American researcher Roof (1993) demonstrated that there had been major defections from organized religion in the 1960s and 1970s, coupled with an increase in New Age type movements which emphasized the superiority of direct spiritual experience over institutional religion. Roof found that one well-educated segment ("highly active seekers") of this group, was specifically focused on developing a highly individualized spirituality that rejected religious orthodoxy and instead favoured mystical experience and New Age ideas. They characterized themselves as "spiritual" but not "religious"[189] It is this generation that appears to have driven the rising legitimacy of meditation in the West. The perspective of these highly active seekers is now reflected in wider social attitudes and perceptions of religion, as seen in data presented in the next several paragraphs.

For instance, the National Church Life Survey (see http://www.ncls.org.au/) is an ongoing research program aimed at understanding Australian religious life and particularly investigating the substantial decline in mainstream church attendance. Described by the socially active Anglican organization Anglicare, as "an immense cooperative research venture designed to resource congregations for mission,"[190] it is essentially sociological examination, market research and intelligence gathering exercise supported by a cartel of the major churches. The survey methodologies are scientifically robust and have provided some important insights into the nature of contemporary Australian spirituality. For instance, the survey found that although 74% of Australians professed to believe in some form of deity, only 19% currently attended church at least monthly. Between 1996 and 2001, overall weekly church attendance declined by 7%, with the Catholic Church experiencing a 13% decline in attendance rates. Overall, frequent church attendance declined from 45% of the population in 1950 to 20% in 1980.

Surveys of general attitudes to churches as institutions, also show some significant features. The Australian Community Survey (part of the NCLS) found that while 17% of Australians were positive or sympathetic towards churches, 27% were unsympathetic if not antagonistic and 36% were neutral or apathetic. The most commonly stated reason (42%) for not attending church is that it was boring or unfulfilling while the second most common reason (35%) was disagreement with the beliefs propounded in the churches. In line with this was a loss in public confidence in churches, and institutions in general; for instance, in 1983, 56% of respondents indicated that they had confidence in the churches but by 1998 this figure had fallen to 39%[181].

Many activities have been substituted for church attendance. For example 18% of respondents said they often or occasionally sought direction from a horoscope, 9% practiced meditation of one kind or another and 7% used psychic healing or crystals. For obvious reasons the Christian authors downplayed these statistics, stating that "overall such practices are not as widespread as many Christian religious practices"[181] But this fails to take into account the fact that meditation probably only became part of the average person's lexicon in the 1970s. Judging from the gradient upon which interest in meditation and similar practices is growing its popularity may outstrip church adherence within a single generation.

## 3.4 Meditation as understood in the East

So, despite the scientific establishment's equivocal conclusions about the efficacy of meditation, positive perceptions are evident among the Western lay population because of the increasing popularity of the philosophy, metaphysics and folklore associated with the ancient and traditional Indian ideas of meditation[191]. So it is important to develop an understanding of meditation, in the words of Taylor in the context of its:

> particular spiritual tradition, situated in a specific historical time period, or codified in a specific text according to the philosophy of some particular individual[177].

While the biomedical Cartesian worldview that developed in the West from the mid-19th century weakened the connection between health and spirituality, this did not occur in India. There strong associations between health and spirituality were made and utilized to promote better physical wellbeing and quality of life. Typical of this health philosophy was the practice of yoga, which combined spiritual teachings with more mundane health factors such as lifestyle, diet, physical exercise and positive psychology in order to achieve its ultimate aim, the development of consciousness (this will be explained at greater length below). Similarly, the ancient and still widely used Ayurveda health epistemology was used to cure illness and enhance wellbeing by combining spiritual practices such as meditation, mantras and prayer with lifestyle measures such as exercise, diet and massage. Proponents of this epistemology also advocated the use of an extensive herbal pharmacopoeia, while its diagnostic system was based on psychological predisposition and personality type[192]. In fact the followers of Ayurveda proposed a perspective of the human corpus in which the mind was not contained within the confines of the brain, as in Western perceptions. Instead, it was seen to be closely intertwined with the physical body, thus forming a body-mind whole[193, 194] in which physical health status was seen to be a direct reflection of consciousness and vice versa[195, 196].

## 3.5 The meaning of yoga

Thus while Western consumers generally perceive yoga as a system of physical exercises, the tradition is quite different. The term is derived from the Sanskrit *yoga,* meaning "to join" or "union"[197]. Its aim was and is to achieve the perfect union of body, mind and spirit through a system of physical, mental, behavioural and ethical disciplines. These notions form the fundamental underpinnings of Indian culture and thinking.

### 3.5.1 Interconnectedness of body and consciousness in yoga

The system of yoga is thought to have developed progressively over thousands of years but it nevertheless became mostly strongly associated with a single person, Patanjali, who was both a mystic and physician. In his definitive treatise, the *Yoga Aphorisms of Patanjali,* he describes a single, comprehensive integrated system.

At the physical level the aim of yoga is to condition the physical body by using dietary regulation, physical exercises and hygienic practices. In addition to this however, the important relationship between body, mind and behaviour is acknowledged in yoga. It thus promotes practices aimed at exploiting their interconnectedness. Practices such as ethical conduct, pacifying the mind through the cultivation of positive feelings, withdrawal of the senses, the use of cognitive techniques such as concentration exercises and psycho-spiritual exercises such as meditation, might seem purely psychological or behavioural. In fact, they are intended to act on the physical body via subtle energy pathways that mirror modern understandings of the autonomic nervous system. Similarly, practices such as posture-based exercises (*asanas*), breathing control exercises (*pranayama*), may seem physical in nature, and indeed have been mistakenly interpreted by many Western consumers in precisely this way, but are actually intended to modify the workings of the psyche and soul via the same pathways.

In fact, exploratory scientific assessment of specific yogic psycho-physiological practices has yielded promising exploratory data suggesting effects on autonomic system activity, brain function and even specific cognitive task performance[198]. For example, studies of regular yogic practices have been associated with improvement in cardiorespiratory[199] and thermoregulatory[200] functions, body flexibility, and cerebral functions such as mental performance, memory improvement and creation of a sense of wellbeing[201]. Normal healthy participants practicing yoga for a short period appear to improve lipid and carbohydrate metabolism[202], cardiorespiratory performance[203], and cerebral functions. These strategies may therefore not only be preventative but could potentially also be remedial and therapeutic, as the ancient texts attest and as modern yoga therapists will assert. At the moment however, more extensive empirical evaluation of these phenomena in Western institutions is limited by methodological difficulties and a paucity of funding.

Psychologically speaking, the objectives of yoga mirror those of conventional methods designed to enhance self-control and self-regulation. For example, yoga-psychology proposes that negative-affect states, even transient ones, are pathological states of mind. Such states include gloominess, doubt, procrastination, sloth, attachment, hallucination, inability to concentrate and instability**.** Ideas like this delineate an understanding of health that, like the contemporary trend toward holism and wellbeing, extends beyond detection of diagnosable disease to include the day-to-day experience of the average person. This subtle perception of mental wellness has been mirrored in Western culture by schools of thought such as "mental hygiene"[204] "emotional intelligence"[205] and "positive psychology"[206].

### 3.5.2 Yoga as the path to *moksha*

Personal growth in ancient India was specifically defined in terms of spiritual development towards a state of complete union with ultimate reality, a state called *moksha* (liberation). This core theme underpins not only Indian ideas on meditation, but also the general culture. Moksha is achieved when a person has overcome all tendencies to immoral, unethical and self-destructive thoughts and behaviour. False identifications with the body, possessions and social status are abandoned in favour of a deeper self-understanding. The attainment of this unitive state is the culmination of a lifetime (or more traditionally, *lifetimes*) of discipline and psycho-spiritual development and is described in terms of a fundamental and profound reorientation of one's awareness, value systems, motives, sensorial experience and level of consciousness. The path by which the aspirant travels towards this goal has long been understood in India as the discipline and lifestyle embodied by the yoga/meditation tradition. Within this system meditation was not defined as a technique so much as a specific experiential state. Through the meditative experience mystics, yogis, meditators (the terms are interchangeable) progressed along a continuum of ever more profound levels of awareness until they attained full knowledge of ultimate reality, a goal that transcends the ideas of mundane health and which, according to Goleman, might be understood as:

> …an alchemy of the self: the diffusion of the effects of meditation into the meditators' waking, dreaming and sleep states…as the states produced by his meditation meld with his waking activity, the awakened state ripens. When it reaches its full maturity, it lastingly changes his consciousness, transforming his experience of himself and of his universe[207].

Jung described this same phenomenon as "individuation"[208].

### 3.5.3 The yogic mechanism

Of great interest is that the yoga tradition does not just describe philosophical, moral, metaphysical associations between mind, behaviour and health but actually describes the mechanism by which they are interconnected. This is the system of *chakras* (energy plexuses) and *nadis* (energy channels)[209]. Described since ancient times, the physical body is said to be energized via a complex network of 72,000 *nadis* and their associated *chakras*, not unlike the ancient Western understandings of the four "humors"—blood, bile, phlegm and pneuma. Yogic exercises and disciplines are directed at manipulating the subtle energetic system in order to bring about shifts in energy flux which not only impact on physical function, but also on cognitive style, mood and consciousness[210].

States of enlightened consciousness, whether they be described as self-realization, *moksha* or *sahaja* can be characterized by the awakening of an energy called *kundalini*. This energy is said to lie dormant at or near the base of the spine. At the time of awakening it rises through the spine to enter the brain and then exit via the crown of the head[197]. The *kundalini* has been described variously and has been compared to many other psycho-cultural and archetypal symbols[210]. For a useful diagramme, see Subbarayappa, 1997[211].

The ancient subtle-energetic mechanics of the *chakra* system may offer important clues in the quest to comprehensively describe and integrate the otherwise rather disparate psycho-physiological pathways that are coming to be recognized in modern science. Unfortunately further exploration of this fascinating field is beyond the scope of this thesis.

### 3.5.4 Classical perspective on meditation

In antiquity, knowledge and skills regarding meditation were passed on from spiritual master (*guru*) to aspirant (disciple) on a one-to-one basis. This knowledge was unwritten and maintained by word of mouth and direct experience. Later it was documented in Sanskrit which was accessible at first only by members of mystical schools and later only by the elite *Brahmin* stratum of society. Beginning in the 13th and 14th centuries CE texts in the local vernaculars describing the mechanism and methods of meditation, of which the *Jnaneshwara*[212] is the most famous example, became available to the wider community. Thus notions derived from meditation eventually became the stuff of everyday culture in India and as mystics, sages and scriptures travelled to other parts of Asia this spiritual culture was propagated and constantly revitalized throughout the East.

Within the yoga tradition, meditation is defined as an experiential state of awareness specifically involving control over all aspects of mental activity. Feuerstein explains that “the initial purpose of meditation is to intercept the flux of ordinary mental activity"[197]. He translates Patanjali's explanation from the *Yoga Sutras* (aphorism 1.2) as follows: "Yoga is the control of the fluctuations of the mind" (p98).

In this paradigm the highly developed meditator is not only less stressed and more relaxed but also experiences beneficial effects on health[211] and psyche[213], having activated a previously latent potential for positive psychology[214] and optimized wellbeing[198].

The mental complexities with which one gradually becomes encumbered as one progresses through life can be loosely termed as "mind" and they increase in strength as one becomes more involved in the mundane. Yogic systems in fact identify the mind as not only the source of "illusion" that prevents perception of reality, but also as the ultimate source of disease. According to the yogic tradition the true aim of life is to resolve these complexities and therefore progress toward a more profound understanding of one's self. Feuerstein[197] translates the passage of the *Yoga Bhishya* (1.1) in which the five fundamental behaviour patterns of the mind are described as follows:

1. *mudha* – dullness;
2. *kshipta* – restlessness;
3. *vikshipta* – being intermittently distracted;
4. *ekagra* – being focused
5. *niruddha* – a state of control.

The order in which these states are cited is important; indicating a hierarchy in which the controlled mind is the most preferable. The Guru is traditionally seen as someone who, having mastered his own mind and soul, sets out to help others do the same.

#### 3.5.4.1 The taming of the mind

The ideas of yoga, *sahaja*, self-realization and meditation orbit around another central theme in the spiritual culture of the East which, simply put, relates to the idea that one's perception of true reality is obscured by one's own mental complexities (preconceptions, emotions, opinion and intellect). Meditation represents the opposite condition to mental complexity because its essential element is the experience of a trans-mind state.

For example, the Hathayogapradipika is a tract of almost 400 verses on the so-called *Hatha Yoga*. The first chapter of the Hathayogapradipika describes a variety of bodily postures, diet and general topics. The second deals with the control of the life force to be achieved by breathing exercises. The third chapter describes the 10 *mudras* which are said "to destroy ageing and death". The fourth chapter describes the liberating experience of *Samadhi* (a meditative state) which is the culmination of the whole training process wherein "...when the "great force", i.e. *kundalini* is awakened, the life force dissolves and mental activity ceases"[215].

#### 3.5.4.2 Beyond thought

Systems such as yoga/meditation are designed to facilitate that vital transition from the state of mundane, every-day consciousness, primarily characterized by the subjective interference of the poorly controlled mind, to spiritual consciousness characterized by an awareness of the objective reality that exists beyond the mind. Almost as a by-product, ideal mental and physical health become possible as the complexities of the mind are progressively resolved by the *mental silence* of the trans-thought experience.

The yogic idea of *mental silence* therefore implies first, that taming of the mind is the key to successful personal development and second, that the untamed mind is a fundamental factor in the development of disease. These ancient ideas are reflected in modern scientific evidence which demonstrates the deleterious impact of stress and negative affect (emotion/mood) and the constructive impact of positive moods on health. In fact this evidence forms the basis of modern theories such as the bio-psychosocial model of health, positive psychology (and specifically the ideas of mental hygiene, flow state[216], peak experience[217] and plateau experience[218]) and the religion–health connection (to be discussed later)[219]. It represents a development of the idea of psychosomatic disease postulated in the 1970s[220], psychoneuro-immunology and mind-body medicine (also to be discussed later).

So while the immediate aim of yoga is positive psychological adjustment and good physical health in everyday life, the ultimate goal is the practical realization of religious ideals of behaviour and the attainment of a state in which they are expressed spontaneously and effortlessly. This is called the *sahaja* state, a form of *moksha* in which the yogi attains the highest states of consciousness but nevertheless remains aware and involved with the mundane, although in a very different way. Feuerstein puts it another way:

> The spiritual purpose of meditation, however, is not to achieve either physical or mental wellbeing or higher forms of cognition…meditation is never an end in itself. It is simply intended to prepare the ground for the recovery of one's true identity, which is the everlasting Spirit.[197]

## 3.6 Historical descriptions of *mental silence* and trans-mind states

Trans-mind states are extensively described in ancient India, and are regarded as a characteristic aspect of the spiritually developed condition.

### 3.6.1 *Mahabharata*

In one of India's most ancient texts, the *Mahabhrata*,(13.294.16) meditation is described as follows:

> He does not hear…smell…taste…see…or experience touch…his mind ceases to imagine…He desires nothing, and like a log he **does not think**...
> quoted in[197] (p97).

### 3.6.2 *Upanishads*

The Upanishads are some thousands of years younger than the Mahabharata. Mascaro, an eminent translator of Indian spiritual texts, summarizes the *Upanishadic* ideas on meditation and consciousness as follows:

> In the infinite struggle of man to know this world and the universe around him, and also to know the mind that allows him to think, he comes before the simple fact that life is above thought: when he sees a fruit he can think about the fruit but in the end he must eat it if he wants to know its taste: the pleasure and nourishment he may get from eating the fruit is not an act of thought.[221](pp1–47)

Mascaro's authoritative translations of the Upanishads further illustrate these points. In the *Kena Upanishad* it is stated:

> He (God) comes to the thought of those who know him beyond thought, not to those who imagine he can be attained by thought: he is unknown to the learned and known to the simple.[221](p51)

Further, in the *Kaushitaki Upanishad* it is stated "It is not thought which we should know: we should know the thinker".[222] (p105)

And in the *Katha Upanishad:*

> When the five senses and the mind are still, and reason itself rests in silence, then begins the path supreme. This calm steadiness of the senses is called yoga. Then one should become watchful, because yoga comes and goes.[6] (p55)

### 3.6.3 Patanjali

One of the most well known yogic treatise is Patanjali's Yoga Aphorisms. Patanjali was a physician who attempted to synthesise the many disparate texts on yogic discipline (such as the Hathayogapradipika, cited above) into single coherent practical guide for those aspiring to experience higher consciousness and self realisation, it is stated:

> By being aware of the silent void moments pervading the **emptiness between thoughts**, one can glimpse and expand the skill of thought subjugation which leads to transformation[223].

### 3.6.4 Gyaneshwara

A famous teenage saint from Maharasthra, Gyaneshawara (1275–1296) described the ascent of the *kundalini* energy in his commentary on the *Bhagavad Gita*, called the *Gyaneshawari*, the awakening of this energy is associated with a unique state of consciousness which includes the experience of *mental silence*: "...the imagination subsides, activity becomes calm, and the functions of the body and mind become still..."[224]

### 3.6.5 Zen

The ancient Japanese *Rinzai Zen* tradition also encompasses the idea of non-thought — elegantly and famously described in the *Koan* with the question: *"What is the sound of one hand clapping?"*[225]. The answer is, of course, that there is no sound and similarly, the state of meditation involves no mental activity. The aim of this kind of riddle is to challenge the mind into realizing the futility of rational thought, thus triggering a sudden leap of consciousness toward the trans-mind state, described in the Zen tradition as *satori*[226].

### 3.6.6 Buddhism

In the Buddhist tradition, the Mahayana school's *The Awakening of Faith* described several stages in the practice of Buddhist faith, the final one being "the stage of preventing vain thoughts." In meditative posture the aspirant is instructed that "all kinds of ideas, as soon as thought of, must be put away, even the idea of banishing them must also be put away."[227]

### 3.6.7 Christian mysticism

Importantly, the experience of "thoughtless awareness" and its connection to higher states of consciousness is not exclusive to the East (although it is more systematically described in that culture than any other). There are isolated descriptions throughout the religious history of the West. For example in the anonymous Christian mystical text *The Cloud of Unknowing,* the writer encourages the development of a profound, introspective understanding of God that is accessible in the non-thinking state, "strike down every kind of thought under the cloud of forgetting"[228].

St John of the Cross described the state as "silent music" and "the sound of solitude"[229] }; while the poet Wordsworth suggested it in his ode *Intimations of Immortality from Recollections of Early Childhood* which is a meditation on the possibilities and limitations of consciousness: "Our noisy years seem moments in the being of the eternal Silence"[230].

## 3.7 *Sahaja* and the trans-mind state

*Sahaja* is one of a number of terms that have been used to describe the trans-mind condition. *Sahaja* is derived from the Sanskrit *saha*, meaning “together” and *ja*, meaning “born”[213] and can be translated to mean “innate”. It is a term that has long been associated with Indian mystical thought and practice, although its popularity has fluctuated as different Indian spiritual movements encouraged, revised or ignored it. Davidson[231] provides seven contexts in which *sahaja* has been used over the recorded history of Indian, especially Buddhist, spiritual thought. The most pertinent to this discussion include the assertion that *sahaja* is:

> [A] fundamental, irreducible condition, decidedly a noun. It is roughly equivalent to *svabh¯ava* or *svar ¯upa*, and is used to described the inherent and inalienable attributes that exist irrespective of accidental circumstances.[231]

And,

> the present moment when one thing occurs with another, a temporal value differentiated from the prior and subsequent moments, when the two items were not associated.[231]

Synonymous terms and ideas include *jivan mukta*, “Buddha state” and “liberation”. Modern Western equivalent descriptions might include, but are not restricted to, “unitive state”, “self-realization”, “self-actualization”, “peak experience”, “sainthood” and “state of grace”.

*Sahaja* signifies one’s natural or spontaneous self, divested of all external influences and the mental conditioning produced by them. This natural state is demonstrated by young children, for example, who are free of the complex adult mind and its attendant pretences, “hang-ups” and neuroses. The *sahaja* state flows naturally to the one who has attained the depths of meditation and is therefore a logical consequence of the *mental silence* or “trans-mind” principle — a kind of renascent freedom. It can be described as the optimal state in which the body, the psyche and the soul find a synergistic integration to realize the potentiality that exists within each human being.

Neki (1970) describes the *sahaja* state as a mental health ideal in more detail, asserting that it combines the elements of illumination (the direct experience of reality, devoid of the filtering effect of the mind), equipoise (the absence of emotional turbulence) and its replacement with a sense of underlying joy and spontaneity. It creates a personality that is well adjusted but without pretence, affectation or hidden agenda and also freedom from the desires and motivations that give rise to frustration and destructive behaviours. It leads to harmonization of the subtle inner rhythms of one's being and the greater cosmos, a sort of suprasensory perception[213]. All of this suggests a positive, robust and fully functional state of health combined with ongoing and continuous perception of the deeper significance of reality.

Legend, myth and spiritual tradition from many parts and historical periods in India describe how the *sahaja* state is traditionally associated with extraordinary physical health, mental robustness and recuperative powers[211]. S*ahaja* is a state of being characterized by: the complete actualization of all one's positive potential, the elimination of all that is destructive, and empowerment by which one harnesses not only the mundane aspects of general life but also of the noetic dimension as well. *Sahaja* is thus a state that is both superhuman and yet no more than the complete fulfilment of human potential. Its central idea is that each person can achieve complete fulfilment of their human potential by striving towards Eastern ideas of spiritual perfection (as opposed to Western conceptions of what it is to be human). Thus the concept has been deeply incorporated into Indian spirituality and underlies many of the basic principles that make the Indian worldview unique.

### 3.7.1 Historical descriptions of *sahaja*

Throughout Indian spiritual history, there has been an irregular lineage of *sahaja* proponents who have periodically revived and refined the principle and attempted to release it from various misconceptions that arise from time to time about the idea.

### 3.7.2 Buddhist literature

The Buddhist tradition makes extensive use of the idea of s*ahaja*. Kvaerne (1975) describes the characteristic features of the *sahaja* state:

> 1. it is ineffable, 2. it is blissful, 3. it is timeless, 4. it is a state of omniscience, 5. it is an abolition of the duality of subject and object, 6. it is cosmic, 7. it transcends the universe, 8. it is sacred, and 9. it is the luminosity of one's own mind."[232]

### 3.7.3 *Sahajaiya* Buddhists

The Buddhist tradition also gave rise in about 800 CE, to a *sahaja* sub-movement known as the *Sahajaiya* Buddhists[233]. Its founder, Saraha, achieved enlightenment spontaneously with little extreme effort (*sahaj*). He described how the spiritual experience filtered into his everyday life giving not only freedom from disease but also mental equipoise integrated by a state of effortless spiritual enlightenment:

> In sahaja there is no duality; it is perfect like the sky.
> The intuition of this ultimate truth destroys all attachment and it shines through the darkness of attachment like a full moon in the night.
> Sahaja cannot be heard with the ears, neither can it be seen with the eyes;
> It is not affected by air nor burnt by fire;
> It is not wet in intense rain, it neither increases nor decreases,
> It neither exists nor does it die out with the decay of the body;
> The Sahaja bliss is only oneness of emotions – it is oneness in all.
> Our mind and the vital wind are unsteady like the horse;
> But in the Sahaja-nature both of them remain steady.
> When the mind thus ceases to function and all other ties are torn aside,
> All the differences in the nature of things vanish; and at that time there is neither the Brahman (priest) nor the Sudra (untouchable).
> Sahaja cannot be realized in any of its particular aspects – it is an intuition of the whole, the one underlying reality pervading and permeating all diversity.
> As the truth of the lotus can never be found either in the stalk or in the leaves, or in the petals or in the smell of the lotus, or in the filament, - it lies rather in the totality of all these parts, - so also Sahaja is the totality which can only be realized in a perfectly non-dual state of mind."[233]

### 3.7.4 *Maharastran* poet mystics

In the 15th century CE, a number of *bhakta* saints in India began promoting the idea of *sahaja*, knowledge of which they had received, along with their self-realization, from *gurus* such as the influential Ramanand, who may well have inherited it from the Nath yogis, successive generations of whom maintained the tradition of *kundalini* awakening and *sahaja* awareness which they passed to the householder/*bhakta* saints and also, later, to the Sufis. A phrase attributed to the possibly legendary Matsyendranath (11th century CE?) occurs in the Nath text, the *Gorakhbodh*:

> Without night, the day would have merged into sahaj; had there been no day, the night would have passed into sahaja.[234]

### 3.7.5 Kabir

Kabir, whose teachings and poems challenged the pervasive and dysfunctional religious orthodoxy and prejudices of the people of northern and central India, frequently praised the principle of s*ahaja*. He described the experience as involving physical wellbeing, which included not only freedom from disease and physical vigour, but also an experience of psychological equipoise ("all pain is gone, joy and peace are mine") as well as the bliss of spiritual realization, a state in which mind and thought are conquered:

> Mount the steed of your own thought and place your foot in the stirrup of sahaj. With bit and bridle I'll curb my horse – I'll saddle it with a fine saddle and spur it up to the sky.[235]

### 3.7.6 Nanak

Nanak (1469–1539), a Punjab-based *guru* who taught unity between Hindu and Islam, and whose teachings became the foundation of the Sikh religion, acknowledged Kabir as a contemporary and also promoted the principle of *sahaja*. He encouraged his followers to lead simple, balanced, moral lives and assured them that spiritual growth would occur naturally, in other words *Sahaja,* through devotion to the divine principal;

> In the calm of sahaja's cave you can discover the True One,
> Sayeth Nanak, the True One loves the truthful.
> By the gentle path of Sahaja
> Attain God, Purest of the Pure.[236]

### 3.7.7 Dadu Dayal

Dadu Dayal (1544–1603) from Rajasthan exhorts his listeners in one of his songs:

> Let us proceed to that land of Sahaja where none lives or dies;
> There is no fear of the whirl of coming or going, one realization for all time;
> Let us proceed to the land where neither the sun nor the moon can go,
> where there is no access for day and night, everything remains merged in Sahaja."[233]

### 3.7.8 Ramana Maharshi

In a more contemporary context the tradition of s*ahaja* has been expounded by mystics such as Ramana Maharshi, who rose to prominence in the first half of the 20th century:

> When we have tendencies that we are trying to give up, that is to say when we are still imperfect and have to make conscious efforts to keep the mind one-pointed or free from thought, the thoughtless state which we thus attain is nirvikalpa samadhi. When, through practice, we are always in that state, not going into samadhi and coming out again, that is the Sahaja state. In the Sahaja state one sees only the Self and one sees the world as a form assumed by the Self.[237]

On another occasion, in reply to the question: "What is *samadhi*?", he explained:

> In yoga the term is used to indicate some kind of trance and there are various kinds of samadhi. But the samadhi I speak to you about is different. It is Sahaja samadhi. In this state you remain calm and composed during activity. You realise that you are moved by the deeper self within and are unaffected by what you do or say or think. You have no worries, anxieties or cares, for you realise that there is nothing that belongs to you as ego and that everything is being done by something with which you are in conscious union.[237]

In reply to a question from a *sanyasin* (an anchorite) about *samadhi* (the state of meditation), Ramana Maharshi made the following statement:

1. Holding on to reality is samadhi.
2. Holding on to samadhi with effort is savikalpa samadhi.
3. Merging in reality and remaining unaware of the world is nirvikalpa samadhi.
4. Merging in ignorance and remaining unaware of the world is sleep.
5. Remaining in the primal, pure, natural state without effort is sahaja nirvikalpa samadhi.[238]

### 3.7.9 Shri Mataji Nirmala Devi

A contemporary exponent of the *sahaj* state is Shri Mataji Nirmala Devi. She has extensively described the state as well as how it can be achieved through what she has called "*Sahaja Yoga* Meditation", which she has developed and refined since approximately 1970[239]. The *Sahaja Yoga* technique is based on both the traditional yogic understanding of *chakras* and *kundalini* in conjunction with the unique notion that the natural awakening of the otherwise dormant *kundalini, sahaj*, leads to the experience of the trans-mind, or "*Sahaja* State". In terms of this hypothesis, individuals are encouraged to test themselves within the reference frame of their personal experience.

The method is comprised of a number of discrete, simple techniques stemming from a single basic technique which involves a series of psycho-spiritual affirmations combined with hand positions that correspond to the location of the major *chakras*. The novice is encouraged to use these techniques until they become familiar with the affirmations, hand positions and, most importantly, the experience of *nirvichara samadhi* or "thoughtless awareness" (*mental silence*). With ongoing practice the meditator can deepen both the experience and the therapeutic effects by judiciously using one of a handful of sub-techniques which have been designed to address various patterns of imbalance and dysfunction that may become evident in the *chakra* system of the practitioner. Imbalance of the system usually arises from various behavioural and lifestyle patterns or other psychosocial factors. Correction of the imbalance requires the meditators to address both the lifestyle factor as well as the subtle energetic factors. The more balanced the inner system of *chakras* and *nadis* becomes, the more profound the experience of *sahaja* and its resulting benefits.[52]

Since its inception, *Sahaja Yoga* has been propagated worldwide by a grassroots movement of volunteer practitioners. Its proponents claim that it is now practiced in over 80 countries around the world. Instruction in the technique, in keeping with the founder's philosophy, has been on a free-of-charge, non-commercial basis[240].

### 3.7.10 Summary

In summary, what can be taken from these ideas and descriptions is that the state of *sahaja* is characterized by:

- present moment awareness
- expanded consciousness
- positive mood
- a sense of integration/ synergy of faculties
- positive health/wellness in all spheres (bio-psycho-social and spiritual)
- a sense of cosmic connection and unity
- trans cognitive/beyond thought
- specific somatic sensations/descriptors that somehow reflect intuitive knowledge.

The central feature of these ideas is is the trans-mind state of non-thought.

What should be evident at this point is that the idea of *sahaja* and the traditional psycho-physiology used to explain it, encompasses not only the idea of transformation of consciousness, but also that the ultimate basis of health and wellbeing (or disease) is psycho-spiritual in nature. The Indian view does not relegate spirituality to an isolated corner of life; rather it proposes that spirituality is the underlying engine and uniting force of the entire system, which constitutes a dynamic, seamless "*theo*-psychosomatic" model of health. In terms of this model, one's level and state of consciousness is both the key influencing factor as well as the ultimate recipient of influences from the body, mind and behaviour.

It should also be evident by now that William James' ideas[241] of direct spiritual experience informing one's religious outlook are practically realized by the cogent methodology described within the *yoga*, self-realization and the *sahaja* traditions.

### 3.7.11 Modern description of the *sahaja* state

Finally, to demonstrate that neither these ideas or experiences are exclusive to Indian culture a present day example of this state of consciousness is described in Appendix 5.

## 3.8 Meditation as it is understood in the West

In order to contrast the traditional Eastern ideas of meditation with ideas that are currently prevalent in Western culture, it is useful to examine popular, broadly consensual definitions of meditation as an insight into how the modern Western consumer has come to conceptualise it. Both basic and advanced Google searches were conducted using "meditation" and "definition" and "definition of meditation" as search terms.

General, medical and religious dictionary definitions were sought and found. As shown in Table 3.1. the first 50 definitions were selected, since according to the Google search system, they are listed in descending order of popularity. An informal content analysis was performed to identify key terms and ideas, and is summarized in Table 3.1. Using this as a "straw poll" of popular opinion the two most common definitions of meditation are as a mental exercise that involves either "contemplation" or "continuous thinking" while the third most common definition is as an exercise involving focused attention. So it is clear that meditation is popularly conceptualised as a technique that involves prolonged thought/contemplation and concentration and that is not necessarily spiritual or religious.

Table 3.1 Content analysis of first 50 definitions of Google search on meditation.

| Content | Number |
|---|---|
| Contemplation, reflection, discourse | 37 |
| Close, continued, deep, prolonged thought, revolving in the mind | 26 |
| Concentration, focus | 18 |
| Spiritual activity, soul | 13 |
| Calm/relax the mind | 9 |
| Relaxation | 9 |
| Religious activity | 9 |
| Involving the mind | 7 |
| Emptying the mind, reducing thoughts | 6 |
| Directing or developing awareness | 6 |
| Musing | 5 |
| Consciousness | 5 |
| Involving the attention | 4 |
| Devotional exercise | 4 |
| Reduce stress | 3 |
| Introspection | 2 |
| Clarity | 1 |
| Present moment | 1 |
| Reality | 1 |

The more specific notion that it involves control of the mind is considerably less widespread, despite the fact that these factors are repeatedly mentioned in traditional Indian texts. Interestingly, the more specific notion of reducing thinking activity appears to be little known, while the key notion of *mental silence* was mentioned only once.

In the words of Easwaran (1991), the Western understanding of meditation might be as "a self-directed practice in which the meditator makes a concentrated effort to focus on a single thought, physical experience, sound or memorized passage"[242]. It is also worth recalling the NCCAM's definition: "a conscious mental process that induces a set of integrated physiological changes termed the *Relaxation Response*"[5]. As is evident from the content analysis described above, this earlier version represents one of the most prevalent conceptualizations of meditation in the West. These conceptualizations clearly imply that meditation is a process that can legitimately involve mundane, repetitive cognitive patterns. An important weakness in this definition is that it becomes so broad that almost any activity that involves either repetitive cognitive patterns or physiological relaxation can be admitted into the genre.

## 3.9 Overtly similar but functionally different

In contrast to these popular Western definitions, the traditional Indian idea of meditation is of a qualitatively unique phenomenon (described in section 3.6)[191], involving a state of awareness, or *mental silence*. The highly developed meditator who attains this state, is not only less stressed and more relaxed, but has also realized his/her various physical, psychological and spiritual potentials. According to the Indian tradition it is the meditative experience that confers clinical benefit as a by-product of advanced consciousness. Thus, as will be demonstrated, while ancient Indian approaches to meditation involving *mental silence* may superficially resemble modern approaches to meditation as mere relaxation, they are experientially and philosophically very different.

## 3.10 A culturally foreign concept

The conceptualization of meditation as involving *mental silence* is virtually absent in Western scientific discussion. Why has this important notion been ignored? How did contemporary, popular notions of meditation become almost diametrically opposed to the ancient Indian ideas which form their source? Some explanations are examined below.

When René Descartes made the philosophical statement “cogito ergo sum” (I think therefore I am) in his *Principles of Philosophy* he laid down a foundation element of Western philosophy[243]. The “cogito ergo sum argument” essentially states that “I am thinking therefore I exist”. The metaphysical implications of Descartes’ phrase, which equate thinking activity with self identity contrast sharply with the Eastern metaphysical idea that existential reality can be perceived only when one is not thinking, which might be stated in Latin as “sum cogito ergo” — I am, therefore I think!

The influence of Descartes’ “cogito” on Western thought is widely acknowledged and cannot be overstated. It offers some explanation as to why the idea of *mental silence* has failed to find currency in the Western scientific literature on meditation. For example, Wright (2001), in an attempt to dispel myths and misconceptions about meditation (as he, a Western scientist, sees it) completely contradicts the Indian tradition when he states:

> When we close our eyes to meditate our mind does not go completely blank, void of thoughts at one with the universe, because just as hearts are meant to beat and lungs to breath, brains are meant to think and will never be completely devoid of thought, perhaps until they are dead.[244]

Wright’s comments in many ways are a reflection of Descartes’ cogito argument. It suggests that Western scholars having been brought up in the milieu of a Western philosophy built on the notion of “I think therefore I am”, might have difficulty acknowledging the possibility that a state of consciousness which is devoid of thought might be possible Could Western scholar’s difficulty with or ignorance of the concept of *mental silence* have hampered the development of Western understandings of meditation?

This cultural inability to appreciate the validity and importance of *mental silence* might explain why scholars, of whom Wright is representative, have focused on conceptualizations of meditation that are more intellectually digestible, for example, as a highly developed method of relaxation or technique of patterned thinking[245].

Accordingly, Western understandings of meditation have crystallized around a number of key concepts that are unrelated to the notion of *mental silence*. These are examined below.

### 3.10.1 The relaxation paradigm

Early uncontrolled or own-control studies of meditation suggested that psycho-physiological parameters such as heart rate could change quite dramatically in a single meditation session[246] and this led to initial enthusiasm for meditation as a potentially unique self control strategy.

Later however properly controlled studies reported considerably less positive outcomes[246]. For instance, a controlled study comparing TM, general relaxation training and muscle relaxation using electromyographic (EMG) biofeedback, demonstrated that while TM significantly reduced parameters associated with arousal (i.e. a significant within-group difference), it was not any more effective than the comparator interventions. In other words, there were no significant between-group differences[247]. Similarly a study comparing TM to listening to music, found that oxygen consumption and carbon dioxide production dropped in the meditating group (consistent with reports in uncontrolled studies) but that the same change occurred in a non-meditating control group (who simply listened to music) and that there were no significant differences between the two practices[248]. In other words, when meditation was compared to rest, and relaxation or other appropriate controls, it demonstrated minimal differences in both the magnitude and direction of any major parameters. Thus emerged the notion that meditation, contemplation, prayer and rest and relaxation, were psycho-physiologically equivalent.

## 3.11 Holmes' seminal review

Scientific evidence has repeatedly to confirmed the idea of "psycho-physiological equivalence". For instance, in 1984 Holmes published a definitive review of published physiological investigations into meditation and spuriously found that the widely held perception of meditation as a superior method for reducing arousal was based on studies that did not use experimental methods[246]. Vigorous debate ensued between enthusiasts and critics of meditation with Holmes strongly and effectively defending his position[74].

### 3.11.1 Findings of the Holmes review

***Heart rate***: of the 18 experiments he reviewed, none evidenced reliable differences in heart rate between meditating and resting participants. In fact five trials showed that meditation was associated with increased heart rate in meditators compared to rest.

***Electrodermal activity***: of 14 trials, only one demonstrated a reliable difference between meditation and rest. However the description of the study raises the possibility that that this difference was artefactual.

***Respiration rate***: of nine trials, two demonstrated that meditation lowered respiratory rate more than rest, and one experiment showed meditation increased respiratory rate more than rest.

***Blood pressure***: of five trials in which BP changes were assessed, only one small trial found that meditation reduced BP more effectively than rest.

***EMG***: of six trials, three indicated that meditation was superior to rest.

***ST***: of four trials, none showed any difference in ST.

Predictably, Holme's findings generated consternation among the meditation community. In 1987 he revised and updated his review, but found that his conclusions if anything, were strengthened, namely that there is no consistent evidence to suggest any major physiological difference between meditation and rest and relaxation despite the claims of meditation enthusiasts[76]. The cogency of Holmes' observations and arguments appear to have withstood the test of time.

This type of thinking is typified in the work of Herbert Benson. He argued that Eastern meditative traditions[249], Western religious practices[249] and even secular activities such as hypnosis or simple rest[75] were essentially the same despite their philosophical or metaphysical differences. He coined the term "*Relaxation Response*"[245] and proposed it as a universal physiological process underlying apparently divergent tasks such as listening to music while sitting in a chair, light sleep, Christian prayer and yogic meditation. His bestselling book, *The Response*[249], sets out methods of eliciting reduction of autonomic arousal. Since its publication in 1975 it has sold in excess of two million copies and is now considered a classic of the self help genre. Benson describes the *Relaxation Response* as a secular form of meditation which captures the essentials of the Eastern meditative tradition while discarding the unnecessary religious, spiritual and sometimes cultic paraphernalia that can accompany Eastern forms[10, 245].

The flaw in this line of reasoning lies within the definition of meditation; if it is defined simply as rest or relaxation, then any practice that may induce the same pattern of physiological changes could also be termed as "meditation" or "meditative". In these circumstances, it should be no surprise that the majority of well-designed trials find few significant differences between meditation and rest, sleep or other stress reduction strategies[9, 74]. Logically, since the concept of meditation accepts such a wide diversity of practices so long as they physiologically resemble simple rest, means that the original idea of a specific experiential state with specific psycho-spiritual characteristics, has been lost.

Holmes and other reviewers justifiably argue that, since many of the therapeutic effects of meditation and meditative practices appear to rely on reducing arousal as a key component of the process, the absence of evidence for meditation having a unique effect on physiology has implications that also extend to the claims for the therapeutic value of meditation. This is borne out by the systematic review in Chapter 2 of this thesis, which clearly demonstrates that the extant RCT database does not demonstrate any convincing evidence for a specific effect. Thus the search for a unique physiological dimension to meditation and the search for a definition that may facilitate the observation of any such uniqueness are interlinked and are of broad significance[74].

The relaxation versus *mental silence* dichotomy can be simply described: while the former aims to modify and focus mental activity and reduce physiological arousal as a kind of therapeutic intervention, the latter aims, without reducing self control or alertness, to eliminate mental activity altogether as part of an overarching strategy to facilitate the development of consciousness[250]. The "relaxation" conceptualization of meditation thus completely ignores the Indian concept of *mental silence* or "trans-thought awareness".

## 3.12 *Mindfulness*meditation

More recently, "*Mindfulness* meditation" has emerged as a new contender offering a cognitive behavioural, rather than physiological, paradigm for meditation. *Mindfulness* meditation (MM) is currently receiving considerable scientific attention and is somewhat more aligned with the ancient Eastern ideas of “mental control”. *Mindfulness* is described as Buddhist in nature[251] whereas descriptions of meditation as *mental silence* can be found in texts such as the *Upanishads* that are pre-Buddhist and therefore possibly better described as Hindu[197].

MM aims to “develop enhanced awareness of moment-to-moment experience of perceptible mental processes”[252]. Kabat-Zinn, the best known scientific exponent of the technique, states that it involves “training practitioners to attend to a wide range of changing objects of attention while maintaining moment-to-moment awareness (*Mindfulness*), rather than restricting one’s focus to a single object such as a mantra”[251]. By attending to the moment-to-moment experience, attentional processes are more or less prevented from becoming engaged in these events. Therefore it is implicit that *Mindfulness* involves an “attention-orientated” definition of meditation. Exponents distinguish it from “concentrative” forms of meditation such as transcendental meditation, which involves focusing the attention on, and active repetition of a mantra[251, 253].

In other words, while *Mindfulness* may be defined as a state in which one passively observes the ebb and flow of thoughts while not getting involved with them, the ancient Eastern meditator seeks to unite their awareness with the “space between the thoughts” Thus, while *mental silence* is a specific experience that can be preceded if not facilitated by present-moment observation and other *Mindfulness* methods, it is distinguished from

*Mindfulness* by its *sine qua non,* the elimination of thought activity. Hence the definition of meditation being put forward in this thesis — *mental silence* — is orientated towards a specific state of consciousness that is "experience-orientated" rather than "attention-orientated" (as in MM) or "relaxation-orientated" (as in Benson's *Relaxation Response*).

Much of the research on *Mindfulness* has been published in the past ten years while the amount of research activity in the field appears to be escalating exponentially with each year. To the present, the results of 18 RCTs of *Mindfulness* have been published, all reporting promising results. Enthusiasm for the method should however be tempered by the fact that few of these RCTs used control methods that prevented the exclusion of non-specific effects (for a full explanation of the "non-specific effect" concept, see Chapter 2). Of those that did, little evidence has emerged to suggest a specific effect.

## 3.13 Conclusion

Holmes himself suggested that the available data on the physiology of meditation led to a limited number of possible conclusions. Either:

1. meditation is no different to rest and relaxation; or
2. meditation may have a specific effect but the measures used to assess it in scientific trials are not sufficiently sensitive to its specific effects; or
3. the assumption that "what is being tested as meditation is real meditation" may be wrong.

In this thesis it is argued that the third point is more relevant to the question about whether or not meditation has a specific effect. Holmes himself points out in his review the assumption that whatever techniques labelled as "meditation" were sufficiently homogenous to allow inter-trial comparability[76]. However, quite apart from the issue of homogeneity, the cultural naivety of Western researchers raises an additional question as to whether the independent variable labelled “meditation” bears any resemblance to the notion of meditation as it was originally intended. The issue of definition is a crucial weakness in Western thought, both scientific and non-scientific, and it is asserted here that Western researchers have in fact failed to provide the necessary definitions to allow meaningful study and experimentation.

The ancient Eastern idea of meditation as a state of non-thought has strong philosophical roots, however in the West’s process of assimilating meditation this important notion appears to have been “lost in translation”. This may be explained, for the most part, by the cultural and philosophical differences between East and West, notably the contrasting ideas that underlie Cartesian vis-à-vis non-Cartesian thought. An additional more modern factor is that meditation has become an important part of what may be termed "the New Age industry". Many of meditation’s leading proponents have made fortunes by selling books, CDs, courses and qualifications on or about meditation. However few of these mass marketed products refers to the *mental silence* experience. A broader definition such as that derived from the “relaxation” paradigm has commercial advantages since it allows a plethora of practices to be marketed under an attractive banner without obligating its promoters to deliver much more than a sense of rest, relaxation or simply an odd sensation. Nevertheless, the fact that the Western scientific database, despite more than almost 40 years of interest and more than 3000 peer-reviewed publications, has failed to yield any consistent evidence for a specific effect strongly suggests the need to explore new and radically different understandings of this ancient practice.

Perhaps in recognition of this, in 2007 the NCCAM revised its definition of meditation. Moving away from the idea of meditation as relaxation, it now states:

> In meditation, a person learns to focus his [sic] attention and suspend the stream of thoughts that normally occupy the mind. This practice is believed to result in a state of greater physical relaxation, mental calmness, and psychological balance. Practicing meditation can change how a person relates to the flow of emotions and thoughts in the mind.[254]

In this radically revised position, one of the key citations is a publication derived from this thesis which specifically spells out the nature and significance of meditation as *mental silence*[191]. Therefore it seems important that this newly rediscovered idea is subjected to detailed scientific exploration and that is the aim of this thesis.

# Chapter 4. Research Approach

## 4.1 Overview

### 4.1.1 Why look for a new definition?

More than 30 years of scientific research into the practice of meditation has produced no consistent body of evidence to support the idea that meditation has a specific effect (see Chapter 2). It seems that there are only three possible conclusions that can be drawn: 1) that there is no effect to be found, or 2) that the measures used to assess this practice are not sensitive to its specific effects or 3) as has been argued in previous chapters, that the "meditation" studied and practiced in the West is significantly different from the original concept. And therefore a fruitful avenue of research might be to investigate aspects of meditation using a new clear definition, as outlined in Figure 4.1.

### 4.1.2 Multifaceted assessment

To test the effect of a new and specific definition of meditation in a variety of contexts I designed a series of studies. These studies were carried out in the following fields:

1. Psycho-behavioural
2. Medical
3. Patho-physiological
4. Physiological
5. Subjective experiences (self-report data)
6. Objective changes (patho-physiological severity, medication consumption)
7. Epidemiological (population surveys).

This approach and methodology is summarized in Figure 4.2.

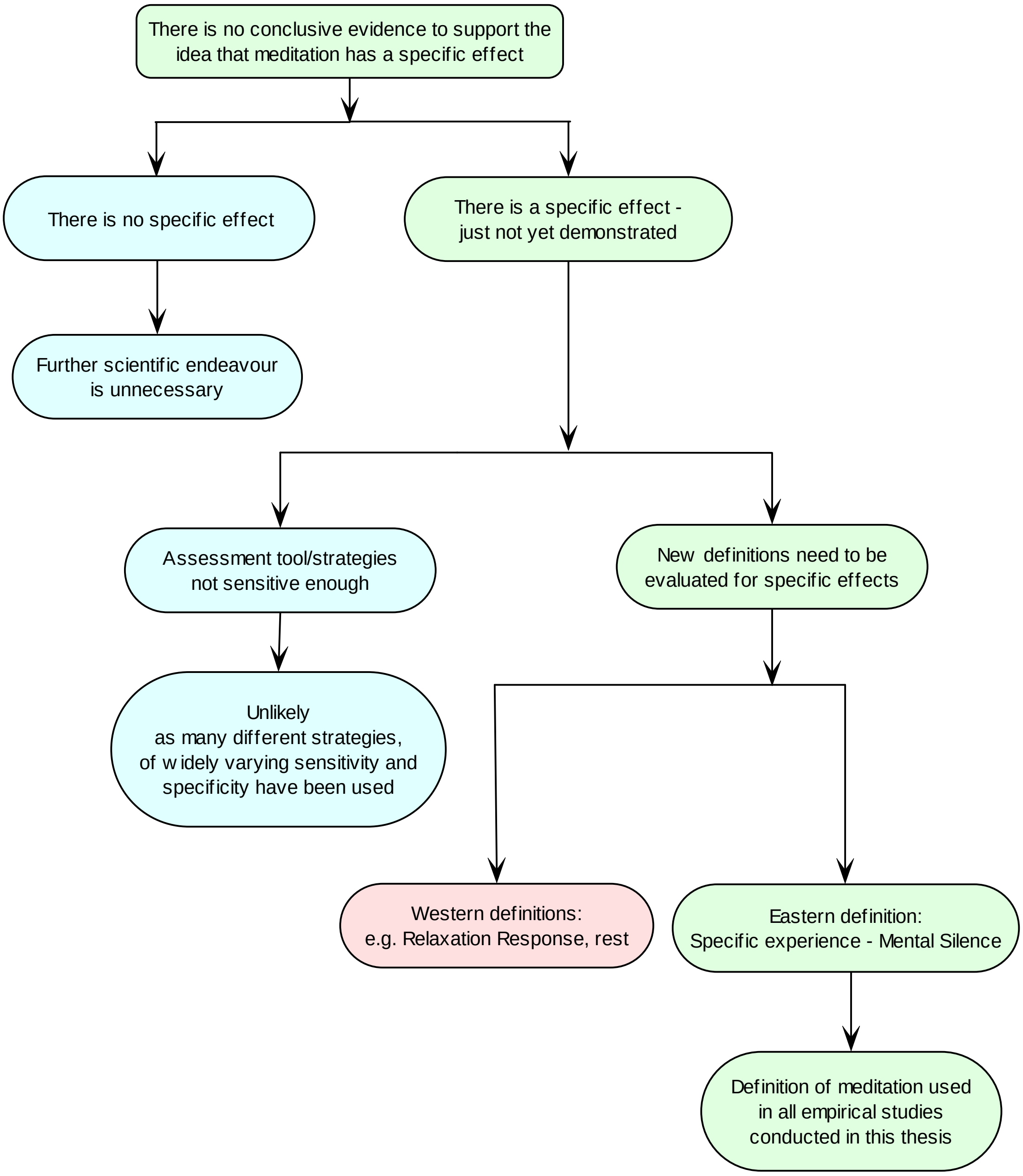


Figure 4.1 Research approach justification according to definition.

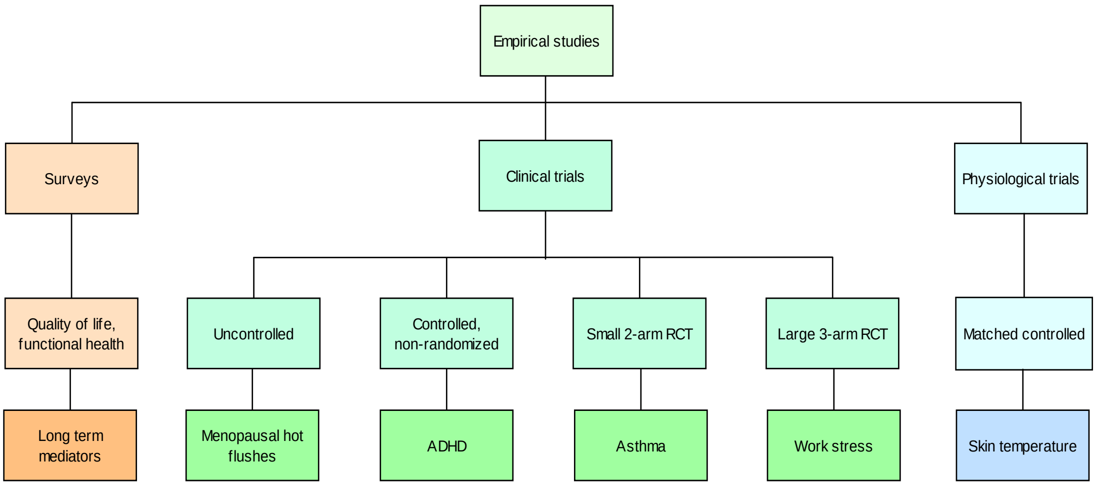


Figure 4.2 Methodological approach.

### 4.1.3 Methodological progression

The studies in this thesis represent a progression in methodological rigour as the overall research moved toward the final goal of implementing an experiment that addressed the key methodological problems that limit the current research literature, as shown in Figure 4.3. In other words, final studies incorporated a well-designed RCT with plausible control methods using a more precise and authentic definition of meditation. The *Sahaja Yoga* meditation technique was used because *mental silence* is its defining feature.

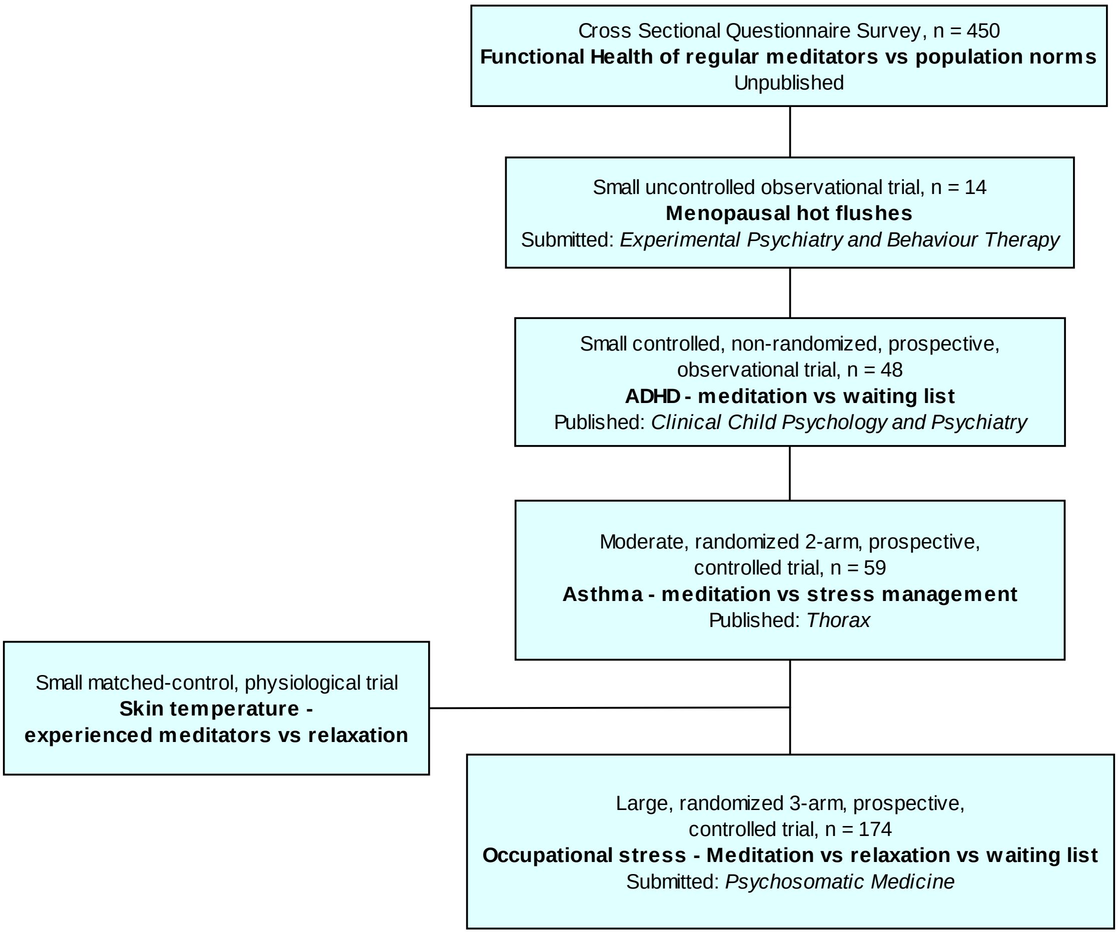


Figure 4.3 Progression of methodological rigour.

A schematic overview of the literature review process and the way that it informed the development of both my conceptual and methodological strategies is represented in Figure 4.4.

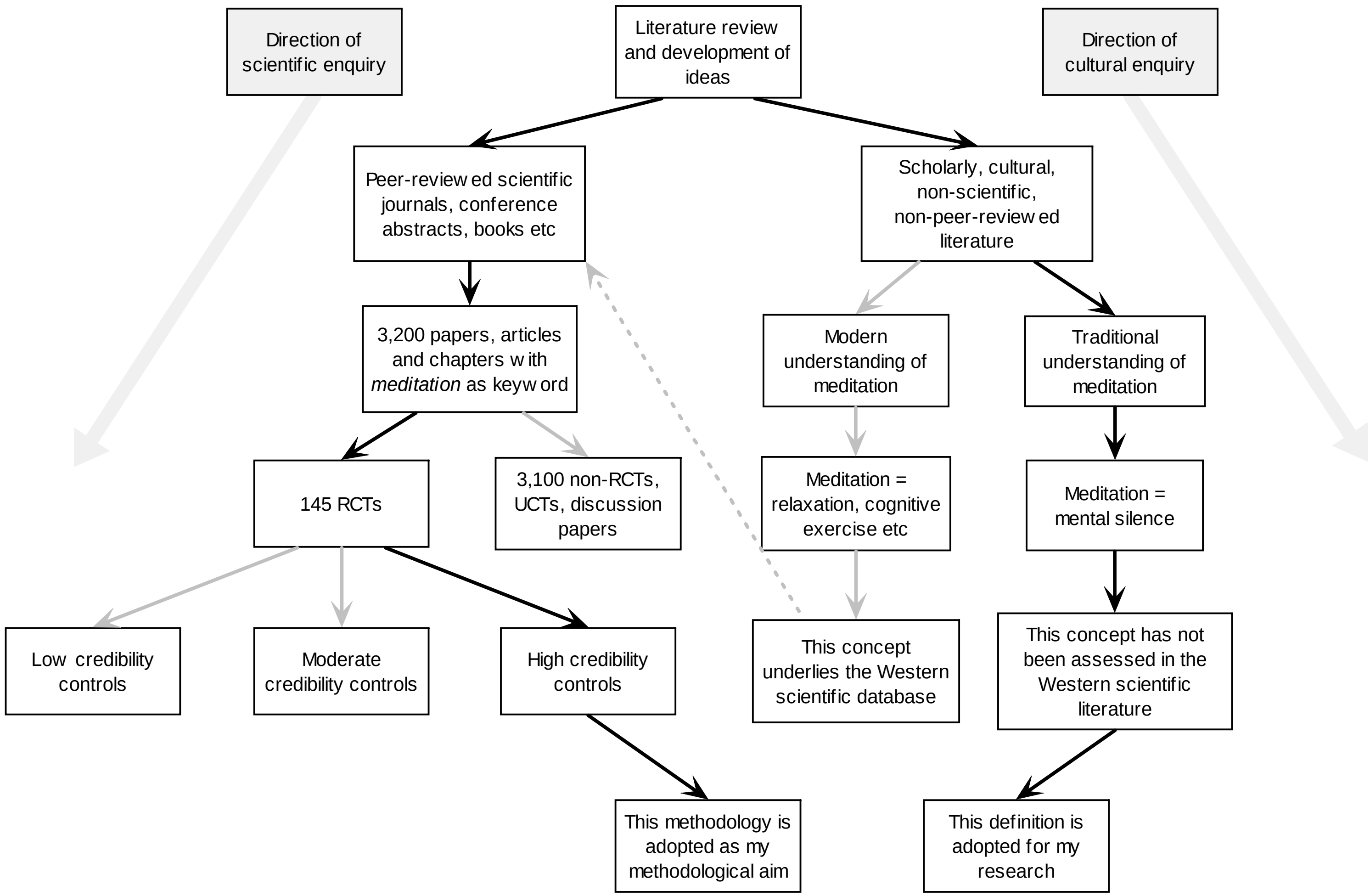


Figure 4.4 Schematic representation of the development of my conceptual and methodological strategies.

As reported in the previous chapter, an extensive search of the scientific literature demonstrated that of the approximate 3,500 journal articles reviewed, only 118 (less than 4%) fulfilled the very basic requirements of experimental, scientific evaluation, i.e. using a randomized controlled trial methodology. Once these papers had been identified, they were systematically critiqued using a standardized data extraction procedure as described next.

#### 4.1.4 The Jadad score

The Jadad scoring system is a widely used method of rating RCTs for basic methodological rigour. The Jadad system is inadequately structured to meaningfully discern the methodological standards of meditation trials. This is because the unique issues associated with controlling for non-specific effects and sources of bias are not adequately represented in this system.

#### 4.1.5 General findings of the scientific review

As a result of the scientific review (see Chapter 2), it was concluded that much of the evidence base regarding meditation suffers from two crucial methodological shortcomings. First, there is a paucity of robust experimental studies (i.e. RCTs). Less than 4% of the publications on meditation in the peer-reviewed literature were genuine RCTs. Second, even among these RCTs, it was rare to find adequate attempts to control confounding effects, such as placebo effect, inadequate blinding of participants and experimenters, conflict of interest and poor statistical design and analysis.

#### 4.1.6 Addressing methodological weaknesses

Methodological validity is therefore the major challenge to meditation research, and the chief problems within this broad category are first, the use of appropriate control strategies, second, the need for randomization and other strategies to exclude bias and third, a definition of meditation that allows inter-trial comparability and remains consistent with the traditional ideas of meditation as a state of non-thought.

4.1.6.1 Plausible controls

Plausible control groups are critical in behaviour therapy research because of the need to exclude the significant confounding effects of non-specific factors (such as placebo, therapeutic contact and researcher expectancy). The significance of this issue is borne out by the fact that even comparative trials of behaviour therapies often end up demonstrating equivalence of effect[255]. Such non-specific factors are also significant in meditation research. Expectancy alone, for instance, has been shown in a number of studies to positively influence the apparent effect of meditation[4].

The essential criteria for a control strategy in meditation trials should therefore be first, convincing plausibility as an active intervention in its own right and second, a process that involves relaxation and reduction of somatic arousal (since this is the nearest conventionally understood phenomenon that resembles meditation).

4.1.6.2 Randomization and other strategies to exclude bias

There are a large number of controlled meditation trials using dissimilar cohorts in non-randomized trials. The need for randomization to exclude selection bias is obvious, yet as previously pointed out, less than 4% of the total number of peer-reviewed publications used random allocation of participants.

## 4.2 Functional health survey of long term meditators

### 4.2.1 Ethics

Approval was obtained from the Ethics Committee of the South-Eastern Sydney Area Health Service (SESAHS).

### 4.2.2 Design

A national, cross sectional survey of long term meditators was undertaken, using self-report measures of health and quality of life. To maximise homogeneity of the independent variable, the survey focused exclusively on SYM practitioners.

### 4.2.3 Population and sampling strategy

A researcher travelled to each of the main capital cities of Australia and attended the city's main collective meditation meeting. They also attended one-day and weekend meditation retreats that were held on a regular basis between six and ten times per year. At these meetings meditators were requested to participate anonymously. Advice from state and local coordinators indicated that people attending the main collective meetings and retreats were much more likely to be regular meditators than those who did not and that most regular meditators attended most of these events. In other words, the sample captured in this way reflected practitioners with maximum commitment to the "meditation lifestyle".

In addition, further informal lists of local phone contacts were used to identify those who did not attend the collective meetings but who nevertheless may have classified themselves as meditators. These people were sent a questionnaire by mail and follow-up phone calls were made to try and maximize return rates. SYM practitioners suggested that the majority of people contacted in this way were probably less regular meditators but nevertheless probably had some degree of commitment to a lifestyle that involved meditation.

### 4.2.4 Procedure

Participants were informed about the nature of the survey and given the option of completing it. Those participants recruited at collective meetings were asked to complete and return the survey immediately. Those that received the survey by mail were given an addressed, reply paid envelope and a reasonable deadline to complete the survey and mail it back.

### 4.2.5 Measurement instruments

#### 4.2.5.1 MOS SF-36

The MOS SF-36 is a widely used health and quality of life self-report questionnaire. It is used to assess perceived quality of life in 36 physical and mental health areas. Eight dimensions of health are evaluated in the MOS SF-36v1The measures are generic (not age, disease, or treatment specific) and therefore are suitable for screening the general population. The SF-36 has been used extensively in Australia for both population health and clinical applications. The SF-36 has also been used to assess the general health of religious populations[256]. Previous studies have verified the reliability and validity of the SF-36 for use with medical and general population samples. The SF-36 was scored in this study according to the procedures outlined in the accompanying manual. Both US and Australian population norms also exist for the SF-36. The Australian norms were collected in the 1995 National Health Survey[257].

#### 4.2.5.2 Kessler 10

The Kessler Psychological Distress Scale (K10) was first documented by Kessler and Mroczek in 1994 and was developed for screening populations for psychological distress[258, 259]. The K10 has been used in a number of population health surveys in Australia, such as state-based CATI population surveys[260] and the National Mental Health Survey conducted in 2001 by the Australian Bureau of Statistics[261]. It was used in the health surveys conducted by the Epidemiology and Surveillance Branch, NSW Health Department in 1997 and 1998. The scale consists of 10 questions on non-specific psychological distress and is designed to measure the level of anxiety and depressive symptoms a person may have experienced during the previous four-week period.

4.2.5.3 Meditative lifestyle self report questionnaire

Focus groups and discussion forums with SYM practitioners were conducted to establish what the basic “meditation lifestyle” entailed. A self-report questionnaire was developed around this information to ascertain the degree to which each individual observed the tenets of the “meditation lifestyle”. Items to capture basic demographic data on age, sex, income, educational level and the consumption of drug, alcohol and tobacco were also incorporated into this questionnaire.

Correlation studies were done to determine if an association between any aspect of the meditative lifestyle might be related to the physical and mental health scores of the regular meditator population.

## 4.3 Intervention studies

Having established compelling evidence for a relationship between health scores and the experience of *mental silence*, it became necessary to determine whether or not the association was causal or simply coincidental. This question could only be answered by interventional studies and so a series of increasingly rigorous trials were designed and conducted. Health conditions were selected for each trial, summarized below:

1. Menopausal Hot Flushes – uncontrolled, observational trial

2. Attention Deficit Hyperactivity Disorder – non-randomized, wait list controlled trial

3. Asthma – 2 arm, randomised controlled trial

4. Work Stress – 3 arm, randomised controlled trial

## 4.4 Hot flushes

### 4.4.1 Ethics

Approval was obtained from the SESAHS ethics committee.

### 4.4.2 Design

A preliminary, uncontrolled observational intervention trial was designed to observe for further, stronger evidence of a causal effect.

### 4.4.3 Participants and recruitment

Fourteen women were enrolled into a specifically designed programme conducted at the Sydney Menopause Centre (SMC), Royal Hospital for Women, Sydney, Australia. All previous and current patients of the Sydney Menopause Centre were sent a letter informing them of the study and inviting them to phone the SMC to ascertain if they qualified. Eligible participants gave informed consent.

4.4.3.1 Inclusion/exclusion criteria

The criteria for inclusion were:

- last menstrual period less than six months previous
- no other treatment (natural or conventional) for menopausal symptoms over the previous eight weeks
- no history of breast cancer
- age between 40 and 60
- no history of any significant psychological or physical illness

- non-smoker
- less than two standard alcoholic drinks per day
- experiencing a minimum of five hot flushes per day as measured by a hot flush diary.

Exclusion criteria included:

- surgically/medically induced menopause
- unwillingness to comply with treatment guidelines of the study.

#### 4.4.4 Measures

The questionnaires and hot flush diaries were filled out at baseline, and in week 4, week 8 (immediately post intervention) and week 16 (8 weeks post intervention). These measures were included.

##### 4.4.4.1 The Flush Count Diary

This is a standard menopausal assessment tool. Participants were asked to tally each hot flush episode as they occurred. This measure has been found to be reliable and have validity compared to daily monitoring.

##### 4.4.4.2 The Kupperman index of menopausal symptoms

This is a menopause-specific symptom measure which uses a scale (0—3, none–marked symptoms) to summate the menopausal symptoms and yield a total menopause symptom index[262, 263]. It is the oldest self-report instrument (although initially designed to be administered by physicians) which focuses primarily on symptomatic relief.

4.4.4.3 Menopause specific quality of life questionnaire (MENQOL)

This is a validated quality of life questionnaire[264]. It assesses the impact of menopausal symptoms on quality-of-life using 29 questions, each with a 7-point severity scale and was designed to detect changes in quality-of-life as a result of treatment.

4.4.4.4 State Trait Anxiety Index (STAI)

There are two 20-item self-report scales designed to measure anxiety proneness (trait) as well as current level of tension and apprehension (state)[265]. The STAI is easily administered and scored and is widely used in a variety of research settings. It is particularly useful for research on anxiety reduction.

4.4.4.5 Greene's climacteric scale

A 21-item self-report scale designed to measure the severity of common menopausal symptoms[266]. Symptoms are based on three broad categories: psychological, somatic, and vasomotor. These symptoms have been confirmed by other factorial studies as having a statistically significant factor loading. The scale can also be used to identify menopausal women who are severely and possibly clinically depressed.

### 4.4.5 Treatment

The meditation strategy involved attending the Sydney Menopause Centre twice per week in the evening for 8 weeks. Instructional sessions took one-and-a-half hours each. All participants began the program simultaneously. Attendance rolls were kept and the participants were encouraged to practice the techniques that they learned in the instructional sessions on a twice-daily basis at home, for about 15 minutes twice per day. Instructional audiotapes were given as well as written guidelines of how to meditate and optimize the meditation experience.

### 4.4.6 Instructional sessions

The instructor was a health professional with expertise in SYM instruction. Each class began with the calling of an attendance roll, followed by a brief talk on the principles of meditation that were to be learned that day. Questions were taken to help clarify any difficulties that the participants were experiencing. Following this, two guided meditation sessions were conducted, separated by a short break, and after that by a brief question-and-answer session. The participants were encouraged to practice what they had learned in that session at home.

## 4.5 Attention deficit hyperactivity disorder in young children

The characteristic features of attention deficit hyperactivity disorder (ADHD), such as hyperkinesis, poor attention and impulsiveness, are seem to be more or less the opposite of those qualities that meditators wish to cultivate. Meditation, in many ways seemed like an ideally designed antidote.

### 4.5.1 Ethics

Approval was obtained from the SESAHS ethics committee.

### 4.5.2 Participants and recruitment

The SYM trial treatment program was publicized in a newspaper article and an introductory lecture which was open to parents of school-age children diagnosed with ADHD. Parents were encouraged to participate with their children in a 6 week program in which SYM was taught in twice-weekly sessions.

### 4.5.3 Inclusion/exclusion criteria

The children admitted to this trial had a formal diagnosis of ADHD, that is, they met the DSM-IV criteria made by a paediatrician or child psychiatrist [267, 268], and scored above threshold for ADHD (i.e. a score of 15 and over) on the Conners Parent-Teacher Questionnaire.

### 4.5.4 Treatment program

The intervention was conducted over a 6 week period and consisted of twice-weekly 90 minute clinics, held in large meetings rooms at Prince of Wales Hospital, Sydney. For the first 3 weeks, the clinic consisted of guided meditation sessions, with parents attending one group and the children another. The sessions were conducted by meditation instructors experienced in SYM techniques. The meditation process involved practising techniques which helped participants to achieve a state of "thoughtless awareness". Instructors directed participants to become aware of this state within themselves by becoming silent and focusing their attention inwardly. Parents were also asked to conduct shorter meditation sessions at home twice a day.

In the clinic there were usually two periods of meditation of 5 to 15 minutes each, supplemented by information about how to meditate and the sharing of experiences. The parent sessions had one to two instructors, but the child sessions had a higher instructor-to-child ratio (normally, one instructor for every three children). From week 4 to week 6, one of the weekly sessions was conducted as a joint parent-child meditation. This enabled instructors to train parents on how to guide their child's meditation. Children and parents were asked to meditate regularly at home and to record their progress in a diary, which was checked each week to encourage compliance.

### 4.5.5 Assessment procedures - overview

Children and parents contributed to a range of data collection procedures, which drew on child self-report questionnaires and parent-rated questionnaires. Child data included information on ADHD symptoms, medication status, self-esteem, cognitive testing and perceptions of the meditation program. Child-parent relationship quality was also assessed. Parents were asked to give their views on the effectiveness of the program, for their children and themselves. ADHD symptoms (parent rating), medication consumption and perceptions of the programme are reported here. Assessments were conducted at three points: at recruitment or commencement of the meditation program (Week 1), at the midway point of the program (Week 3), and at the end of the program (Week 6). The full schedule of assessments was completed for the Study 1 sample. Study 2 assessments were only completed at the commencement and end of the program.

### 4.5.6 Child assessment measures

#### 4.5.6.1 Conners Parent-Teacher Questionnaire

ADHD symptoms were assessed via parent report, using the Conners Parent-Teacher Questionnaire Conners parent-rated checklists, which are shorter versions of the 93-item original, are commonly used tools in ADHD research and clinical practice[269]. The measure chosen for the present study presents 10 behavioural descriptors (e.g. excitable/impulsive, fail to finish things they start, short attention span) that parents rate on a four-point scale (0 = not at all, 1 = just a little, 2 = pretty much, 3 = very much), and one overall question “How serious a problem do you think the child has at this time?” (0 = none, 1 = minor, 2 = moderate, 3 = severe). These 11 items achieved a high level of internal reliability.

#### 4.5.6.2 Perceived outcomes of SYM for the child

At the middle and endpoints of the program, parents were asked to complete a short questionnaire asking whether they felt the meditation had benefited the child and whether it had made a change to the relationship they had with the child. Simple five-point rating scales were used to obtain information on the level of benefit (1 = little benefit; 5 = much benefit) for the child in the areas of emotions (less anxious, less angry, more able to manage negative feelings, less conflict, more cooperative), self-esteem (more confident), attention (improved memory, more able to settle down) and sleep (improved sleep pattern). Additional questions were included at the final point about the perceived benefits of the meditation program for the child's schoolwork. These included attitudes to school (more positive about school attendance), social relations (less difficulty with the teacher and other children) and attention to work (more able to manage schoolwork and homework). Samples of the questionnaires are found in Appendix 3.

#### 4.5.6.3 Psycho-stimulant medication

The SYM treatment program did not ask or advise parents to reduce their child's pharmacological treatment for ADHD, but it was clear from comments made by a number of parents at recruitment that they were looking for alternatives to medication. At the middle and endpoints of the program, parents were asked: "Have you been able to reduce your child's level of medication and still maintain an acceptable level of behaviour?" If medication had been reduced, parents were asked to report the proportion – less than half, half, or more than half. See Appendix 3.

### 4.5.7 Parent measures

4.5.7.1 Perceived outcomes of SYM

Parents were asked in a short questionnaire presented at the middle- and final points of the program, to report on their own experiences of the meditation program and whether they felt it had been beneficial to them. A five-point rating scale was used (1 = little benefit, 5 = much benefit), which measured the extent to which they felt happier, less stressed and more able to manage stress, less angry and more able to manage anger. At the end of the program, parents were also asked to provide written examples of recent positive and negative interactions with their child. See Appendix 3.

### 4.5.8 Analysis

Data was analysed to determine changes in Conners' Scale scores as well as between the two groups, to exclude some confounding effects to which both groups may have been exposed over the course of the meditation program.

## 4.6 Randomised controlled trials

The literature review clearly indicated that the question as to whether meditation has a specific effect had not been adequately answered despite having been subjected to almost 133 RCTs. The vast majority of these trials suffered from key weakness in design, mostly relating to selection of adequate control procedures, clarity of definition, statistical analysis, sample size and other methodological features. To avoid these pitfalls, an endeavour was made to design and implement two RCTs using the following:

- acceptable randomization methods

- blinding of investigators to subject allocation
- blinding of participants to the complete hypothesis of the RCT
- use of comparators that appropriately control for non-specific effects
- larger sample sizes
- appropriate statistical methods of analysis.

The health conditions selected for each trial were:

1. Asthma – 2 arm, randomised controlled trial
2. Work Stress – 3 arm, randomised controlled trial

## 4.7 Asthma

As a result of the findings in the non-randomized ADHD study a more thorough and reliable assessment of this technique seemed warranted. A RCT was designed and funding for it was sought from various institutions. Asthma was chosen as a condition amenable to meditation since it had been associated for many years with psychosomatic factors such as stress and emotional upset. Some funding was granted by the Royal Australian College of General Practitioners (RACGP) and further support was provided by the Royal Hospital for Women. This randomized study was designed to exclude the usual confounding effects that effect any clinical trial. In addition, it was designed to test the hypothesis that the beneficial effects of SYM are specifically related to the *mental silence* experience, rather than simple relaxation alone. In order to achieve this aim, a highly credible control intervention was developed that taught participants on the use of relaxation and stress management procedures. If significant differences were observed, that would support the idea that *mental silence*, rather than the less specific effects of relaxation alone, was the source of the specific effect of SYM. Extrapolating further, such an outcome would lend support to the idea that meditation, when defined as the *mental silence* experience, was associated with the specific effects predicted by both modern and ancient proponents of the technique.

### 4.7.1 Ethics

Approval was obtained from the SESAHS ethics committee, South Western Sydney Area Health Service and the RACGP ethics committees.

### 4.7.2 Study design

A parallel group, double blind, randomized controlled trial was conducted. After a 2 week baseline assessment period, participants were randomly allocated to SYM and placebo control intervention groups.

### 4.7.3 Intervention

Both the yoga and the control interventions required the participants to attend a 2 hour session once per week for 16 weeks. Participants were informed that the project aimed to assess relative effectiveness of two alternative relaxation techniques for the management of asthma. Outcome assessments were undertaken at the conclusion of the 16 week intervention period and again 8 weeks later.

### 4.7.4 Recruitment

Participants were recruited by newspaper advertisement, reviews of asthma clinic records, recruitment through GP’s and from the Asthma Clinic of two major teaching hospitals. A total of 850 people were screened from newspaper advertising, 200 from the Asthma Clinic records, and 30 from GP referrals. A final 120 people satisfied the phone-screening criteria and of these, 59 were found to satisfy the eligibility criteria after completion of baseline diary card, lung function and methacholine challenge and were therefore randomized into the study.

#### 4.7.5 Inclusion/exclusion criteria

The aim was to select adult patients with asthma who remained poorly controlled on moderate to high doses of inhaled steroids (i.e. optimal conventional management) and who were amenable to the idea of a non-pharmacological, stress management intervention.

People with asthma were eligible for inclusion if they were aged 16 or over and had a history of asthma symptoms for a least one year. Other inclusion criteria were: at least moderate to severe asthma, as evidenced by a combined asthma score of 7 or more out of 12[270] (see below); airway hyper-responsiveness ($PD_{20}FEV_1 < 12.2\mu$mol methacholine or > 15% $FEV_1$ bronchodilator response); daily inhaled treatment with ≥ 1500µg beclomethasone, 1200µg budesonide or 750µg fluticasone for at least the preceding 6 weeks; and stable asthma treatment for the preceding 6 weeks.

Exclusion criteria included those with a history of exacerbative or respiratory tract infections in the preceding 6 weeks, current smokers, pregnant or lactating women, people who could not communicate in English and anyone not amenable to stress management intervention.

#### 4.7.6 Meditation intervention

The SYM session was conducted by an experienced SYM instructor. Participants were taught how to achieve a state of *mental silence* by the use of silent psychological affirmations. They were encouraged to achieve this state twice each day for a period of 10 to 20 minutes.

The sessions were held on a weekly basis in the evenings at the local hospital. Each session lasted for two hours and involved meditation, instructional videos, personalised instruction and discussion of problems in relation to improving the experience of meditation.

The key experience of SYM, “thoughtless awareness”, is a state in which the meditator is fully alert and aware but is free of any unnecessary mental activity. The proponents of SYM claim that attainment of this state is crucial for its beneficial effects on physical and psychological health to be experienced. All instructional sessions and the advice given in those sessions was directed at facilitating and enhancing that experience.

#### 4.7.7 Placebo intervention

The control sessions were structured in such a way as to replicate the intervention sessions as exactly as possible. The sessions were held on a weekly basis at the same venue, and at the same time in the evening that the intervention group was held. The duration of the sessions was the same and the participants were required and encouraged to practice twice daily at home for the same amount of time that was recommended in the meditation group.

The method used in the control sessions was a combination of relaxation methods, group discussion and cognitive behaviour therapy-like (CBT) exercises. The program was highly plausible as a meditation-like programme. Relaxation methods involved positive affirmations such as "I can breathe easily and without restriction", progressive muscle relaxation, and visualisation of the lungs functioning easily. Group discussion was semi-formal and enabled participants to share experiences and develop a sense of community. The CBT-like exercises were designed to give the subject insight into the way in which their thoughts, feelings and reactions to stress, influenced the severity and perception of their illness. This approach was based on a workbook on relaxation and stress management techniques called "Learn to Unwind", produced by the Health Media and Education Centre, NSW Department of Health[271]. The sessions were supervised by an experienced and highly motivated professional.

There are a number of methodological difficulties in constructing a strict placebo intervention that has no clinical effect. The control intervention must be sufficiently convincing in order to motivate participants to maintain compliance but must not itself have a significant specific clinical effect. Yet, participants who do not experience clinical improvement will tend to drop out of the study or begin to suspect that they have been allocated to the placebo group, thus confounding the significance of the results. In this a comparison group was employed that was likely to elicit some clinical effect, most likely non-specific in nature. This would both ensure subject compliance as well as help differentiate between non-specific effects and any specific effects that may be associated with the SYM method. Since the SYM method focuses primarily on the experience of *mental silence* any significant differences in outcome between the two groups could be reasonably attributed to the *mental silence* construct.

### 4.7.8 Outcome measurements

Outcome assessments at baseline undertaken by an investigator who was blinded to the group allocation of the participants, at the end of the intervention and two months after its completion.

#### 4.7.8.1 Written diary cards

Subject were required to record twice daily, peak expiratory flow rates, symptoms, and bronchodilator use, for two-week periods at each assessment. The combined asthma score[270] the sum of these three components, was then calculated for each subject for each assessment period. The possible range of scores was 0 to 12. Average morning peak flow (am PEF) and lowest peak flow as a percentage of the highest peak flow (low% high) were calculated for each diary card.

4.7.8.2 Maintenance report

At each assessment, participants completed a questionnaire to assess the need for urgent doctor visits, time off work and changes in medication compared to baseline, over the preceding one month period.

4.7.8.3 AQLQ

A disease-specific asthma quality of life questionnaire[272] (AQLQ, University of Sydney) was used to measure a range of well-being scores. Total AQLQ scores and subscale scores for breathlessness, mood disturbance, social disruption and concerns about health were calculated on a scale of 0 (no impairment of quality of life) to 4 (maximum impairment).

4.7.8.4 POMS

The measure of mood states, Profile of Mood States[273], was also administered.

4.7.8.5 Spirometric function

This was measured at least 4 hours after the last dose of short-acting bronchodilator and 12 hours after the last dose of long-acting bronchodilator.

4.7.8.6 Methacholine challenge

In those whose $FEV_1$ was greater than 60% predicted[274] and who did not have a big breath effect (that is a 10% or greater fall after saline) a methacholine challenge test was performed to assess airway responsiveness. The rapid, hand-held dosimeter method was used[275] with a maximum cumulative dose equal to 12.2 μmol. The provoking dose required to cause a 20% reduction in $FEV_1$ from the post-saline value ($PD_{20}FEV_1$), was measured by linear interpolation on a log-dose response curve or by linear extrapolation to a maximum of twice the final dose administered. All extrapolated values greater than this were assigned a value of twice the final cumulative dose.

#### 4.7.8.7 Bronchodilator response

In participants with low lung function ($FEV_1$ < 60% predicted) or a big breath effect, the response to inhalation of salbutamol 200µg was assessed. For the purpose of measurement of change in airway responsiveness as an outcome measure, these participants were assumed to have severe airway hyper-responsiveness and were assigned a $PD_{20}FEV_1$ value of 0.1µmol. Values of $PD_{20}FEV_1$ and were log-transformed for analysis. Change in $PD_{20}FEV_1$ was expressed in units of doubling doses.

### 4.7.9 Analysis and sample size

Analysis was by intention-to-treat. Primary outcome variables were the combined asthma score, the AQLQ (total) score and $PD_{20}FEV_1$. All other outcomes were secondary outcome variables. Details of participants' record of attendance at the SYM and placebo control sessions were quantified to assess compliance.

All outcomes measured at the conclusion of the intervention and 8 weeks later were expressed as changes from baseline. Between-group differences in these changes were calculated, together with 95% confidence intervals. The changes were compared for statistical significance using Student's two sample t-test. Wilcoxon's non-parametric test was used to check the results of the parametric analysis for non-normally distributed data.

It was estimated that a sample size of 25 in each group would allow the detection of a one doubling dose difference between groups in $PD_{20}$ with 80% power ($\alpha = 0.05$). This sample size would also be sufficient to detect a clinically meaningful difference in

AQLQ scores between groups. To ensure 25 participants were available for evaluation, it was planned to randomize 30 participants into both groups.

## 4.8 Work stress

Since the asthma study indicated that a specific effect could be detectable in certain key parameters (see Chapter 8), a larger trial was designed to address the weaknesses of the asthma trial. The key weaknesses of the asthma trail were its small sample size and relatively high drop out rate. Moreover, while some clinical parameters did indicate significant benefits, others did not. The parameters in which specific effects seemed most pronounced were in those relating to mood, mental health and quality of life. Looking at the range of clinical conditions that might be best suited to the intervention, it became obvious that work stress was well suited to the apparent effects of meditation observed in the previous trial. Work stress is a pervasive, increasingly important issue in Western society, so recruitment for such a trial would be relatively easy and development of a simple strategy such as meditation as a method for dealing with the experience of work stress, was likely be welcomed by the community. This study again aimed to explore the hypothesis that *mental silence* was the key factor in the clinical response. Therefore a comparison group was selected that was also overtly meditative but which used the modern Western idea of meditation (relaxation, contemplation). A third "no treatment, waiting list" control group was included in the design to observe the relative effects of the two interventions as compared to no intervention at all, in order to gauge the magnitude of the non-specific effect, which it was contended would generate the changes in the relaxation-meditation group.

### 4.8.1 Ethics

Approval was obtained from the SESAHS ethics committee.

### 4.8.2 Design

This was designed as a three-arm randomized controlled trial which aimed to compare the relaxation-meditation intervention with the mental-silence intervention. In addition to these two groups a waiting list control was also used.

### 4.8.3 Instructional program

The instructional program spanned 8 weeks, and involved one hour evening sessions twice weekly. Participants travelled directly from work and were asked to practice daily with the aid of written and audio materials. Between classes instructors made themselves available to take queries or to give specific advice to participants.

### 4.8.4 Interventions

The two interventions were structured identically with the core experience of the meditation being the only major difference. To this end classes for both intervention groups were conducted at the same locations, in similar rooms, at the same time of day, and were of equal duration with equivalent periods between interventions. Both groups had as principal instructors, experienced health professionals with demonstrated proficiency in meditation instruction. The instructors were aware of the general aims of the study but not of the exact hypothesis. Both classes used hardcopy instructional material as well as an audiotape/CD[276,277] to facilitate daily practice at home. The fact that both classes had no significant differences in drop-out rates suggests that both interventions had similar credibility, expectation and demand characteristics.

### 4.8.5 Participants

To be eligible participants had to satisfy the following criteria:

- be in full time employment (more than 30 hours per week)
- be prepared to commit to the instructional programme and twice daily practice at home
- be non-smokers
- imbibe less than two units of alcohol daily
- be free of serious psychological/psychiatric morbidity
- not be using other stress management strategies
- have experienced no recent major life events
- not be using recreational drugs
- have no major medical illness
- be willing to fill out a questionnaire battery before and after the program.

### 4.8.6 Recruitment

Participants were recruited through advertising in local newspapers and other popular media over a two year period. The advertisements invited people interested in using meditation to relieve work stress to contact the research centre where they were telephonically screened for eligibility. The trial was conducted in the central business district of Sydney. A total of 178 people were accepted, 142 of these being females (M = 41.0 yrs, SD = 10.15 yrs) and 36 males (M = 45.9 yrs, SD = 7.9 yrs). They were from a variety of professional backgrounds; 22.9% from management and business related areas, 14.5% were in administrative-support roles, 11.2% were teachers or other types of educators, 8.4% were from medical and health related professions, 6.7% were in marketing and sales, 3.9% in financial services. The remainder (32.4%) were in various other professional categories. The educational status of the participants was as follows: 31% had completed high school, 51.9% had completed diploma or degree education and 27.4% had completed postgraduate education.

### 4.8.7 Procedures

Eligible candidates were invited to attend an orientation evening at a metropolitan hospital where the design of the study was explained. Those who wished to commit themselves to the study were asked to remain and fill out the baseline questionnaire battery. Participants were then randomly allocated to one of three groups:

#### 4.8.7.1 Relaxation-based meditation (RM)

RM is a generic meditation technique based on Western ideas of meditation as contemplation and relaxation. It involved a combination of modifying and focusing thinking activity and visualisation. Participants were instructed to sit comfortably, to breathe regularly and commence their meditation by reflecting on the day's events. They were then shown how to focus this mental activity by reflection and visualization. Troublesome experiences during the day were recorded in a notebook for self-assessment of progress. *Mental silence*-based *Sahaja Yoga* Meditation (SYM)

This group was taught the SYM *mental silence* technique which seeks to cultivate "a oneness with the present moment", to distinguish "the space between two thoughts" and thus achieve "thoughtless awareness"[239] i.e. *mental silence*. During this state the meditator remains fully alert, aware and in control of their cognitive faculties but remains free of unnecessary mental activity.

#### 4.8.7.2 Waiting list (WL)

The non-intervention group was comprised of participants who were told that they were on a waiting list to be admitted into one of the meditation groups at a later date but were required to fill out the same questionnaires at the same times as the two active intervention groups did. They were not told that they were a control group. At the end of the study these participants were given meditation classes in the same manner as the first two groups. The waiting list group was included primarily to control for practice effect associated with the psychometric questionnaires, regression to the mean and other non-specific effects which are common confounding factors in stress management studies[278].

### 4.8.8 Measures

The questionnaire battery was administered at baseline (at the orientation session) and then at the end of the eight week programme. Participants were mailed the post-intervention questionnaire and asked to complete it at the same time as the baseline questionnaire. Data was entered, scored and analysed blind to group status.

#### 4.8.8.1 Work Related Stress- The OSI's PSQ

A measure designed to assess strain resulting from work stress, the Psychological Strain Questionnaire (PSQ) (a component of the Occupational Stress Inventory, OSI)[279] was used. The PSQ measures vocational strain (VS), psychological strain (PSY), interpersonal strain (IS) and physical strain (PHS). The OSI is one of the most widely known and accepted measures of work stress.

#### 4.8.8.2 Work Related Anxiety-The STAI's "State" subscale

The State Trait Anxiety Inventory for Adults (STAI)[280] is a state and trait anxiety self report scale. It has been widely used for the assessment of anxiety. It is one of the most commonly used measures in stress management research. The State component of the STAI was used as a measure of work-related anxiety.

4.8.8.3 Work Related Depressive Symptoms- the POMS' "DD" subscale

The depression-dejection (DD) subscale of the Profile of Mood States (POMS) was used to assess depressive symptoms[273]. The POMS is not restricted to work stress but addresses general emotional states. While there are a wide variety of validated measures available for the assessment of depressive symptoms, my review of meditation RCTs found that the POMS was the second commonest measure used.

4.8.8.4 GHQ

The General Health Questionnaire 28 (GHQ28), a 28-item self-report scale[281], is a test designed to screen for subclinical anxiety, depression and psychosis and therefore identify those people at risk of progressing from moderate to severe psychological/psychiatric disorder. This test was selected for two purposes, one, as a screening tool to detect any adverse effects that may be associated with the interventions and, two, to provide an indication of whether or not the sample as a whole was experiencing significant psychological distress prior to the intervention.

## 4.9 Physiological trial

Finally, given the significant outcomes observed in the previous trials, particularly in the two RCTs, it was important to determine whether the state of *mental silence* is physiologically different from that of relaxation (one of the most prevalent definitions of meditation in the West literature). Participants in the meditating trials in fact reported that during *mental silence* meditation, they experienced cool sensations on their glabrous skin. This perception seems paradoxical, since it directly contradicts the Western understanding of meditation as a typical state of reduced autonomic arousal (i.e. para-sympathetic activation and sympathetic deactivation).

A reduction of autonomic arousal leads to diversion of blood flow to viscera and away from skeletal muscle of the body. Accordingly this leads to increased blood flow to the surface of glabrous skin and thereby an increase in palmar skin temperature. SYM practitioners appear to perform exactly the same overt task since, like conventional meditators, they appear to sit quietly. If however the physiological changes that occur are different then it would suggest that despite overt similarities, the biological events are quite different. This would suggest that SYM (and hence presumably the *mental silence* experience) is physiologically atypical. The *mental silence* experience may be associated with a unique spectrum of physiological activity.

### 4.9.1 Ethics

Approval was obtained from the SESAHS ethics committee and the Swinburne University Research Ethics Committee.

### 4.9.2 Design

The trial compared advanced meditators with a convenience sample of non-meditators matched for gender, age (within 2 years) and interest in participating in a study about the effects of relaxation and meditation.

### 4.9.3 Participants

The study involved 16 SYM meditators with between 1 and 25 years of experience and 10 novices with no experience of any meditation technique.

### 4.9.4 Procedure

Participants were seated in comfortable chairs in a quiet, climate-controlled room. A thermistor was attached to the centre of the palm of the non-dominant hand and a pulse oximeter was attached to the index finger of the same hand. The subject was allowed to be become acquainted with the environment for 30 minutes, after which time a research assistant asked them if they were ready to commence the data collection session. When the participant indicated that they were ready, the lights were dimmed and the subject commenced either meditation or relaxation by closing their eyes. The participant was asked to either meditate or relax as best they could for the next 10 to 15 minutes. At the end of the meditation or rest session the subject opened their eyes to indicate that they had finished.

### 4.9.5 Measures

#### 4.9.5.1 Heart rate

Heart rate was measured by a standard WR413 pulse oximeter with sensor placed on the middle-finger of the participant's dominant hand.

#### 4.9.5.2 Skin temperature

Skin temperature was measured with a thermistor sensor affixed to the palm of the non-dominant hand. Heart rate was recorded every 7 seconds and skin temperature every 60 seconds. The thermistor was calibrated and accurate to 0.1 degrees Celsius. The meditation/rest session was 10 minutes. Meditators reported that they found it difficult to meditate for much longer in the laboratory environment.

### 4.9.6 Analysis

The change in skin temperature between each 60 second interval was noted. The number of meditators who manifested either a decrease or increase in skin temperature compared to the number of “relaxers” who manifested the same phenomena. Degree of skin temperature change was compared to subjective ratings of *mental silence*. Heart rate changes were compared each group.

## 4.10 Summary

The studies described in this dissertation represent a progression in methodological rigour toward the successful implementation of a well-designed randomized controlled trial sufficiently sensitive and specific to detect specific effects that may arise as a result of the mental silence experience.

SYM was used because it utilizes a *mental silence* orientated understanding of meditation, which is a clearly defined meditative technique based on ancient traditional descriptions of the meditative state as a “trans-mind” experience.

By implementing this methodological strategy I was able to propose a different, more scientifically verified understanding of meditation which is more closely aligned with traditional ideas and seems more capable of generating a specific effect than the conventional Western definitions of meditation.

If it is possible to verify that the *mental silence* experience is associated with a specific effect, this would provide researchers with a promising new definition of meditation. An evidence based definition could not only resolve the current lack of clarity about meditation and the divergent and often conflicting perceptions promoted in the popular media and the modern scientific literature but also provide a rational platform by which the ancient tradition emanating from India can be compared, contrasted and perhaps even reconciled with modern thinking.

# Chapter 5. Functional Health of Long Term Meditators

## 5.1 Overview

Having established the rationale for the *mental silence* experience as the critical dimension of meditative practice, it is now necessary to determine if there is empirical data to support the validity of this proposition. The various studies in this dissertation thesis represent a stepwise progression in methodological rigour, the ultimate aim being to determine whether or not a causal link can be established between the experience of *mental silence* and health outcomes. This chapter, the first step in this process, is a cross sectional survey, which, while it cannot test for causality, can provide information about the hypothesis (i.e. existence and strength of any relationship between the variables of interest) as a relatively inexpensive and rapid-turn-around strategy. It will thereby provide an understanding of whether or not further allocations of resources and effort are justified.

It emerged from this survey's findings that long term meditators who use a *mental silence* orientated form of meditation, do experience better mental and physical health than the general population and that the "meditative lifestyle" appears to be specifically associated with better health scores. Importantly, the strongest and most consistent relationship between the health advantages experienced by this sample was with the experience of *mental silence*. Interestingly, those who participated in a convenience sample of meditators using meditation techniques not focused on *mental silence*, did not appear to experience the same health advantage. This finding strengthens the notion that *mental silence* and its associated yogic philosophy, may provide a basis for a typology of meditation that has practical salience. Furthermore, the empirical data here suggests a meaningful link between a specific state of consciousness and health and wellbeing benefits thereby providing a new perspective for scholars interested in the relationship between religiosity and health.

## 5.2 Introduction

### 5.2.1 Long-term effects of contemplative practices

It is evident from the introductory chapters that a substantial amount of scientific attention has been focused on assessing the effects of meditation and other contemplative practices within the context of intervention studies, the majority of which are of considerably poor quality. In the systematic review of meditation RCTs in Chapter 2, the median intervention period was 8 weeks. Less than one-third involved comprehensive follow-up assessment and the findings of those that did conduct follow-up assessments are considerably compromised by high levels of attrition, follow-up failure and other problems. In other words, the scientific information about these practices is limited to relatively short durations of practice and numerous methodological flaws. Moreover, none used the *mental silence* construct to define the independent variable. It should also be said that despite the considerable limitations in the extant data about the long term effects of meditation the data on the effects of other contemplative practices, such as prayer, is even less than that available on meditation.

Yet meditation as it was traditionally conceived, was intended to be a life-long practice, the benefits of which were not necessarily expected to manifest in the short term. Unfortunately, interventional studies to assess benefit (or detriment) over periods of years and decades, are difficult to execute and are prone to a wide range of confounding effects.

### 5.2.2 Religiosity, psycho-spiritual practices and health

While meditation is frequently perceived and portrayed in the West as a secular lifestyle or therapeutic practice, its origins are distinctly spiritual. The most comprehensive systems of meditation were derived from Hindu and Buddhist religious traditions. While many studies have assessed the relationship between health and religiosity in populations practicing conventional Western religious lifestyles, few have assessed that associated with Eastern religiosity. There is a growing body of evidence that points to a significant association between religiosity (a term under which both "spirituality" and "religion" will be subsumed for the purposes of this discussion) and health.

Probably the best known research concerned with this association comprises the approximately 200 studies on Seventh Day Adventists (SDAs) that have demonstrated specific physical health advantages, such as reduced risk of coronary heart disease and other chronic conditions. In the case of the SDAs, most of this health benefit appears secondary to their relatively specific diet and lifestyle, which includes avoidance of alcohol, tobacco and meat[282].

The association between religiosity and mental health is however not always positive. For example, Larson reviewed 50 studies that appeared in the *Journal of Psychiatry* and the *Archives of General Psychiatry* between 1978 and 1989, exploring the relationship between religious commitment and mental health[283]. Of these studies, 36 (72%) reported a positive relationship but 8 (16%) reported a negative relationship and 3 (6%) reported a neutral association.

This raises the question of how religiosity and its associated practices might enhance (or damage) health. Levin proposed some explanations[284]: Religious affiliation promotes adoption and maintenance of positive health behaviour and lifestyle factors such as lower rates of alcoholism, drug use, smoking, risky sexual activity, drink driving and other hazardous activities; fellowship buffers the effects of stress and isolation (it is well established that social support has substantially protective effects on health[285]); belief systems promote positive thinking and personality styles while ideas about faith promote optimism and hope, thereby providing important psychosocial resources for better coping; spiritual practices such as prayer and meditation may reduce the impact of stress.

Interestingly, there is also evidence that some associations between religiosity and health persist even after controlling for standard demographic, psychosocial and health factors. While there is still debate about both the veracity and strength of this relationship, the crucial and fascinating implication is that religiosity, rather than the lifestyles and behaviours secondary to it, may itself have a direct positive effect on health[286]. For example, in his extensive critical review of epidemiological studies Powell[287] found that, even after controlling for demographic, socio-economic, health related confounders and other conventional risk factors, there was a persistent relationship between regular churchgoing and a substantial reduction in mortality. In fact in two studies, this association was sufficiently strong for a dose response relationship to be observed[288]. Easterbrook went so far as to say "Lack of religious involvement has an effect on mortality that is equivalent to 40 years of smoking one pack of cigarettes per day"[289].

On the other hand there is also a potential for religiosity to have adverse effects on health, especially mental health. These include erosion of self-esteem and of feelings of competence as well as the cultivation of feelings of guilt and shame. Belief in Divine determinism and justice or other directives and norms, can induce passivity and abdication of responsibility. Religious congregations can be sources of stress and of negative pressures to conform[290,291,292].

Currently, the scholars who are driving much of the academic discussion about the association between religiosity and health have been primarily concerned with Western, Judeo-Christian forms of religiosity[293]. The data that they cite are mostly derived from epidemiological surveys and similar studies. While such studies can point out associations between religion and health, they cannot establish a causal relationship in the same way that observational trials, especially RCTs, can. Ironically, Eastern practices of meditation and yoga currently do demonstrate the kind of strong causal evidence — a significant proportion of which is based on RCTs, albeit for a non-specific effect[294], that the research focused on Judeo-Christian religiosity is lacking. While there is still debate as to whether or not these Eastern religious practices have specific or unique effects, it is clear that they do have an effect. It can thus be argued that the Eastern meditative tradition is a potentially rich, yet untapped, source of information for scholars seeking to understand how religiosity might impact on long-term and population health outcomes.

Therefore a study of long term meditators, with their inherent focus on meditative insight, modulation of consciousness and other key differences from Western styles of religiosity, offers an opportunity to:

- answer some important questions about long term benefits (or adverse effects) of regular meditation
- examine the relevance of the *mental silence* construct

- extend our understanding of religiosity beyond the confines of Judeo-Christian culture.

### 5.2.3 Studies of the health effects of prayer and meditation

5.2.3.1 Positive effects

In a 2001 US study Meisenhelder surveyed a sample of 1,400 Presbyterian pastors and found that they had considerably better health in comparison to US normative values. After controlling for age and other demographic variables, a small correlation was found between frequency of prayer and certain important health dimensions, particularly mental health (r = 0.117, $p < 0.0001$), vitality (r = 0.1032, $p < 0.0001$) and general health (r = 0.0879, $p < 0.001$), of the SF-36[256]. The investigators hypothesized that this correlation may have been due to the direct effects of prayer, the meditation-like activity of which combined with reduced physiological arousal and psychological support derived from seeking solace in “a divine other”.

One of the few recent cohort studies of meditation and health was undertaken by Reibel[295], who conducted a year-long observational study of *Mindfulness* among a heterogeneous sample of patients, for health related quality of life. Reibel used the SF-36, the Medical Symptom Checklist (MSCL) and Symptom Checklist-90 Revised (SCL-90-R). An 8 week *Mindfulness* stress reduction instructional program involving 136 participants was designed to instil in them *Mindfulness* skills that they were then expected to use regularly for as long as possible. At the one year assessment point, all indices of the SF-36 improved (all $p < 0.01$), physical symptoms reduced by 28% on the MSCL ($p < 0.0001$) and psychological distress decreased on the SCL-90-R by 38% ($p < 0.0001$).

#### 5.2.3.2 Negative effects

Despite the very positive perception enjoyed by meditation, there is a small but significant literature describing both serious and non-serious adverse reactions. In 1971 at the Stanford Research Institute, Otis conducted a follow-up survey of more than 1,000 people who had participated in the local student meditation instructional program. Approximately half (47%) responded to the questionnaire. To his surprise long-term meditators described a range of negative effects such as antisocial behaviour, anxiety, confusion and depression which were positively correlated with the length of time that participants had been practicing meditation. In contrast, dropouts from the program (people who ceased practicing meditation) reported significantly fewer complaints compared to experienced meditators[296].

Thus the only two long term studies of meditators currently available put forward a mixed picture about the long term benefits of meditation.

The important issue of adverse effects associated with meditation is covered in greater detail in Chapter 11.

### 5.2.4 Advantages of studying Western meditators

While the strong metaphysical linkage between Eastern religiosity, its psycho-spiritual practices and health may offer important new perspectives on the relationship between religiosity and health, there are a number of practical difficulties associated with studying the epidemiology of non-Western forms of spirituality. These include:

- differing criteria of religiosity
- new confounding variables relating to language, culture, ethnicity, diet and environment

- an absence of validated and reliable measures

- accurate data regarding the background population may be unavailable.

Given these considerable limitations, the study of a Western sub-population that has adopted a well-defined aspect of Eastern religiosity may be particularly useful as it allows comparison with well-developed, validated databases and commentary while avoiding a number of the confounders mentioned above. Studies such as this may provide important conceptual bridges by which researchers can extend their understandings of the relationship between religiosity and health in non-Western groups using a common set of empirical scientific tools.

### 5.2.5 *Mental silence* orientated forms of meditation

In order to establish how health is associated with traditional Eastern notions of religiosity, it is first of all necessary to identify well-defined constructs derived from this body of thought. It has been shown in the introductory chapters that "higher" states of consciousness are a key aspect of the Eastern spiritual and metaphysical paradigm. As we have seen in Chapter 3 *mental silence* is a distinct construct within that Eastern tradition of meditation and is indeed, one of its defining features. The advantage that the *mental silence* construct offers in studies such as this, is that it involves a discrete and definable factor by which competence at meditation can be assessed.

Two examples of meditation techniques available in the West that clearly involve the notion of *mental silence* are Zen and *Sahaja Yoga* (SYM).

#### 5.2.5.1 *Sahaja Yoga* Practitioner Population

In Australia the *Sahaja Yoga* meditation technique is practiced by several hundred people, many of whom are accessible through a network of grass roots collectives around the country. According to these practitioners, the meditative experience is a state of *mental silence* or “thoughtless awareness” in which the meditator is fully alert, aware and in control of their faculties, but does not experience any unwanted thought activity. According to its practitioners, this experience is the source of its benefits on health and wellbeing.

The SYM meditator aims to achieve and cultivate the experience of “thoughtless awareness”. As in the notion of “mindful awareness”[297] the meditator aims to sustain that experience even while not formally meditating. Unlike *Mindfulness* however, the state is not one of introspective, non-judgmental observation of one’s cognitions, but rather a state in which unnecessary mental activity is eliminated. An adequate analogy for the practice of SYM is that it can be likened to surfing, in that the meditator tries to capture a “wave” of *mental silence*, usually during the formal meditation at the beginning of the day, and then to ride that wave for as long as possible. The wave may last for a few seconds or for minutes or hours. As the meditator becomes more skilled, their ability to ride the wave increases. Moreover the state can ebb and flow throughout the day and the meditator learns over time to recognize the onset of the state and maximize it. With more experience the meditator also learns by trial and error, which internal and external factors can recreate the state, and over time adjust their lifestyle to optimize this.

The ultimate aim is to be in the state of thoughtless awareness continuously, which enables the meditator both to activate thought processes whenever necessary and also to deactivate them and return to the state of silence whenever they are not necessary.

By eliminating unnecessary thought, the meditator is more able to attend with clarity to the demands of the moment, and is less likely to react negatively to adverse situations.

When analytical thought is necessary, the meditator can think more clearly because the mind is uncluttered by random thoughts and background mental noise. Thus practitioners describe the experience of thoughtless awareness as an enhancement of awareness and self-control.

There are thus several advantages to studying a defined population of SYM practitioners. First, it offered a single, well-defined and therefore homogenous method of meditation. Second, as an experientially-orientated technique, SYM allowed assessment and comparison of the relationship between factors such as external practices (appearing to meditate) and the actual experience of meditation (*mental silence*) with health outcomes. Third, it provided for a measure of competency, albeit self reported, which is an important confounder when assessing the impact of meditation on health outcomes. And fourth, the various SYM collectives around Australia were willing to participate in the study without applying preconditions.

Accordingly, a cross sectional survey of the SYM population's physical and mental health using the SF-36 and K10 questionnaires was conducted. These data were compared to national population norms derived from recent national health surveys as well as a convenience sample of meditators who used a miscellany of techniques that did not involve the *mental silence* experience. The relationship between the practice of meditation, meditative experience and mental and physical health indicators was also explored.

#### 5.2.5.2 Zen

Zen meditation is also practised in Australia however we were unable to identify a defined population available for sampling.

## 5.3 Methodology

### 5.3.1 Measures

5.3.1.1 SF-36

The Medical Outcomes Study Short Form 36 (MOS SF-36) is a widely used health and quality of life self report questionnaire. It is used to assess perceived quality of life in 36 physical and mental health domains. The measures are generic (in other words, they are not age, disease or treatment specific) and therefore are suitable for screening the general population as well as allowing cross comparison between various subpopulations. Previous studies have verified the reliability and validity of the MOS SF-36 version 1 for use with medical and general population samples[298,299,300].

The SF-36 has been used extensively in Australia for both population health and clinical applications. Population norms exist for the SF-36 in both the USA and Australia. The Australian norms were collected in the 1995 National Health Survey[257]

Eight domains of health are evaluated in the SF-36, each relating to a specific valence of health experience:

1. **Bodily pain (BP) –** severity of pain and its impact on daily activities.

2. **General health (GH)** – a rating of one's own health, a comparison with other's health and proneness to illness.

3. **Mental health (MH)** – the degree of nervousness or calmness, happiness or sadness.

4. **Physical functioning (PF)** – the ability to perform activities (walking, climbing stairs, bending and stretching, lifting and carrying objects) without limitation.

5. **Role limitation–emotional (RE)** – limitations that emotional problems put on the range and extent of activities the individual is able to perform.

6. **Role limitation–physical (RP)** – the limitations that reduced physical health has on the range and extent of physical activities one is able to perform.

7. **Social functioning (SF)** – the impact of physical and emotional health on the ability to perform normal social activities.

8. **Vitality (V)** – the individual's level of energy or tiredness.

5.3.1.2 Kessler 10

The 10-item Kessler psychological distress scale (K10) is used to measure general psychological distress symptoms[259]. It was first documented by Kessler and Mroczek, in 1994 and was developed for screening populations in psychological distress[301]. It is therefore useful for assessing the prevalence of psychological distress at the community level and for use in epidemiological surveys.

The K10 has been used in a number of population health surveys in Australia, such as state-based CATI population surveys [260, 302] and the National Mental Health Survey conducted in 2001 by the Australian Bureau of Statistics[261]. It was used in the NSW 1997 and 1998 health surveys conducted by the Epidemiology and Surveillance Branch of the NSW Health Department. The K10 has yielded sound psychometric properties[259], and has been validated in the Australian population against clinical diagnoses of depressive episodes and generalized anxiety disorders[259].

The scale consists of 10 questions on non-specific psychological distress and is about the level of anxiety and depressive symptoms a person may have experienced in the most recent four-week period. The K10 enquires into feelings of nervousness, hopelessness, restlessness, worthlessness and depression — a typical question is: "During the past 30 days, how often did you feel so depressed that nothing could cheer you up?". Responses to each item are indicated on a 5-level response scale based on the amount of time, from 1 (none of the time) to 5 (all of the time) experienced in the past four weeks. Thus, the total K10 score for each person can range from 10 to 50 points, experiencing anxiety and depression none of the time through to all of the time.

The K10 scores can be grouped according to the criteria developed by the ABS for the 1997 National Mental Health and Wellbeing Survey[303], based on work by Andrews and Slade[261] into four levels of psychological distress:

1. low (10–15)
2. moderate (16–21)
3. high (22–29)
4. very high (30+).

The last category represents the portion of the population previously found to meet diagnostic criteria for clinical depression and anxiety requiring professional help.

The scores can also be grouped into two groups: 1) "low" or "moderate" levels of psychological distress (10–21) and 2) "high" and "very high" levels of psychological distress (22 and over). Or into 3 groups as developed by the Clinical Research Unit for Anxiety and Depression (CRUFAD) in the UNSW School of Psychiatry[152]. Deriving these categories for the K10 is also necessary to indicate prevalence according to levels of severity[304]. However for the purposes of this study, the ABS categories were used for ease of comparison with the population norms developed thereof.

#### 5.3.1.3 Meditation lifestyle survey (MLS)

This instrument was developed to quantitatively assess the frequency of meditative practices among meditators and their adherence to various lifestyle guidelines. Variables in the meditator's lifestyle that could act as confounders in the assessment of relationships between factors of interest and health outcomes were also included. The primary factor of interest was the experience of *mental silence* or "thoughtless awareness" in the SYM technique. The rationale of the SYM lifestyle and meditative practices is that they are designed or observed in order to maximize the meditator's ability to tap into the *mental silence* experience. Conceptual validity analysis of the MLS (in the analysis and results section) demonstrated that it explained at least 75% of the variance in meditators' self reported experience of *mental silence*, indicating that the MLS was effective in capturing the salient factors in the SYM lifestyle.

##### *5.3.1.3.1 Conceptual development of the MLS*

Interviews, focus groups and discussion forums with SYM practitioners were conducted to determine the basic factors that comprised their "meditative lifestyle". They described a common set of lifestyle factors adopted to enhance their ability to experience "thoughtless awareness" and hence their overall wellbeing and quality of life. These involved:

1. Regular meditation once or, ideally, twice, per day.

2. Use of established variations of meditation to enhance the quality of meditation and reduce the long term impacts of stress. The main technique was "foot soaking" which is ideally done regularly, preferably daily. Foot soaking is a relatively ubiquitous home ready used in many societies, it involves immersing the feet in a basin of salt water for approximately 15 minutes. SYM meditate while footsoaking

who regard it as being especially effective in reducing tension and stress and improving the quality of the *mental silence* experience.

3. Regular collective meditation, defined as involving at least three SYM meditators but preferably the whole collective of SYM meditators in the local area. This is usually done within the context of a weekly meditation meeting at a meditation centre. Some practitioners who live in the same suburb, or even the same residence as other practitioners, may meditate collectively on a daily or even twice daily basis.

4. A certain amount of social interaction with SYM meditators within the context of their grass roots organization.

5. Ethical and moderate behaviour.

6. Abstention from alcohol, tobacco and recreational drugs or any substance that affects awareness, but not necessarily caffeinated beverages.

7. Avoidance of extreme or risk-taking behaviours, and observance of one's social and community responsibilities such as family, gainful employment and observance of the law.

8. Avoidance of sexual relationships outside of marriage.

Using this information, a survey was developed to assess the way in which these various factors influenced the various outcomes of the survey (see Appendix 3) within the SYM population. The items in the Meditation Lifestyle Survey (MLS) relate specifically to:

1. **RM** = whether they consider themselves to have been regularly meditating over the last few weeks.

2. **FM** = frequency of formal meditation, defined as "when you are not doing any other simultaneous activity besides meditation".
3. **CM** = frequency of formal "collective" meditation, involving at least three SYM practitioners doing formal meditation in the same location.
4. **SM** = frequency of attending social gatherings that mostly involve other SYM practitioners but does not involve formal group meditation.
5. **MM** = frequency of attendance of the main collective meeting.
6. **TA** = frequency of experiencing "thoughtless awareness" for more than one or two minutes.
7. **FS** = frequency of foot soaking and similar practices designed to enhance the quality of meditation.
8. **DP** = duration (in years) for which they consider themselves to have been a SYM practitioner.
9. Frequency of consumption of tobacco, alcohol, marijuana or other recreational drugs.

These were then developed into specific items reflecting the various factors and constructs described above.

It is important to note that while FM identified the frequency with which meditators went through the overt actions of meditating (such as assuming a specific posture, during which a specific technique is applied, in a formally defined session) TA related to the specific meditative experience of *mental silence*.

*5.3.1.3.2 Adapting the MLS for non-mental silence forms of meditation*

Any person practicing regular meditation, regardless of technique, is likely to develop a lifestyle that resembles the factors represented in the MLS. On the other hand, as has been argued in Chapters 2 and 3**,** there may also be important differences leading to variations in how meditation is incorporated into practitioners' daily lives. Therefore, before applying the MLS to the comparison group, it was necessary to adapt it sufficiently to broaden the meaningfulness of the survey for use by practitioners of other techniques. The following minor changes were made to the MLS:

1. References to SYM were exchanged for the more generic term "meditation".

2. The term "collective meditation" was changed to "formal group meditation" although the definition was maintained as "involving at least three meditators doing formal meditation in the same location".

3. The item inquiring about frequency of attending main collective meetings was removed as this did not consistently reflect the practices and attitudes of many of the meditation organizations contacted.

4. The term "thoughtless awareness" was substituted by "informal meditation", although it became evident that this was not an effective equivalent construct that could be applied across the various meditation techniques included in this sample. *Data relating to this item was excluded from the final analysis*.

5. Participants were specifically requested to report in writing the technique of meditation they practiced.

Despite conceptual differences between meditation techniques, it was still possible to maintain cross compatibility for a large proportion of the variables.

### 5.3.2 General survey procedure

5.3.2.1 *Mental silence* practitioners

A national cross-sectional survey of regular SYM practitioners in Australia was carried out. A researcher travelled to each of the capital cities of Australia and attended the main collective meditation meeting. They also attended one-day and weekend meditation retreats held between six and ten times per year.

The SYM meditators stated that they did not maintain formal membership lists. They suggested that it was more useful to distinguish “practitioners” from “non-practitioners” such that any person who strove to maintain the basic tenets identified in the focus groups was implicitly a “practitioner” of SYM. Practitioners chose to be involved in the local grass roots “collective” to the degree that they wished.

An important challenge was to identify individuals maximally engaged in the various behavioural and lifestyle factors being studied in order best to accentuate any contrasts between them and the general population. In the focus groups, as well as in interviews with state and local coordinators, the consensus view was that people attending the main collective meetings and retreats were much more likely to be regular meditators (i.e. “practitioners”) who observed the various tenets of the SYM lifestyle as described above, than those who did not attend. In other words, this particular section of the SYM population was comprised of practitioners who conscientiously followed the SYM lifestyle. Accordingly, these practitioners were specifically targeted in the recruitment process. At each meeting/retreat, the study was explained to the group and SYM practitioners were requested to participate anonymously. It was evident that the vast majority of practitioners responded. A formal head count indicated that of the total of 336 practitioners present at these meetings/retreats, 311 participated in the survey.

In addition to this, further informal lists of local phone contacts were used to identify those who did not attend the collective meetings but who nevertheless may have classified themselves as practitioners. Questionnaires were mailed to them to encourage them to participate and they also received follow-up phone calls to maximize return rates. Practitioners suggested that while the majority contacted in this way were probably less regular meditators, they nevertheless had some degree of commitment to a lifestyle that involved meditation. A close examination of the various local and national phone lists of SYM practitioners revealed 551 names. Each person was phoned by a research assistant. In order to eliminate duplication they were asked if they had filled out a survey at any other meeting or retreat. If they had not, a survey was mailed to them with a self-return envelope. Thirty-two surveys from this section of the population were returned.

#### 5.3.2.2 Comparison meditators

In order to develop a meaningful understanding of the survey results, it was important to contrast this "intervention" sample against a comparable group whose demographics and lifestyle practices were as similar as possible in all variables other than those characteristic of the intervention. For the purposes of this exploratory study, a convenience sample of meditators drawn from the surrounding population was used.

Current scientific opinion does not recognize any major feature that practically differentiates between meditation techniques, despite the diversity of their background philosophies and methodologies. In this study however, it is argued that the primary differentiating feature of SYM is the experience of "thoughtless awareness" or *mental silence*, since this is characteristic that is unique among other popular meditation techniques available in the West. Given these considerations, practitioners of any technique were included in the comparison group as long as the experience of “thoughtless awareness” or *mental silence* was not a feature of that technique’s defining criteria.

This comparison sample was a convenience sample. Unlike those in the SYM sample, who all more or less adhered to a homogenous set of lifestyle factors, there are probably considerable differences in the lifestyles,underlying philosophies of various respondents. Therefore it is likely that there were a substantial number of confounding differences in this sample that are impossible to control for in a survey like this. For these reasons it may be best to understand this as a “comparison” group rather than a “control” group and the resulting differences between them and SYM should be understood in an exploratory rather than definitive context.

The comparison sample was recruited using Internet, telephone listings and other information sources. A wide variety of meditation organizations that either taught or supported the practice of meditation in the general community were contacted. If the organization agreed to participate in the survey, the research assistant sent the relevant contact person as many survey forms as they requested along with self-return envelopes. These were then distributed internally via various channels such as meetings, with newsletters, notice boards and personal contacts.

## 5.4 Analysis and results

### 5.4.1 Response rates

It is difficult to determine the exact response rate for the two samples since there is no definitive data available on what proportion of the general population could be classified as regular meditators.

#### 5.4.1.1 SYM practitioners

A total of 343 surveys were returned, Of these, 311 were derived from collective meetings and retreats (of which total attendance, by head count, was 336) whereas 32 were mailed to the research assistant after 'phone contact (out of a total of 115 which were mailed out after 'phone contact). Hence the 311 surveys collected from meetings and retreats represent approximately 93% of practitioners who might be regarded as conscientiously incorporating SYM practices into their daily lifestyle in accordance with the guidelines developed from the focus groups and interviews described above. The surveys represent 63% of the total population of the 550 practitioners in Australia.

#### 5.4.1.2 Comparison practitioners

Considerably less information about membership was available from the Comparison meditation groups and organizations. For example, the Sydney Buddhist Meditation Centre had a newsletter which was distributed to several hundred recipients, but this centre's management felt that the number of meditators who used the facility on an ad hoc basis was several times greater although official records of attendance were not kept. Surveys were distributed by both newsletter and personal contact at the centre. Other centres had policies preventing the release of such information.

Due to restrictions imposed by some of the organizations that agreed to cooperate with the study, it was not possible to include both the SF-36, K10 or MLS in all circumstances. Hence, although 400 surveys were sent out to various meditation organizations, as set out below, the return rates were different for different components of the survey:

- 184 respondents provided information on age, gender and ethnicity

- 74 responses were obtained for the SF-36 only (which included age, gender, ethnicity but no other demographic details)

- 53 responses comprised the MLS and the SF-36

- 55 responses included the MLS, SF-36 and K10.

Due to the small size of the K10 dataset, only the data for the MLS and the SF-36 was analysed.

The various techniques represented in the comparison sample and their respective frequencies are summarized in Table 5.1.

Table 5.1 Relative frequency of various meditation techniques used by the comparison sample.

| Technique | Percentage of total sample |
|---|---|
| Vipassana | 27% |
| *Mindfulness* | 16% |
| Mantra | 11% |
| Christian | 11% |
| Buddhist | 5% |
| Zen | 5% |
| Not specified/miscellaneous | 24% |

### 5.4.2 Demographic data and MLD comparison

The demographic data for the two groups is summarized in Table 5.2.

Table 5.2 Demographics of *mental silence* (MS) and comparison (Comp) samples.

| Factor | MS | Comp |
|---|---|---|
| Number of responses | 343 | 184 |
| % Male | 39.6 | 22.5 |
| Mean age | 44 | 49 |
| % Caucasian | 77.2 | 94.3 |
| % Asian | 21.9 | 5.6 |
| %Single/never married/divorced/widow | 27 | 48.1 |
| %Married/de facto | 73 | 51.9 |
| High school, highest level | 25.9 | 19 |
| Undergraduate, highest level | 49.4 | 45.2 |
| Postgraduate, highest level | 21.2 | 31 |
| No history of mental illness | 87.9 | 66.7 |
| History of minor mental illness | 10.4 | 30.6 |
| History of major mental illness | 1.7 | 2.7 |

Meditation lifestyle data, on comparable domains, are summarized and compared in Table 5.3.

Table 5.3 Meditation lifestyle data of *mental silence* (MS) and comparison (Comp) groups.

| Meditation Lifestyle Data | MS | Comp |
|---|---|---|
| Total responses (n) | 343 | 108 |
| Duration of practice (years) | 12.9 | 9.7 |
| Meditate regularly | 95.6 | 96.3 |
| Formal meditation, twice/day | 51.2 | 16.7 |
| Formal meditation, once/day | 31.8 | 22.2 |
| Formal meditation, most days | 12.1 | 32.4 |
| Formal meditation, once /week or less | 5.0 | 28.7 |
| Group meditation, once /day or more | 10.1 | 1.9 |
| Group meditation, most days | 10.2 | 1.9 |
| Group meditation, once /week | 60.5 | 25.5 |
| Socialize with meditators most days or more often | 11.6 | 1.0 |
| Socialize with meditators once /week | 37.8 | 9.7 |
| Socialize with meditators less than once /week | 50.6 | 89.4 |
| Do not consume alcohol | 92.3 | 30.8 |
| Do not smoke | 92.6 | 89.7 |
| Do not use marijuana or other recreational drugs | 98.0 | 87.9 |

### 5.4.3 MS experience of thoughtless awareness

Just over half of the SYM sample, 51.9%,claimed to experience the state of *mental silence* or “thoughtless awareness” for more than one or two minutes several times a day or even more frequently. A little over one quarter, 28.6%, experienced this state once or twice day. Approximately one tenth, 11.3%, experienced once or twice per week. A much smaller proportion experienced it less often. This data is summarized in Figure 5.1.

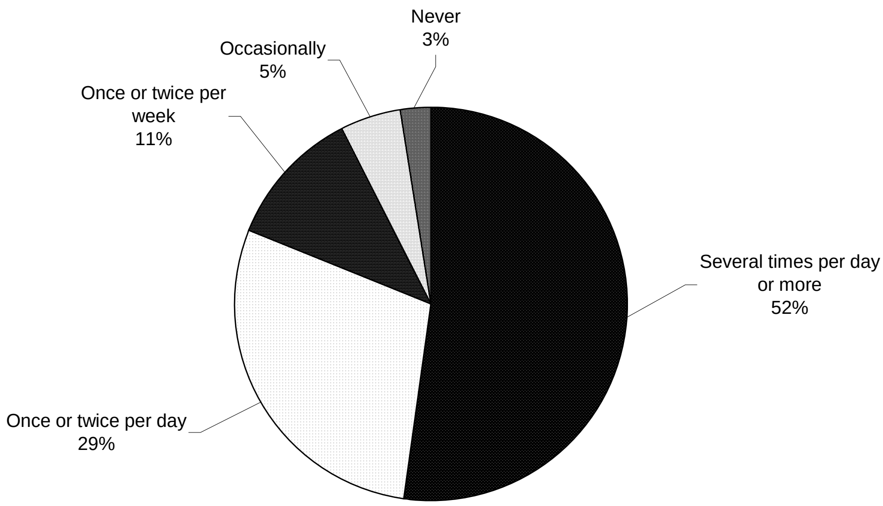


Figure 5.1 Proportion of SYM respondents experiencing *mental silence* of more than a few minutes, separated into categories.

### 5.4.4 SF-36 scores of the *mental silence* meditators

Functional health scores for SYM practitioners were high. Table 5.4 shows the mean and standard deviation for the 8 subscales, the mental health summary score (MCS), physical health summary score (PCS) and total score (SF-36) of the SF-36 Health Survey, on a scale of 0 – 100 with a high score indicating good health.

The SF-36 is standardized to a mean of 50 and a standard deviation of 10. This data is also depicted in Figure 5.2.

Table 5.4 Mean and standard deviation for 11 functional health scores for SYM practitioners.
– 8 subscales, MCS, PCS and total score for SF-36.

| Health score | SYM group n | SYM group Mean | SYM group SD | Comparison group n | Comparison group Mean | Comparison group SD |
|---|---|---|---|---|---|---|
| PF | 346 | 86.21 | 25.50 | 182 | 87.19 | 19.17 |
| RP | 346 | 78.54 | 41.04 | 182 | 83.51 | 65.93 |
| BP | 346 | 80.84 | 22.12 | 182 | 71.92 | 22.58 |
| GH | 333 | 82.52 | 15.37 | 180 | 74.10 | 19.51 |
| V | 338 | 70.25 | 17.61 | 182 | 63.15 | 18.32 |
| SF | 338 | 88.77 | 18.04 | 182 | 85.17 | 22.11 |
| RE | 335 | 89.18 | 23.74 | 182 | 80.21 | 38.72 |
| MH | 337 | 85.31 | 12.31 | 182 | 78.15 | 16.82 |
| PCS | 329 | 80.94 | 15.51 | 180 | 76.04 | 20.95 |
| MCS | 318 | 83.45 | 11.56 | 180 | 76.10 | 17.92 |
| SF-36 | 318 | 83.86 | 12.47 | 180 | 77.96 | 18.38 |

n = number of samples, SD = standard deviation

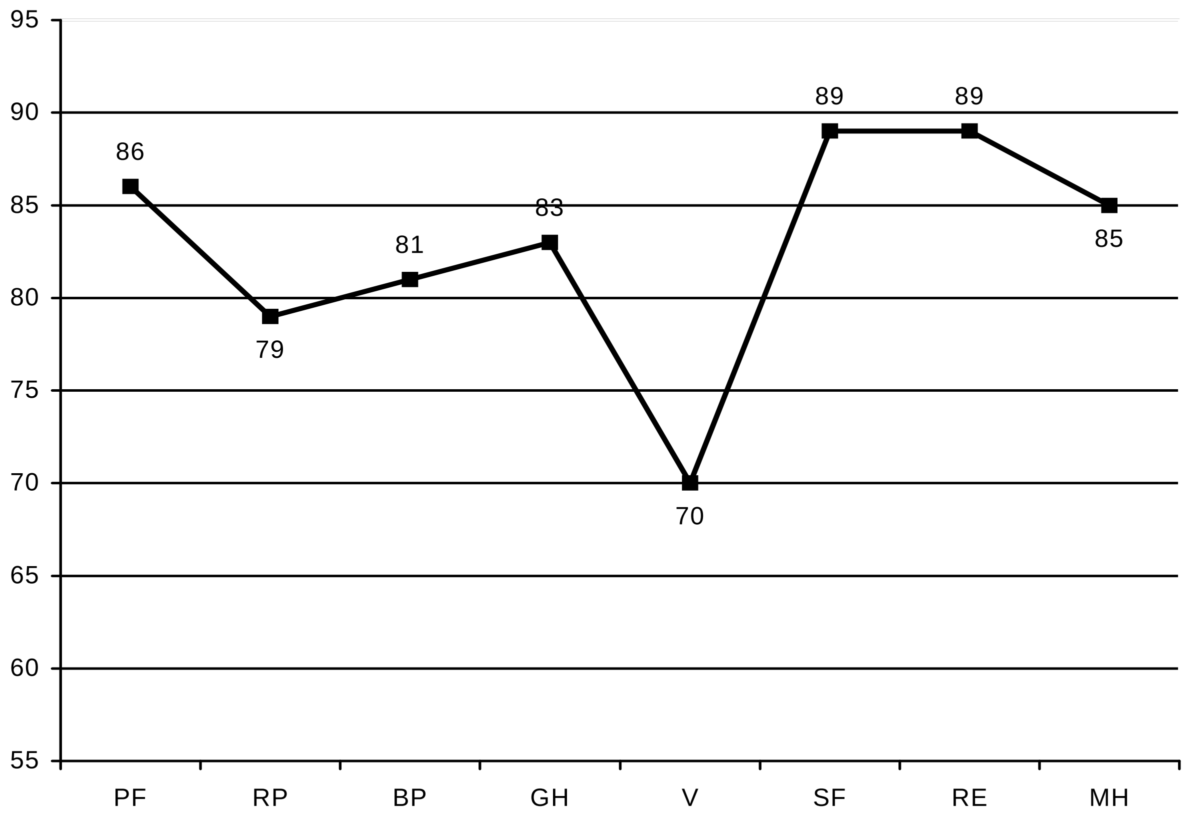


Figure 5.2 SF-36 polygon for SYM sample.
Each data point represents one of the 8 subscales of the SF-36 health questionnaire.

A total of 92% of the respondents described their health as “excellent” (28.6%), “very good” (43.8%), or “good” (19%).

Nearly half, 48.6%, described their health as “much better” or “somewhat better” than a year ago, while 45.7% described their health as “about the same” as a year ago. While 88.1% agreed that their health was “definitely” or “mostly” excellent.

Based on the data presented in the literature review, current opinion might indicate that a relationship between meditation and health scores might be observed. To identify any potential relationships between frequency of formal meditation (FM) and health, the means of the various SF-36 subscale scores were calculated for each FM category. Categories 4 (once per week), 5 (once every two or three weeks) and 6 (once a month or less) were combined because the number of participants in these categories was very small. This data is summarized in Table 5.5. Upon gross inspection of the data no relationship was obvious.

Moreover, Pearson Product Moment calculations comparing the SF-36 total, the PCS, the MCS and the SF-36 subscale scores with raw FM scores, did not reveal any notable correlations. See Table 5.6.

Table 5.5 Mean and standard deviation for SF-36 subscales of formal meditation categories.

| FM categories | | PF | RP | BP | GH | V | SF | RE | MH | PCS | MCS | Total SF-36 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Twice per day or more** | M | 88.44 | 83.05 | 82.31 | 84.28 | 72.40 | 89.25 | 90.14 | 86.84 | 82.71 | 84.87 | 85.26 |
| | n | 174 | 174 | 174 | 167 | 171 | 171 | 172 | 169 | 165 | 158 | 158 |
| | SD | 19.44 | 33.79 | 19.45 | 14.62 | 16.34 | 17.42 | 23.62 | 10.66 | 13.17 | 10.71 | 10.93 |
| **Once per day** | M | 87.59 | 72.22 | 79.11 | 80.21 | 68.11 | 87.13 | 87.66 | 84.15 | 78.18 | 81.50 | 81.45 |
| | n | 108 | 108 | 108 | 106 | 106 | 106 | 105 | 107 | 105 | 103 | 103 |
| | SD | 20.94 | 43.28 | 23.46 | 17.05 | 19.28 | 19.88 | 25.83 | 13.24 | 18.24 | 13.42 | 14.76 |
| **Most days** | M | 88.90 | 90.24 | 83.07 | 82.66 | 67.80 | 90.63 | 90.05 | 83.80 | 82.46 | 83.33 | 84.75 |
| | n | 41 | 41 | 41 | 41 | 41 | 41 | 40 | 41 | 41 | 40 | 40 |
| | SD | 20.23 | 23.64 | 17.46 | 13.59 | 17.82 | 17.58 | 18.76 | 11.24 | 13.14 | 9.28 | 10.61 |
| **Once per week or less** | M | 81.47 | 75.00 | 78.29 | 79.80 | 69.38 | 90.20 | 87.50 | 83.25 | 81.53 | 82.13 | 83.80 |
| | n | 17 | 17 | 17 | 15 | 16 | 15 | 16 | 16 | 15 | 15 | 15 |
| | SD | 36.13 | 55.90 | 33.37 | 16.63 | 15.59 | 13.36 | 24.02 | 12.41 | 15.30 | 11.34 | 13.90 |

M = mean, n = number of samples, SD = standard deviation

Table 5.6 Correlation of FM scores with SF-36 subscale scores.

| | | PF | RP | BP | GH | V | SF | RE | MH | PCS | MCS | Total SF-36 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **FM** | Pearson Correlation | 0.079 | 0.077 | 0.020 | 0.051 | -0.030 | 0.015 | 0.040 | -0.104 | 0.085 | 0.003 | 0.061 |
| | Significance (2-tailed) | 0.146 | 0.155 | 0.710 | 0.353 | 0.580 | 0.784 | 0.468 | 0.059 | 0.124 | 0.951 | 0.276 |
| | n | 340 | 340 | 340 | 329 | 334 | 333 | 333 | 333 | 326 | 316 | 316 |

n = number of samples

In line with the notions outlined in Chapters 2 and 3 of this thesis, the same data was examined to identify any potential relationship between TA and health scores. The means of the various SF-36 subscale scores were calculated for each TA category to facilitate inspection.

The categories for TA, based on frequency of experience were: "Experience *thoughtless awareness*":

1. several times per day or more
2. once or twice per day
3. once or twice per week
4. once or twice per month
5. less than once per month.

Upon gross inspection of the data (and unlike the FM item), a linear relationship did seem obvious for some categories. See Table 5.7. The relationship is illustrated graphically in Figure 5.3 using the mental health subscale of the SF-36 data.

Table 5.7 Cross-tabulation of TA Categories with SF-36 subscale scores in the SYM sample.

| Category of MS | | MH | PF | RP | BP | GH | V | SF | RE | PCS | MCS | Total SF-36 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| >2x per day | M | 87.98 | 87.46 | 82.77 | 80.79 | 85.09 | 72.60 | 88.42 | 91.17 | 82.17 | 85.32 | 85.21 |
| | n | 172 | 177 | 177 | 177 | 171 | 175 | 176 | 173 | 170 | 163 | 163 |
| | SD | 10.04 | 20.66 | 35.25 | 21.27 | 13.97 | 18.03 | 19.48 | 22.39 | 14.85 | 11.14 | 11.916 |
| 1 or 2x per day | M | 85.35 | 88.45 | 79.04 | 82.13 | 80.97 | 69.58 | 89.91 | 87.10 | 80.41 | 82.77 | 83.20 |
| | n | 98 | 99 | 99 | 99 | 98 | 96 | 97 | 98 | 95 | 94 | 94 |
| | SD | 10.46 | 19.16 | 36.02 | 18.9 | 16.50 | 16.47 | 15.89 | 26.06 | 15.69 | 12.06 | 13.03 |
| 1 or 2x per week | M | 81.05 | 85.13 | 80.13 | 83.62 | 79.36 | 68.29 | 90.08 | 90.14 | 81.58 | 81.79 | 83.47 |
| | n | 38 | 39 | 39 | 39 | 36 | 38 | 36 | 37 | 36 | 34 | 34 |
| | SD | 12.043 | 30.25 | 41.03 | 24.31 | 14.35 | 14.81 | 15.09 | 19.00 | 13.64 | 8.53 | 11.03 |
| 1 or 2x per month | M | 74.46 | 83.08 | 55.77 | 78.23 | 77.42 | 60.00 | 80.00 | 83.42 | 76.67 | 76.83 | 78.58 |
| | n | 13 | 13 | 13 | 13 | 12 | 13 | 13 | 12 | 12 | 12 | 12 |
| | SD | 22.30 | 36.55 | 61.37 | 22.64 | 22.53 | 20.82 | 21.25 | 22.45 | 19.34 | 13.22 | 14.88 |
| < 1x per month | M | 71.69 | 88.46 | 73.08 | 81.31 | 74.77 | 59.62 | 87.62 | 82.00 | 75.31 | 75.15 | 77.31 |
| | n | 13 | 13 | 13 | 13 | 13 | 13 | 13 | 13 | 13 | 13 | 13 |
| | SD | 21.45 | 21.83 | 40.13 | 17.65 | 16.50 | 19.41 | 18.40 | 35.08 | 15.88 | 13.52 | 15.16 |

M = mean, n = number of samples, SD = standard deviation

1x = once

2x = twice

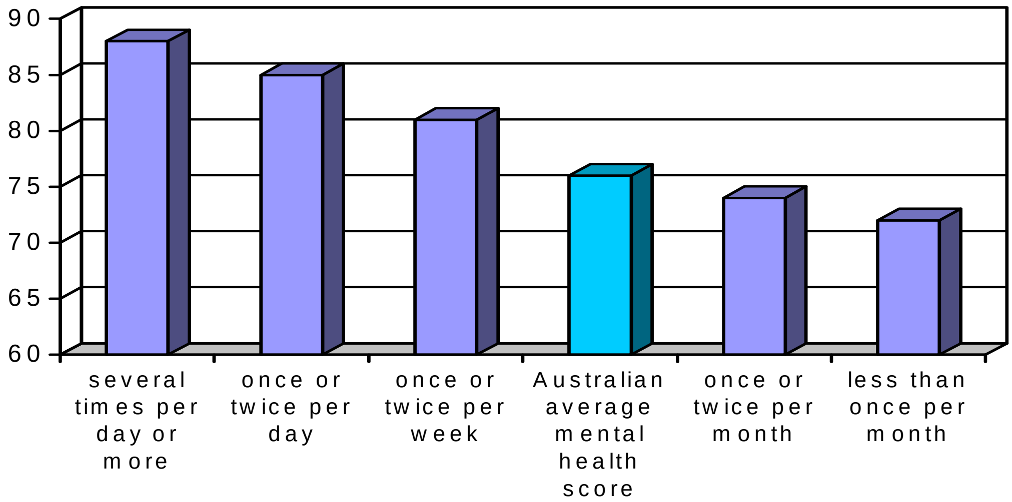


Figure 5.3 Mental Health subscale score for each category of TA.

When Pearson Product Moment calculations comparing the SF-36 total, the PCS, the MCS and the SF36 subscales with TA raw scores were calculated, a number of notable correlations emerged. This data is summarized in Table 5.8. Linear relationships were apparent for mental health (MH), general health (GH), vitality (V), mental health summary score (MCS) and SF-36 total score. The most clearly obvious linear association was with the MH subscale.

As shown in Table 5.9, comparing the MH score of each TA category, the mean score of the first three categories is significantly higher than the national norm score for the same category.

Table 5.8 Correlation of thoughtless awareness and SF-36 scores.

| | | PF | RP | BP | GH | V | SF | RE | MH | PCS | MCS | Total SF-36 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **TA** | Pearson Correlation | -0.039 | -0.099 | -0.005 | -0.200** | -0.217** | -0.030 | -0.097 | -0.345** | -0.125* | -0.243** | -0.175** |
| | Sig. (2-tailed) | 0.474 | 0.067 | 0.928 | 0.000 | 0.000 | 0.586 | 0.077 | 0.000 | 0.024 | 0.000 | 0.002 |
| | n | 341 | 341 | 341 | 330 | 335 | 335 | 333 | 334 | 326 | 316 | 316 |

n = number of samples

* = 0.05 — Probability of a Type I error

** = 0.01 — Probability of a Type I error

Table 5.9 Comparison of the MH score for each TA category.

| TA Category | Number in sample | TA category mean score | TA category score SD | t | df | Significance | Mean difference |
|---|---|---|---|---|---|---|---|
| Several times per day | 172 | 87.98 | 10.04 | 15.97 | 171 | 0.001 | 12.22 |
| Once or twice per day | 98 | 85.35 | 10.46 | 9.07 | 97 | 0.001 | 9.59 |
| Once or twice per week | 38 | 81.05 | 12.04 | 2.71 | 37 | 0.010 | 5.30 |
| Once or twice per month | 13 | 74.46 | 22.30 | -0.21 | 12 | 0.838 | -1.29 |
| Less than once per month | 13 | 71.69 | 21.45 | -0.68 | 12 | 0.508 | -4.06 |

### 5.4.5 Kessler 10 scores for *mental silence* meditators

The mean score for the SYM sample was 13.5. The lowest possible score (i.e. 10) was reported by 18.4% of respondents. The scores were then grouped according to the criteria established by the ABS[303]

1. low (10–15)
2. moderate (16–21)
3. high (22–29)
4. very high distress (30+).

The last category represents the portion of the population previously found to meet diagnostic criteria for clinical depression and anxiety requiring professional help. These are summarized in Table 5.10.

Table 5.10 SYM in K10 ABS categories.

| ABS category | Number in sample | % of sample |
|---|---|---|
| Low (10–15) | 271 | 78.3 |
| Mod (16–21) | 63 | 18.2 |
| High (22–29) | 9 | 2.6 |
| V. High (30 or more) | 3 | 0.9 |

To identify any potential relationships between frequency of meditation (FM) and health, the means of the K10 scores were calculated for each FM category (See Table 5.11). Categories 4 (once per week), 5 (once every two or three weeks) and 6 (once a month or less) were combined because the number of participants in these categories was too low to allow sensible analysis as separate categories. A weak linear relationship seemed apparent on visual inspection. (See Table 5.11 and Figure 5.3).

Table 5.11 Number of participants in each formal meditation category and K10 risk categories.

| FM category | Number in each FM | Mean K10 score | SD | Number in each K10 ABS risk category | | | |
|---|---|---|---|---|---|---|---|
| | | | | Low | Medium | High | V. High |
| Twice per day or more | 174 | 12.86 | 2.82 | 149 (86%)† | 23 (13%) | 2 (1%) | 0 (0%) |
| Once per day | 108 | 14.19 | 4.28 | 78 (72%) | 25 (23%) | 3 (3%) | 2 (2%) |
| Most days | 41 | 14.95 | 3.55 | 27 (66%) | 11 (27%) | 3 (7%) | 0 (0%) |
| Once per week or less | 16 | 15.69 | 5.17 | 11 (69%) | 3 (19%) | 1 (6%) | 1 (6%) |

† Numbers in brackets are percentages of total for each FM category
SD = standard deviation

Accordingly, Pearson Product Moment calculations comparing the K10 raw score with the FM raw score were done and the data is presented in Table 5.12. A minor linear relationship was apparent.

Table 5.12 Correlation of formal meditation and K10 score.

| | | K10 Total Score |
|---|---|---|
| FM | Pearson Correlation | 0.153** |
| | Sig. (2-tailed) | 0.005 |

n=348
** = 0.01 — Probability of a Type I error

To explore the relationship between K10 scores and TA, the TA scores were again collapsed into categories and the number of participants that fell into each of the K10 risk categories were then calculated for each TA category — refer to Table 5.13 and Figure 5.4 and Figure 5.5.

Table 5.13 Numbers in *mental silence* categories broken down by K10 ABS risk category.

| MS category | K10 ABS risk category Low | Moderate | High | V. high | Total |
|---|---|---|---|---|---|
| Several times per day | 147 (83%)† | 29 (16%) | 1 (1%) | 0 (0%) | 177 |
| Once or twice per day | 79 (80%) | 17 (17%) | 3 (3%) | 0 (0%) | 99 |
| Once or twice per week | 27 (71%) | 9 (24%) | 1 (3%) | 1 (3%) | 38 |
| Once or twice per month | 7 (54%) | 3 (23%) | 2 (15%) | 1 (8%) | 13 |
| Less than once per month | 6 (46%) | 4 (31%) | 2 (15%) | 1 (8%) | 13 (0%) |

† percentages are of total for each SYM category

On inspection, linear trends seemed apparent in the low and moderate risk categories. Similar patterns were not evident in the high and very high risk categories however, probably because the number of participants in each of these categories was very small.

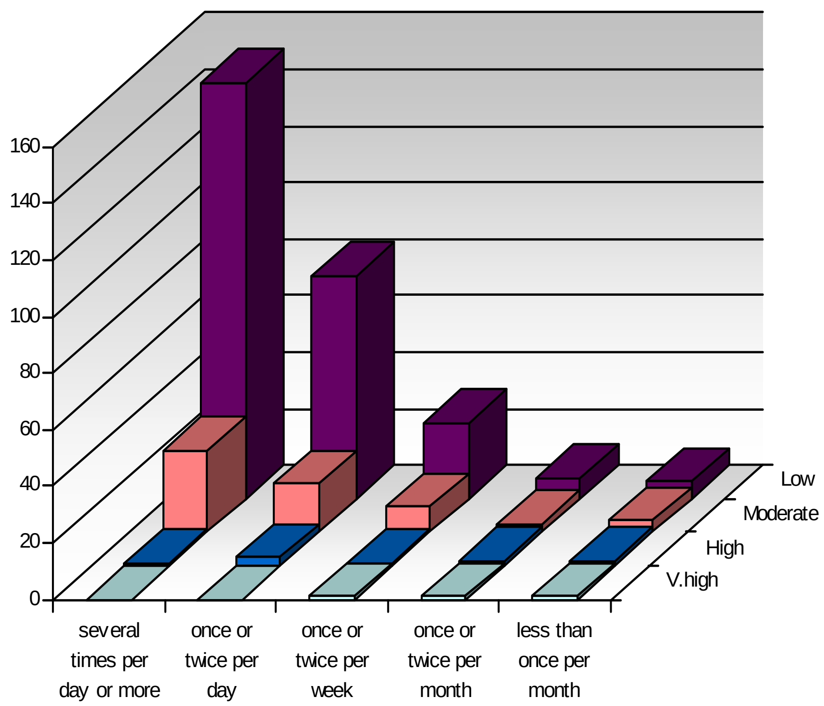


Figure 5.4 Number of participants in each K10 ABS risk category according to TA category.

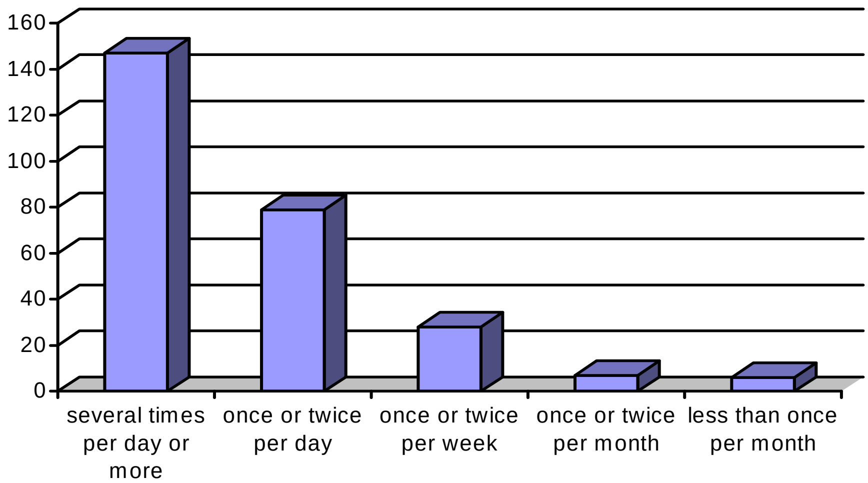


Figure 5.5 Number of "low risk" participants in each TA category.

Mean K10 scores for each TA category were calculated, and linear trends were again evident. See Table 5.14.

Table 5.14 K10 sum mean score for each TA category.

| TA category | Mean K10 score | n | SD |
|---|---|---|---|
| 1 | 12.9 | 177 | 2.8 |
| 2 | 13.4 | 99 | 3.1 |
| 3 | 14.6 | 38 | 4.0 |
| 4 | 18.0 | 13 | 6.1 |
| 5 | 18.0 | 13 | 6.6 |

n = number of samples, SD = standard deviation

Accordingly, Pearson Product Moment calculations comparing the K10 raw score with the TA raw score were done. A relatively substantial linear relationship was apparent. See Table 5.15 below.

Table 5.15 Correlation of TA and K10 score.

| | | K10SUM |
|---|---|---|
| TA | Pearson Correlation | 0.371** |
| | Sig. (2-tailed) | 0.000 |
| | n | 340 |

** = 0.01 — Probability of a Type I error

### 5.4.6 SF-36 scores of the comparison meditators

A total of 88.5% of the respondents described their health as either: "excellent" (20.9%), "very good" (41.8%), or "good" (25.8%). Approximately half (51.1%) described their health as "much better" or "somewhat better" than a year ago while 41.2% described their health as "about the same" as one year previously.

SF-36 scores for the Comparison group are summarized inTable 5.4.

The scores are expressed graphically in Figure 5.6 below.

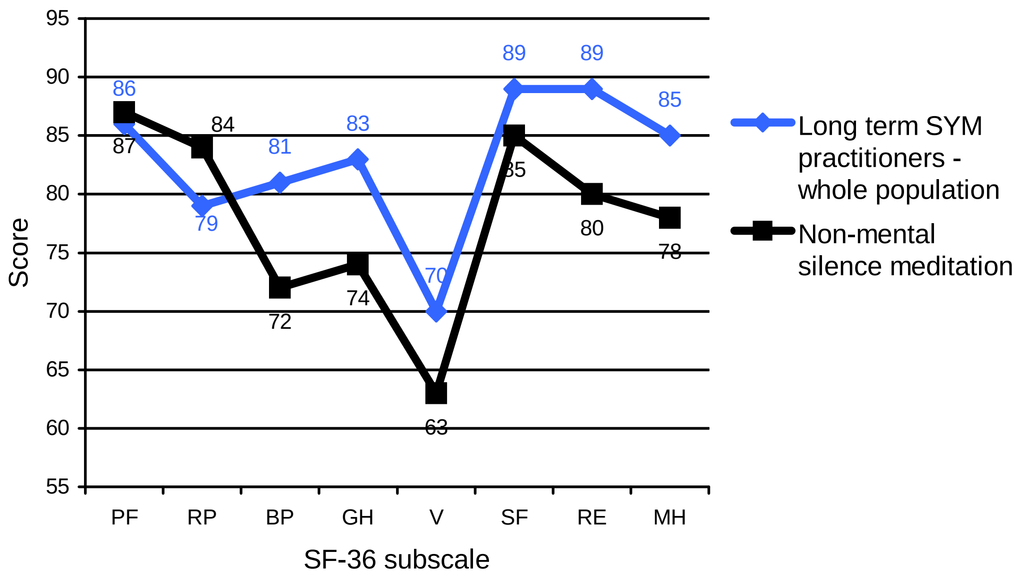


Figure 5.6 SF-36 polygon for SYM sample and comparison sample.

### 5.4.7 Comparing SF-36 scores of SYM meditators and comparison meditators

The subscales PF and RP were higher in the comparison group than in the SYM group but these differences were small and not significant.

The remaining subscales (BP, GH, V, SF, RE, MH) were considerably lower in the comparison compared to the SYM group. These differences were statistically significant. See Table 5.16.

### 5.4.8 Comparing SF-36 scores of SYM meditators and Australian national norms

The SF-36 was administered in the 1995 Australian National Health Survey (see Table 5.17) but not in subsequent national health surveys. Comparing the SYM group to the national data, measures in the SYM sample were substantially higher than Australian normative data. These differences are illustrated in Figure 5.7 and Table 5.18.

For example, in the 1995 National Health Survey, 82.1% of respondents described their health as good or better than good. Of these, 16.6% said their health was "excellent", 35.6% said it was "very good" and 29.9% as "good". Also, 19.6% described their health as "much better" (8.1%) or "somewhat better" (19.6%) than a year previously, while 65.8% said it was "about the same". These differences were significantly lower than the SYM sample. The same patterns are reflected in all subscales as well as for the summary scores (PCS and MCS). The largest differences appear to be in the MH, RE and GH subscales. All differences except PF and RP were significant. See Table 5.19.

Table 5.16 Comparison of SF-36 subscale scores for *mental silence* and comparison samples.

| SF-36 subscale | Mean Diff | t | df | Sig |
|---|---|---|---|---|
| PF | -0.98 | -0.457 | 526 | 0.648 |
| RP | -4.98 | 1.066 | 526 | 0.287 |
| BP | 8.92 | 4.373 | 526 | 0.000 |
| GH | 8.42 | 5.374 | 511 | 0.000 |
| V | 7.09 | 4.317 | 518 | 0.000 |
| SF | 3.60 | 2.000 | 518 | 0.046 |
| RE | 8.97 | 3.261 | 515 | 0.001 |
| MH | 7.16 | 5.540 | 517 | 0.000 |

Table 5.17 SF-36 scores for Australian national norms.

| SF-36 subscale | All | | Females | | Non-smokers | |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD |
| PF | 83.8203 | 22.84347 | 82.3311 | 2336.906 | 8462.59 | 2258.836 |
| RP | 80.6409 | 34.58420 | 79.3983 | 3559.289 | 8197.17 | 3366.236 |
| BP | 77.0491 | 24.75640 | 75.9608 | 25.15653 | 78.6240 | 23.89764 |
| GH | 71.8071 | 20.18935 | 71.9890 | 20.18100 | 73.3657 | 19.77539 |
| V | 64.2076 | 19.78643 | 62.1177 | 20.08876 | 64.8878 | 19.57087 |
| SF | 85.2532 | 22.11145 | 84.3170 | 22.60387 | 86.1393 | 21.22468 |
| RE | 83.4426 | 31.92097 | 82.2973 | 33.08456 | 84.5257 | 30.92235 |
| MH | 75.7547 | 16.97426 | 74.5546 | 17.15227 | 76.2602 | 16.59995 |

SD = standard deviation

Table 5.18 SF-36 means for *mental silence* meditators and Australian national norms.

| GRP | | PF | RP | BP | GH | V | SF | RE | MH |
|---|---|---|---|---|---|---|---|---|---|
| **MS** | Mean | 86.21 | 78.54 | 80.84 | 82.52 | 70.25 | 88.77 | 89.18 | 85.31 |
| | n | 346 | 346 | 346 | 333 | 338 | 338 | 335 | 337 |
| | SD | 25.50 | 41.04 | 22.12 | 15.37 | 17.61 | 18.04 | 23.74 | 12.31 |
| **Norm** | Mean | 83.82 | 80.64 | 77.05 | 71.81 | 64.21 | 85.25 | 83.44 | 75.75 |
| | SD | 22.84 | 34.58 | 24.75 | 20.18 | 19.78 | 22.11 | 31.92 | 16.97 |

n = number of samples, SD = standard deviation

Table 5.19 Comparison of SF-36 subscale scores between *mental silence* meditators and Australian national norms.

| Subscale | Test value (national norm) | t | df | Significance | Mean difference |
|---|---|---|---|---|---|
| PF | 83.82 | 1.75 | 345 | 0.082 | 2.39 |
| RP | 80.64 | -0.95 | 345 | 0.342 | -2.10 |
| BP | 77.05 | 3.19 | 345 | 0.002 | 3.79 |
| GH | 71.81 | 12.72 | 332 | 0.001 | 10.72 |
| V | 64.27 | 6.24 | 337 | 0.001 | 5.98 |
| SF | 85.25 | 3.59 | 337 | 0.001 | 3.52 |
| RE | 83.44 | 4.43 | 334 | 0.001 | 5.74 |
| MH | 75.75 | 14.26 | 336 | 0.001 | 9.56 |

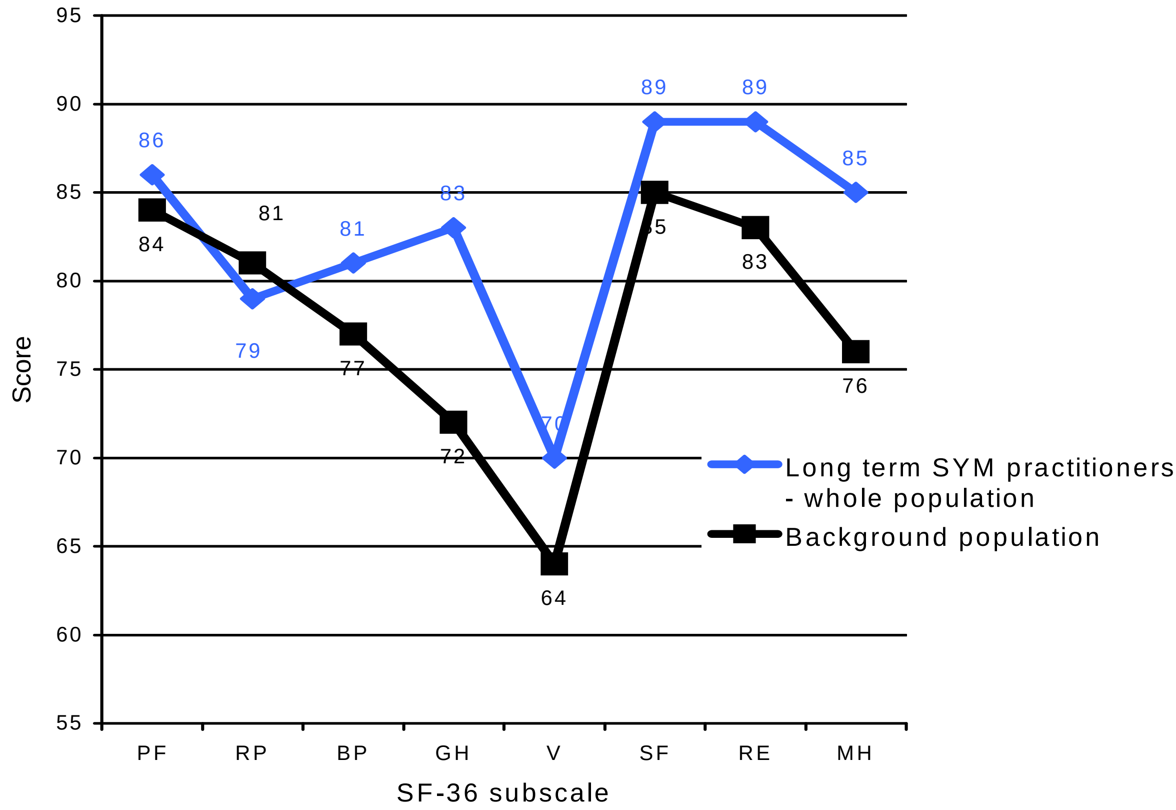


Figure 5.7 SF-36 polygon for national norm data and *mental silence* sample.

However, there were fewer differences between the comparison meditators' scores and the national norms. PF was significantly higher in comparison meditators' group compared to the norm (i.e. better) whereas BP was significantly lower (i.e. worse) compared to norm. See Table 5.20.

Table 5.20 Comparison of SF36 subscale scores for national norms with comparison meditators.

| Subscale | Test value (national norm) | t | df | Significance | Mean difference |
|---|---|---|---|---|---|
| PF | 83.82 | 2.38 | 181 | 0.019 | 3.38 |
| RP | 80.64 | 0.59 | 181 | 0.557 | 2.88 |
| BP | 77.05 | -3.06 | 181 | 0.003 | -5.13 |
| GH | 71.81 | 1.58 | 179 | 0.116 | 2.30 |
| V | 64.27 | -0.77 | 181 | 0.441 | -1.05 |
| SF | 85.25 | -0.05 | 181 | 0.962 | -0.08 |
| RE | 83.44 | -1.13 | 181 | 0.262 | -3.23 |
| MH | 75.75 | 1.92 | 181 | 0.056 | 2.40 |

### 5.4.9 Comparing K10 scores of the *mental silence* meditators with the national norms

#### 5.4.9.1 K10 scores for Australian national norms

Using the K10 data from the National Mental Health Survey, 2001 of the Australian Bureau of Statistics, produced a mean score of 15.5. The ABS categories are summarized below. See Table 5.21 and

Table 5.22.

Table 5.21 K10 ABS categories for national norms.

| | Category | Frequency | Percent |
|---|---|---|---|
| 1 | Low | 11458 | 63.9 |
| 2 | Mod | 4103 | 22.9 |
| 3 | High | 1663 | 9.3 |
| 4 | V high | 694 | 3.9 |
| | Total | 17918 | 100.0 |

Table 5.22 National norm K10 ABS categories, non drinkers, non smokers.

| | Category | Frequency | Percent |
|---|---|---|---|
| 1 | 1.00 | 840 | 67.7 |
| 2 | 2.00 | 226 | 18.2 |
| 3 | 3.00 | 118 | 9.5 |
| 4 | 4.00 | 57 | 4.6 |
| | Total | 1241 | 100.0 |

#### 5.4.9.2 Comparing SYM K10 with national norms K10

The proportion of participants in the low risk category was significantly greater in the SYM group than in the norm sample (78.1% versus 64.3%). The proportion of participants in the moderate risk category was slightly lower in the SYM group compared to the general population (21.6% versus 23%) although these were not significantly different. Collapsing the high and very high risk categories together the proportion of the SYM population was significantly less than the NORM sample (0.9% versus 12.6%) in this category. After controlling for age, smoking and alcohol consumption, the differences persisted although they were slightly weaker. See Table 5.23 and Table 5.34.

Dividing the SYM sample into categories of TA, and then comparing them, demonstrates that the first three categories have significantly higher MH scores than the national norms (national norm score for MH = 75.75)

Table 5.23 Comparison of K10 scores between SYM and national norms

| Risk category | SYM | NORM | $\chi^2$ † | *p* |
|---|---|---|---|---|
| Low | 78.3% | 63.9% | 8.51 | 0.001 |
| Moderate | 18.2% | 22.9% | 1.41 | 0.235 |
| High/Very high | 3.5% | 12.2% | 7.16 | 0.001 |
| n | 348 | 17918 | - | - |

† df = 1

Table 5.24 Comparison of K10 scores and national norms for non-drinkers/smokers

| Risk category | SYM | NORM | $\chi^2$ † | *p* |
|---|---|---|---|---|
| Low | 78.3% | 67.7% | 4.60 | 0.032 |
| Moderate | 18.2% | 18.2% | nd | 1.000 |
| High/Very high | 3.5% | 14.1% | 8.31 | 0.004 |
| n | 348 | 1241 | - | - |

† df = 1; nd = not done

### 5.4.10 Assessment of the MLS

This study is primarily concerned with how the practice of meditation and particularly the meditative experience of *mental silence* or “thoughtless awareness” may be related to mental and physical health outcomes.

The experience of *mental silence* is thought to be facilitated by the various practices and lifestyle factors featured as items in the MLS. These include group meditation with other SYM practitioners, attending weekly meetings to socialize, meditate with and learn more about SYM techniques, regular meditation, ‘foot soaking’ and associated techniques and duration of practice.

### 5.4.10.1 Conceptual validity of the MLS

In order to evaluate the conceptual validity of this proposition, we tested the MLS and the relationship between its items (as independent variables) and TA (as the dependent variable) using Pearson Product Moment correlations. Three factors had significant correlations with TA; foot soaking (FS) ($r = 0.187$, $p < 0.005$), regular recent meditation (RM) ($r = 0.209$, $p < 0.001$) and duration of practice (DP) ($r = -0.229$, $p < 0.001$). These correlations were similar to those predicted by the focus groups, i.e. the more foot soaking and regular meditation practiced, the more frequent the experience of TA. Similarly, as duration of practice increased, so too did the frequency of TA.

The relationship between TA and demographic factors was similarly assessed. TA was positively correlated with age ($r = 0.217$, $p < 0.001$) and gender ($r = 0.112$, $p < 0.05$) i.e. as age increased, the more frequently they experienced TA; in addition, females experienced more TA than males.

### 5.4.10.2 MLS regression analysis

To further explore collinearity between the various MLS and demographic factors and TA, a multiple regression analysis was conducted. A stepwise, forward multiple linear regression was performed using the MLS factors. The proportion of variance explained by this was small ($r^2 = 0.113$). The factors that contributed significantly to this variance were DP ($p \leq 0.001$, $\beta = -0.238$), FS ($p < 0.005$, $\beta = 0.174$) and RM ($p < 0.01$, $\beta = 0.147$). When demographic factors were included along with MLS factors in the regression, the proportion of variance increased slightly ($r^2 = 0.157$). The factors in this model that contributed significantly to this variance were DP ($p \leq 0.005$, $\beta = -0.212$), FS ($p < 0.001$, $\beta = 0.220$), age ($p < 0.01$, $\beta = -0.167$) and RM ($p < 0.05$, $\beta = 0.125$).

#### 5.4.10.3 MLS GM analysis

To further explore the degree to which the MLS predicted TA when controlling for various demographic and MLS factors and their potential interactions, a general linear model (GLM) was used. In this model the independent variable was TA, the dependent variables were DP, RM, FS. The covariates were all other MLS and demographic factors and a number of appropriately selected interactions between these covariates. The GLM using this approach had an $r^2$ of 0.736. In this model the significant factors were gender ($p < 0.05$), alcohol consumption ($p < 0.005$), marijuana/recreational drug consumption ($p < 0.01$), CM ($p < 0.05$), RM ($p < 0.05$), DP ($p < 0.005$), the interaction between FS and RM ($p < 0.005$) and the interaction between FS and DP ($p < 0.05$). The $r^2$ value of 0.736 indicates that the MLS effectively captures the great majority of factors that contribute to how often the meditator experiences *mental silence*. See Table 5.25.

### 5.4.11 Correlations between variables and outcomes

#### 5.4.11.1 Independent variables

In order further to explore the degree to which aspects of SYM practice contribute to health scores, the relationship between various demographic and meditative lifestyle factors from the MLS with outcomes in the SF-36 and K10 were examined using Pearson Product Moment correlations. Two demographic factors, salary and history of mental illness, were excluded from this exploration, because they were likely to be proxies for the dependent variables of interest. Several significant relationships became apparent**.**

Table 5.25 MLS GLM; dependent variable – thoughtless awareness.

| Source | Type III Sum of Squares | df | Mean Square | F | Sig. † |
|---|---|---|---|---|---|
| Corrected Model | 897.968‡ | 131 | 6.855 | 2.399 | 0.000 |
| Intercept | 114.522 | 1 | 114.522 | 40.086 | 0.000 |
| Age | 9.524 | 1 | 9.524 | 3.334 | 0.071 |
| Gender | 14.945 | 1 | 14.945 | 5.231 | 0.024 |
| R’ship | 2.338 | 1 | 2.338 | 0.818 | 0.368 |
| Ethnicity | 0.375 | 1 | 0.375 | 0.131 | 0.718 |
| Education | 5.828 | 1 | 5.828 | 2.040 | 0.156 |
| Salary | 0.019 | 1 | 0.019 | 0.007 | 0.935 |
| Mental illness | 10.696 | 1 | 10.696 | 3.744 | 0.056 |
| Smoking | 3.562 | 1 | 3.562 | 1.247 | 0.267 |
| Alcohol | 29.008 | 1 | 29.008 | 10.154 | 0.002 |
| Marijuana | 19.891 | 1 | 19.891 | 6.963 | 0.009 |
| Formal meditation | 0.006 | 1 | 0.006 | 0.002 | 0.963 |
| Collmed | 15.769 | 1 | 15.769 | 5.519 | 0.021 |
| Social | 5.923 | 1 | 5.923 | 2.073 | 0.153 |
| Meeting | 0.660 | 1 | 0.660 | 0.231 | 0.632 |
| Foot soaking | 31.721 | 5 | 6.344 | 2.221 | 0.057 |
| Meditate | 15.256 | 1 | 15.256 | 5.340 | 0.023 |
| Durnsy | 218.274 | 34 | 6.420 | 2.247 | 0.001 |
| Foot soaking * Meditate | 37.521 | 2 | 18.760 | 6.567 | 0.002 |
| Foot soaking * Durnsy | 276.586 | 67 | 4.128 | 1.445 | 0.042 |
| Meditate * Durnsy | 8.523 | 3 | 2.841 | 0.994 | 0.398 |
| Foot soaking * meditate Durnsy | 0.000 | 0 | 0 | 0 | 0 |
| Error | 322.832 | 113 | 2.857 | - | - |
| Total | 5661.000 | 245 | - | - | - |
| Corrected Total | 1220.800 | 244 | - | - | - |

† Significance

‡ R Squared = 0.736 (Adjusted R Squared = 0.429)

#### 5.4.11.2 K10 and MLS

Interestingly, the largest correlation was between frequency of TA and total K10 score such that greater experience of TA was associated with better mental health (r = 0.366, $p < 0.0001$). There were also smaller correlations between the K10 total score and other factors in the MLS. The following correlations were consistent with the provisional hypotheses of the study:

- FM ($r = 0.242$, $p < 0.0001$) such that more frequent formal meditation was associated with lower K10 scores (i.e. better mental health)

- MM ($r = 0.214$, $p < 0.0001$) such that more frequent attendance of meditation meetings was associated with lower K10 scores (i.e. better mental health)

- RM ($r = 0.209$, $p < 0.0001$) such that engaging in regular meditation over the few weeks prior to the survey was associated with lower K10 scores (i.e. better mental health)

- SM ($r = 0.171$, $p < 0.005$) such that more frequent social contact with meditators was associated with lower K10 scores (i.e. better mental health)

- CM ($r = 0.157$, $p < 0.005$) such that more frequent collective meditation was associated with lower K10 scores (i.e. better mental health).

The following correlations are consistent with other research into the relationship between demographic factors and health:

- Age ($r = 0.257$, $p < 0.001$) such that increasing age was associated with lower K10 scores (i.e. better mental health)

- Relationship ($r = 0.115$, $p < 0.05$) such that a married or an equivalent state was associated with lower K10 scores (i.e. better mental health). See correlation Table 5.26 below.

No correlations were found between K10 scores and the MLS that contradict the hypotheses of this study. See Table 5.26.

Table 5.26 Correlation between MLS items and K10 total score.

| MLS item | K10SUM | | |
|---|---|---|---|
| | n | Pearson Correlation | Significance (2-tailed) |
| Foot soaking | 341 | 0.079 | 0.145 |
| Regular meditation | 341 | 0.209** | 0.000 |
| Formal meditation | 339 | 0.153** | 0.005 |
| Collective meditation | 341 | 0.086 | 0.113 |
| Socialise with other meditators | 335 | 0.084 | 0.123 |
| Attend meditation meetings regularly | 339 | 0.214** | 0.000 |
| Thoughtless awareness | 340 | 0.371** | 0.000 |
| Duration of practice (yrs) | 323 | -0.204** | 0.000 |
| Age | 288 | -0.257** | 0.000 |
| Gender | 343 | 0.043 | 0.429 |
| Marital relationship | 342 | -0.115* | 0.034 |
| Ethnicity | 340 | 0.087 | 0.109 |
| Education | 340 | -0.061 | 0.258 |
| Salary | 321 | -0.021 | 0.704 |
| Mental illness | 336 | 0.266** | 0.000 |
| Smoking | 341 | -0.027 | 0.622 |
| Alcohol consumption | 335 | -0.013 | 0.814 |
| Marijuana use | 340 | 0.067 | 0.221 |

n = number of samples

* = 0.05 — Probability of a Type I error

** = 0.01 — Probability of a Type I error

### 5.4.12 SF-36 and MLS

#### 5.4.12.1 *Mental silence* meditators

The relationship between the MLS factors and the SF-36 total score (SF-36), the physical health summary score (PCS), the mental health summary score (MCS) and the eight subscales, was assessed. These are summarized in Table 5.27.

#### 5.4.12.2 Total SF-36

Again, the largest correlation with total SF-36 score was with TA, such that more frequent experience of *mental silence* was associated with a higher score i.e. better functional health (r = 0.175, $p < 0.005$) although the correlation itself was smaller than that observed in the K10. Slightly smaller correlations were also observed with:

- SM (r = 0.158, $p < 0.005$) such that more frequent collective meditation is associated with higher SF-36 total score (i.e. better functional health)
- MM (r = 0.135, $p < 0.05$) such that more frequent attendance to meditation meetings is associated with higher SF-36 total score (i.e. better functional health).

#### 5.4.12.3 SF-36 subscales

**Bodily pain**

Refers to the severity of pain and its impact on daily activities. Only *Mindfulness* correlated with this score (r= -0.108, $p < 0.05$) such that more frequent attendance of meditation meetings was associated with less impact of pain on daily activities.

Table 5.27 Correlations between MLS items and SF-36 subscales and total score.

| | | PF | RF | BP | GH | V | SF | RE | MH | PCS | MCS | Total SF-36 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Sample size n | | 318 | 318 | 318 | 318 | 318 | 318 | 318 | 318 | 318 | 318 | 318 |
| Foot soaking | r | 0.045 | -0.028 | 0.007 | -0.047 | -0.046 | 0.088 | -0.017 | -0.027 | 0.014 | -0.001 | 0.035 |
| | Sig. | 0.410 | 0.609 | 0.893 | 0.390 | 0.405 | 0.109 | 0.756 | 0.616 | 0.798 | 0.988 | 0.541 |
| | n | 343 | 343 | 343 | 331 | 336 | 336 | 333 | 335 | 327 | 316 | 316 |
| Regular meditation | r | -0.188** | -0.092 | -0.087 | -0.099 | -0.085 | -0.033 | -0.038 | -0.041 | -0.032 | -0.095 | -0.048 |
| | Sig. | 0.000 | 0.088 | 0.109 | 0.073 | 0.120 | 0.541 | 0.495 | 0.455 | 0.568 | 0.091 | 0.397 |
| | n | 343 | 343 | 343 | 331 | 336 | 336 | 333 | 335 | 327 | 316 | 316 |
| Formal meditation | r | 0.079 | 0.077 | 0.020 | 0.051 | -0.030 | 0.015 | 0.040 | -0.104 | 0.085 | 0.003 | 0.061 |
| | Sig. | 0.146 | 0.155 | 0.710 | 0.353 | 0.580 | 0.784 | 0.468 | 0.059 | 0.124 | 0.951 | 0.276 |
| | n | 340 | 340 | 340 | 329 | 334 | 333 | 333 | 333 | 326 | 316 | 316 |
| Collmed | r | 0.085 | 0.081 | 0.024 | 0.087 | -0.001 | 0.001 | 0.029 | -0.066 | 0.084 | 0.018 | 0.059 |
| | Sig. | 0.117 | 0.136 | 0.653 | 0.114 | 0.991 | 0.983 | 0.596 | 0.231 | 0.129 | 0.745 | 0.293 |
| | n | 342 | 342 | 342 | 330 | 336 | 335 | 334 | 335 | 327 | 317 | 317 |
| Social | r | 0.093 | 0.081 | 0.025 | 0.072 | -0.016 | -0.003 | 0.018 | -0.096 | 0.072 | 0.005 | 0.048 |
| | Sig. | 0.087 | 0.139 | 0.652 | 0.195 | 0.779 | 0.961 | 0.749 | 0.082 | 0.194 | 0.929 | 0.392 |
| | n | 336 | 336 | 336 | 326 | 330 | 329 | 329 | 330 | 323 | 314 | 314 |
| Meeting | r | -0.102 | -0.098 | -0.108* | 0.026 | -0.135* | -0.126* | -0.129* | -0.148** | -0.110* | -0.147** | -0.135* |
| | Sig. | 0.060 | 0.072 | 0.047 | 0.645 | 0.014 | 0.021 | 0.018 | 0.007 | 0.048 | 0.009 | 0.017 |
| | n | 340 | 340 | 340 | 328 | 333 | 333 | 331 | 332 | 324 | 314 | 314 |

| | | PF | RF | BP | GH | V | SF | RE | MH | PCS | MCS | Total SF-36 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TA | r | -0.039 | -0.099 | -0.005 | -0.200** | -0.217** | -0.030 | -0.097 | -0.345** | -0.125* | -0.243** | -0.175** |
| | Sig. | 0.474 | 0.067 | 0.928 | 0.000 | 0.000 | 0.586 | 0.077 | 0.000 | 0.024 | 0.000 | 0.002 |
| | n | 341 | 341 | 341 | 330 | 335 | 335 | 333 | 334 | 326 | 316 | 316 |
| Durnsy | r | -0.039 | 0.026 | 0.023 | -0.039 | 0.018 | 0.069 | 0.169** | 0.168** | -0.010 | 0.136* | 0.081 |
| | Sig. | 0.483 | 0.639 | 0.686 | 0.489 | 0.743 | 0.217 | 0.002 | 0.003 | 0.860 | 0.018 | 0.163 |
| | n | 324 | 324 | 324 | 315 | 318 | 319 | 318 | 317 | 311 | 302 | 302 |
| Age | r | -0.132* | -0.087 | -0.108 | 0.085 | 0.077 | 0.089 | 0.155** | 0.078 | -0.060 | 0.142* | 0.012 |
| | Sig. | 0.025 | 0.140 | 0.066 | 0.157 | 0.197 | 0.135 | 0.009 | 0.191 | 0.321 | 0.019 | 0.841 |
| | n | 291 | 291 | 291 | 282 | 283 | 286 | 283 | 285 | 278 | 274 | 274 |
| Gender | r | -0.086 | -0.071 | -0.034 | -0.061 | -0.057 | -0.084 | -0.022 | -0.049 | -0.096 | -0.071 | -0.101 |
| | Sig. | 0.112 | 0.190 | 0.524 | 0.266 | 0.295 | 0.121 | 0.686 | 0.369 | 0.081 | 0.210 | 0.072 |
| | n | 346 | 346 | 346 | 333 | 338 | 338 | 335 | 337 | 329 | 318 | 318 |
| Rship | r | 0.031 | 0.046 | -0.035 | -0.056 | 0.045 | 0.020 | 0.257** | 0.023 | 0.000 | 0.123* | 0.078 |
| | Sig. | 0.564 | 0.392 | 0.518 | 0.307 | 0.414 | 0.710 | 0.000 | 0.670 | 0.997 | 0.029 | 0.168 |
| | n | 345 | 345 | 345 | 332 | 337 | 337 | 334 | 336 | 328 | 317 | 317 |
| Ethnicity | r | -0.140** | 0.046 | 0.022 | 0.048 | 0.077 | 0.016 | 0.036 | -0.029 | 0.064 | .072 | 0.067 |
| | Sig. | 0.009 | 0.397 | 0.680 | 0.385 | 0.161 | 0.767 | 0.518 | 0.592 | 0.249 | 0.201 | 0.235 |
| | n | 342 | 342 | 342 | 329 | 334 | 334 | 332 | 333 | 325 | 315 | 315 |
| Education | r | .019 | 0.049 | 0.070 | 0.074 | 0.126* | 0.104 | 0.065 | 0.087 | 0.085 | 0.113* | 0.090 |
| | Sig. | 0.725 | 0.364 | 0.198 | 0.181 | 0.021 | 0.057 | 0.235 | 0.113 | 0.125 | 0.044 | 0.112 |
| | n | 342 | 342 | 342 | 331 | 335 | 336 | 332 | 334 | 327 | 316 | 316 |
| Salary | r | 0.137* | 0.193** | 0.136* | 0.072 | 0.115* | 0.084 | 0.177** | 0.042 | 0.207** | 0.169** | 0.229** |
| | Sig. | 0.014 | 0.000 | 0.014 | 0.204 | 0.040 | 0.136 | 0.002 | 0.457 | 0.000 | 0.003 | 0.000 |
| | n | 323 | 323 | 323 | 313 | 318 | 317 | 317 | 318 | 310 | 301 | 301 |
| Mental illness | r | -0.070 | -0.132* | -0.095 | -0.189** | -0.238** | -0.189** | -0.359** | -0.277** | -0.241** | -0.388** | -0.356** |

| | | PF | RF | BP | GH | V | SF | RE | MH | PCS | MCS | Total SF-36 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Sig. | 0.201 | 0.015 | 0.080 | 0.001 | 0.000 | 0.001 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| | n | 339 | 339 | 339 | 327 | 331 | 331 | 329 | 330 | 323 | 312 | 312 |
| Smoking | r | 0.045 | 0.031 | 0.052 | 0.085 | 0.063 | 0.061 | -0.001 | -0.048 | 0.063 | 0.054 | 0.052 |
| | Sig. | 0.405 | 0.566 | 0.340 | 0.121 | 0.247 | 0.267 | 0.979 | 0.379 | 0.255 | 0.341 | 0.356 |
| | n | 344 | 344 | 344 | 331 | 336 | 336 | 333 | 335 | 327 | 316 | 316 |
| Alcohol use | r | 0.031 | 0.042 | 0.067 | 0.072 | 0.007 | 0.083 | 0.066 | -0.051 | 0.073 | 0.073 | 0.076 |
| | Sig. | 0.573 | 0.446 | 0.219 | 0.196 | 0.897 | 0.131 | 0.232 | 0.356 | 0.190 | 0.197 | 0.179 |
| | n | 337 | 337 | 337 | 325 | 330 | 330 | 328 | 329 | 321 | 311 | 311 |
| Marijuana use | r | 0.101 | 0.100 | 0.048 | 0.093 | 0.011 | 0.003 | 0.044 | -0.062 | 0.105 | 0.033 | 0.078 |
| | Sig. | 0.061 | 0.064 | 0.381 | 0.093 | 0.840 | 0.955 | 0.428 | 0.260 | 0.059 | 0.554 | 0.168 |
| | n | 342 | 342 | 342 | 330 | 335 | 335 | 332 | 334 | 326 | 315 | 315 |

* = 0.05 — Probability of a Type I error

** = 0.01 — Probability of a Type I error

r = Pearson Correlation

Sig. = significance

n = number in sample

**General health**

A rating of one's own health, a comparison with others' health and proneness to illness. Only TA correlated with this score ($r = -0.200$, $p < 0.001$) such that more frequent experience of *mental silence* was associated with higher (better) general health scores.

**Mental health**

Refers to the degree of nervousness or calmness, happiness or sadness that the respondent was experiencing. The largest correlation was with TA such that more frequent experience was associated with better mental health ($r = 0.345$, $p < 0.0001$). Smaller correlations occurred with SM ($r = 0.242$, $p < 0.0001$) i.e. more frequent socializing with other meditators was associated with better mental health.

Small correlations also existed for:

- DP ($r = 0.168$, $p < 0.005$) i.e. longer duration of practice was associated with better mental health

- MM ($r = 0.148$, $p < 0.01$) more frequent attendance of meditation meetings was associated with better mental health ($r = 0.345$, $p < 0.0001$).

Since the component items of this subscale are so similar to those in the K10, and the K10's relationship with the MLS is the subject of its own detailed analysis, it was decided that further analysis of correlations between the mental health subscale and the MLS was unnecessarily repetitive.

**Physical functioning**

Refers to the ability to perform activities without limitation. The following small correlations were found:

- RM ($r = 0.188$, $p < 0.0001$) i.e. regular meditation in the few weeks prior to participating in the survey was associated with better ability to perform activities without limitation

- Other correlations existed with age ($r = -0.132$, $p < 0.05$) in the expected direction and ethnicity ($r = -0.14$, $p < 0.01$).

**Role limitation (emotional)**
Refers to limitations that emotional problems put on the range and extent of activities individuals could perform.

The largest correlation was with marital relationship ($r = 0.257$, $p < 0.001$).

Small correlations also existed for:

- DP ($r = 0.169$, $p < 0.001$) such that longer practice of SYM was associated with less limitations due to emotional problems

- MM ($r = 0.129$, $p < 0.05$) such that more frequent attendance of meditation meetings was associated with less limitations due to emotional problems

- SM ($r = 0.148$, $p < 0.01$) such that more frequent social contact with other meditators was associated with less limitations due to emotional problems

- Other correlations existed with age (.155, $p < 0.01$), in the expected directions.

**Role limitation (physical)**
Refers to the limitations that reduced physical health imposed on the range and extent of physical activities individuals were able to perform. None of the items in the MLS correlated with this score.

**Social functioning**

Refers to the impact of physical and emotional health on the ability to perform normal social activities. There was a small correlation between MM (r = 0.126, $p < 0.05$) such that more frequent attendance of meditation meetings was associated with better ability to perform normal social activities.

**Vitality**

Refers to how energetic or tired an individual felt. The largest correlation was with TA (r = 0.217, $p < 0.001$) such that more frequent experience of *mental silence* was associated with more vitality.

Smaller correlations existed for:

- MM (r = 0.135, $p < 0.05$) such that more frequent attendance of meditation meetings was associated with more vitality
- SM (r = 0.156, $p < 0.01$) such that more social contact with other meditators was associated with more vitality
- Education (r = 0.126, $p < 0.05$) in the expected direction.

5.4.12.4 PCS

This is a summary score of all physical function subscales and related factors from the other scales of the SF-36.

Small correlations observed were:

- TA (r = 0.125, $p < 0.05$) that more frequent experience of *mental silence* was associated with better overall physical functioning;

- MM (r = 0.11, $p < 0.05$) that more frequent attendance of meditation meetings was associated with better overall physical functioning.

5.4.12.5 MCS

This is a summary score for all mental, emotional and social function subscales and related factors from the other scales of the SF36.

The largest correlation was observed with TA (r = 0.243, $p < 0.0001$).

Smaller correlations were also observed with:

- MM (r = 0.147, $p < 0.01$) such that more frequent attendance of meditation meetings was associated with better overall mental functioning

- DP (r = 0.136, $p < 0.05$) such longer duration of practice is associated with better overall mental functioning

- Age (r = 0.142, $p < 0.05$) in the expected direction

- Relationship (r = 0.123, $p < 0.05$) in the expected direction

- Education (r = 0.113, $p < 0.05$) in the expected direction.

**5.4.13 Regression analysis**

As previously stated, a central notion in this study is the idea that the experience of *mental silence* may be a factor associated with the beneficial effects of meditation. In line with this, the simple correlations clearly demonstrate that TA is the factor most commonly and most strongly correlated with the various health scores.

A multiple regression analysis was conducted to further explore co-linearity between the various demographic factors, meditative lifestyle factors, health scores and the TA experience. The total SF-36, PCS and MCS and K10 health scores were selected as dependent variables.

Since the MLS was constructed around the notion that the experience of *mental silence* is facilitated by the various practices and lifestyle factors featured as items in the MLS, these items (FS, DP, CM, MM, FM, RM) were included in the regression analysis. In addition, demographic factors known to independently influence physical and mental health were also included as factors in the regression analysis. This included age[305], gender[306], relationship status[307,308,309] history of mental illness[310], educational level[311], ethnicity[312], consumption of alcohol[313], tobacco[314,315], marijuana[316] and other recreational drugs[316] and social support[317]. In this case SM, MM and CM were interpreted as factors that assessed different sources of social support.

5.4.13.1 K10 regression

A stepwise, forward multiple linear regression was performed using the above factors. The proportion of variance in K10 scores explained by MLS factors was moderate ($r^2 = 0.315$). The factors that contributed significantly to this variance were TA ($p < 0.001$, $\beta = -1.81$), MM ($p < 0.05$), RM ($p < 0.01$), and gender ($p < 0.05$). See Table 5.28.

Table 5.28 Regression K10/ MLS, model summary.

a) Correlation coefficient (r) and standard error of the estimate (SEE)

| Model | r | r squared | Adjusted r squared | SEE |
|---|---|---|---|---|
| 1 | 0.561 | 0.315 | 0.261 | 3.089 |

b) Coefficients for dependent variable: K10SUM.

| | Non-standardized coefficient | | Standardized coefficient | | |
|---|---|---|---|---|---|
| | B | SE | Beta | t | Sig. † |
| Constant | 7.335 | 2.346 | - | 3.126 | 0.002 |
| Age | -0.025 | 0.017 | -0.095 | -1.473 | 0.142 |
| Gender | 1.072 | 0.455 | 0.147 | 2.358 | 0.019 |
| Relationship | -0.621 | 0.467 | -0.079 | -1.332 | 0.184 |
| Ethnicity | 0.212 | 0.147 | 0.087 | 1.447 | 0.149 |
| Education | -0.402 | 0.273 | -0.089 | -1.474 | 0.142 |
| Salary | 0.135 | 0.162 | 0.068 | 0.828 | 0.408 |
| Smoking | 0.266 | 0.645 | 0.035 | 0.413 | 0.680 |
| Alcohol | -0.605 | 0.480 | -0.105 | -1.261 | 0.209 |
| Marijuana | 0.362 | 0.743 | 0.177 | 0.488 | 0.626 |
| Foot soaking | 0.033 | 0.188 | 0.011 | 0.177 | 0.860 |
| Regular meditation | 2.959 | 1.044 | 0.178 | 2.834 | 0.005 |
| Formal meditation | 0.097 | 0.28 | 0.054 | 0.346 | 0.730 |
| Collmed | -0.025 | 0.255 | -0.025 | -0.097 | 0.922 |
| Social | -0.104 | 0.201 | -0.157 | -0.52 | 0.603 |
| Meeting | 0.436 | 0.192 | 0.154 | 2.265 | 0.024 |
| TA | 0.387 | 0.099 | 0.241 | 3.891 | 0 |
| Durnsy | -0.052 | 0.033 | -0.097 | -1.589 | 0.113 |
| Mental illness | 2.225 | 0.493 | 0.273 | 4.513 | 0 |

† Sig. = significance

To further explore the interrelationship between these factors and to account for potential interactions between factors, a GLM was used. The same factors were used in addition to interactions that were either suggested by the correlation or regression analysis or by clinical experience.

Using this approach, the GLM yielded an $r^2$ of 0.451. In the GLM the significant factors were TA ($p < 0.05$) and MM ($p < 0.05$). See Table 5.29.

To develop an impression of the individual contribution of various constructs to the total variance in the K10, a further set of GLMs was performed: 1) The contribution of TA to the K10 score, a GLM was performed with only TA as the independent variable, resulting in an $r^2$ of 0.166; 2) In order to contrast this with the individual contribution of FM, another GLM was done with FM as the independent variable resulting in an $r^2$ of 0.061; 3) The contribution of demographic factors not thought to directly influence the quality of the *mental silence* experienceSF-36 regression.

A stepwise, forward multiple linear regression was performed using the above factors. The proportion of variance explained by this was small ($r^2 = 0.23$). The factors that contributed significantly to this variance were a history of mental illness ($p \leq 0.001$, $\beta = -5.572$) and TA ($p < 0.05$, $\beta = -2.124$). See Table 5.30.

To further explore the interrelationship between these factors a GLM was used. The same factors were used in addition to interactions that were either suggested by the correlation or regression analysis or by clinical experience. The GLM yielded an $r^2$ of 0.363, and the significant factors were TA ($p < 0.05$) and the interaction between ethnicity and mental illness. See Table 5.31.

Table 5.29 GLM K10/MLS.

Dependent variable: K10SUM.

| Source | Type III Sum of squares | Df | Mean squared | F | Sig.† |
|---|---|---|---|---|---|
| Corrected model | 1420.911‡ | 58 | 24.498 | 2.65 | 0 |
| Intercept | 72.386 | 1 | 72.386 | 7.84 | 0.01 |
| TA | 162.705 | 9 | 18.078 | 1.96 | 0.05 |
| Age | 0.957 | 1 | 0.957 | 0.10 | 0.75 |
| Gender | 3.861 | 1 | 3.861 | 0.42 | 0.52 |
| Relationship | 9.811 | 1 | 9.811 | 1.06 | 0.30 |
| Ethnicity | 1.472 | 1 | 1.472 | 0.16 | 0.69 |
| Education | 0.263 | 1 | 0.263 | 0.03 | 0.87 |
| Salary | 1.932 | 1 | 1.932 | 0.21 | 0.65 |
| Smoking | 2.839 | 1 | 2.839 | 0.31 | 0.58 |
| Alcohol | 20.807 | 1 | 20.807 | 2.25 | 0.14 |
| Marijuana | 0.871 | 1 | 0.871 | 0.09 | 0.76 |
| Foot soaking | 3.24 | 1 | 3.240 | 0.35 | 0.55 |
| Regular meditation | 1.268 | 1 | 1.268 | 0.14 | 0.71 |
| Formal meditation | 1.038 | 1 | 1.038 | 0.11 | 0.74 |
| Collmed | 6.629 | 1 | 6.629 | 0.72 | 0.40 |
| Social | 0.928 | 1 | 0.928 | 0.10 | 0.75 |
| Meeting | 46.522 | 1 | 46.522 | 5.04 | 0.03 |
| Durnsy | 5.628 | 1 | 5.628 | 0.61 | 0.44 |
| Relationship * Ethnicity | 0.000 | 1 | 0.000 | 0.00 | 1.00 |
| Age * Education | 0.000 | 1 | 0.000 | 0.00 | 1.00 |
| Salary | 14.608 | 1 | 14.608 | 1.58 | 0.21 |
| Relationship * Salary | 1.87 | 1 | 1.870 | 0.20 | 0.65 |
| Age * Durnsy | 0.557 | 1 | 0.557 | 0.06 | 0.81 |
| Collmed * Social | 9.751 | 1 | 9.751 | 1.06 | 0.31 |
| Social * Meeting | 29.017 | 1 | 29.017 | 3.14 | 0.08 |
| Collmed * Meeting | 26.45 | 1 | 26.450 | 2.86 | 0.09 |
| Meditate * Collmed | 10.098 | 1 | 10.098 | 1.09 | 0.30 |
| Meditate * Social | 10.513 | 1 | 10.513 | 1.14 | 0.29 |
| Meditate * Meeting | 53.78 | 1 | 53.780 | 5.82 | 0.02 |
| TA * Age | 173.527 | 11 | 15.775 | 1.71 | 0.07 |
| TA * Gender | 191.1 | 9 | 21.233 | 2.30 | 0.02 |
| Error | 1727.675 | 187 | 9.239 | - | - |
| Total | 48388 | 246 | - | - | - |
| Corrected Total | 3148.585 | 245 | - | - | - |

† Sig. = significance ‡ r squared = 0.451

Table 5.30 Regression SF36/ MLS.

a) Correlation coefficient (r) and standard error of the estimate (SEE)

| Model | r | r squared | Adjusted r squared | SEE |
|---|---|---|---|---|
| 1 | 0.479† | 0.230 | 0.166 | 11.065 |

b) Coefficients for dependent variable: Total SF-36.

| | Non-standardized coefficient | | Standardized coefficient | | |
|---|---|---|---|---|---|
| | **B** | **SE** | **Beta** | **t** | **Sig.‡** |
| Constant | 101.315 | 8.525 | - | 11.885 | 0.000 |
| Age | -0.100 | 0.063 | -0.111 | -1.596 | 0.112 |
| Gender | -0.935 | 1.665 | -0.038 | -0.561 | 0.575 |
| Relationship | -1.688 | 1.692 | -0.064 | -0.998 | 0.320 |
| Ethnicity | 0.130 | 0.535 | 0.016 | 0.242 | 0.809 |
| Education | 1.386 | 0.996 | 0.091 | 1.392 | 0.165 |
| Salary | 1.156 | 0.592 | 0.175 | 1.952 | 0.052 |
| Mental illness | -9.855 | 1.769 | -0.365 | -5.572 | 0.000 |
| Smoking | -0.400 | 2.652 | -0.016 | -0.151 | 0.880 |
| Alcohol | 1.324 | 2.169 | 0.063 | 0.610 | 0.542 |
| Marijuana | -0.646 | 2.731 | -0.093 | -0.237 | 0.813 |
| Foot soaking | 0.157 | 0.698 | 0.015 | 0.225 | 0.822 |
| Meditate regularly | -2.155 | 3.755 | -0.039 | -0.574 | 0.567 |
| Formal meditation | 0.118 | 1.016 | 0.019 | 0.117 | 0.907 |
| Collmed | 0.397 | 0.934 | 0.120 | 0.425 | 0.671 |
| Social | -0.167 | 0.740 | -0.074 | -0.225 | 0.822 |
| Meeting | -1.022 | 0.703 | -0.107 | -1.454 | 0.147 |
| TA | -0.768 | 0.362 | -0.143 | -2.124 | 0.035 |
| Durnsy | 0.087 | 0.120 | 0.048 | 0.723 | 0.470 |

† Dependent variable: Total SF-36 ‡ Sig. = significance

Table 5.31 GLM SF-36 total score/MLS.

Dependent variable: Total SF-36.

| Source | Type III Sum of squares | Df | Mean squared | F | Sig.† |
|---|---|---|---|---|---|
| Corrected Model | 12512.463‡ | 39 | 320.832 | 2.860 | 0.000 |
| Intercept | 1422.477 | 1 | 1422.477 | 12.681 | 0.000 |
| TA | 2268.304 | 11 | 206.209 | 1.838 | 0.050 |
| Age | 89.087 | 1 | 89.087 | 0.794 | 0.374 |
| Gender | 71.125 | 1 | 71.125 | 0.634 | 0.427 |
| Relationship | 127.605 | 1 | 127.605 | 1.138 | 0.287 |
| Ethnicity | 144.101 | 1 | 144.101 | 1.285 | 0.258 |
| Education | 35.255 | 1 | 35.255 | 0.314 | 0.576 |
| Salary | 9.822 | 1 | 9.822 | 0.088 | 0.768 |
| Mental illness | 194.819 | 1 | 194.819 | 1.737 | 0.189 |
| Smoking | 20.450 | 1 | 20.450 | 0.182 | 0.670 |
| Alcohol | 15.117 | 1 | 15.117 | 0.135 | 0.714 |
| Marijuana | 23.221 | 1 | 23.221 | 0.207 | 0.650 |
| Foot soaking | 155.913 | 1 | 155.913 | 1.390 | 0.240 |
| Regular meditation | 118.643 | 1 | 118.643 | 1.058 | 0.305 |
| Formal meditation | 15.839 | 1 | 15.839 | 0.141 | 0.708 |
| Collmed | 157.028 | 1 | 157.028 | 1.400 | 0.238 |
| Social | 5.805 | 1 | 5.805 | 0.052 | 0.820 |
| Meeting | 399.592 | 1 | 399.592 | 3.562 | 0.061 |
| Durnsy | 2.623 | 1 | 2.623 | 0.023 | 0.879 |
| Relationship * Ethnicity | 100.046 | 1 | 100.046 | 0.892 | 0.346 |
| Age * Education | 128.506 | 1 | 128.506 | 1.146 | 0.286 |
| Education * Salary | 2.485 | 1 | 2.485 | 0.022 | 0.882 |
| Age * Mental illness | 22.959 | 1 | 22.959 | 0.205 | 0.651 |
| Gender * Mental illness | 166.231 | 1 | 166.231 | 1.482 | 0.225 |
| Relationship * Salary | 0.017 | 1 | 0.017 | 0.000 | 0.990 |
| Education * Mental | 6.159 | 1 | 6.159 | 0.055 | 0.815 |
| Ethnicity * Mental illness | 490.280 | 1 | 490.280 | 4.371 | 0.038 |
| Mental illness * smoking | 33.154 | 1 | 33.154 | 0.296 | 0.587 |
| Mental illness * alcohol | 5.801 | 1 | 5.801 | 0.052 | 0.820 |
| Age * Durnsy | 29.556 | 1 | 29.556 | 0.263 | 0.608 |
| Error | 21986.330 | 196 | 112.175 | - | - |
| Total | 1698539 | 236 | - | - | - |
| Corrected Total | 34498.792 | 235 | - | - | - |

† Sig. = significance ‡ R squared = 0.363

To develop an impression of the individual contribution of various constructs to the total variance in the SF-36 total score, a further set of GLMs was applied:

- The contribution of TA to the SF-36 score, a GLM was applied with only TA as the independent variable resulting, in an $r^2$ of 0.046.
- In order to contrast this with the individual contribution of FM, another GLM was applied with FM as the independent variable, resulting in an $r^2$ of 0.019.

5.4.13.2 PCS Regression

A stepwise, forward multiple linear regression was performed using the above factors. The proportion of variance explained by this was small ($r^2$ = 0.14). The factors that contributed significantly to this variance were a history of mental illness ($p \leq 0.001$, $\beta = -3.854$). Notably, TA was not a significant contributor to the variance of the PCS score in this analysis. See Table 5.32.

To further explore the interrelationship between these factors and the dependent variable and also to account for potential interactions between factors, a general linear model (GLM) was used. The same factors were used in addition to interactions that were either suggested by the correlation or regression analysis or by clinical experience. Using this approach the GLM yielded an $r^2$ of 0.266. In the GLM none of the factors or interactions were significant. See Table 5.33.

Table 5.32 Regression PCS/MLS.

a) Correlation coefficient (r) and standard error of the estimate (SEE)

| Model | r | r squared | Adjusted r squared | SEE |
|---|---|---|---|---|
| 1 | 0.374† | 0.140 | 0.069 | 14.715 |

b) Coefficients for dependent variable: PCS.

| | Non-standardized coefficient | | Standardized coefficient | | |
|---|---|---|---|---|---|
| | **B** | **SE** | **Beta** | **t** | **Sig.‡** |
| Constant | 101.896 | 11.317 | - | 9.004 | 0 |
| Age | -0.148 | 0.083 | -0.130 | -1.775 | 0.077 |
| Gender | -0.613 | 2.210 | -0.020 | -0.278 | 0.782 |
| Relationship | -3.359 | 2.237 | -0.101 | -1.502 | 0.135 |
| Ethnicity | 0.373 | 0.712 | 0.036 | 0.524 | 0.601 |
| Education | 1.304 | 1.322 | 0.068 | 0.986 | 0.325 |
| Salary | 1.267 | 0.786 | 0.153 | 1.613 | 0.108 |
| Mental illness | -9.061 | 2.351 | -0.265 | -3.854 | 0.000 |
| Smoking | 1.667 | 3.524 | 0.052 | 0.473 | 0.637 |
| Alcohol | -0.128 | 2.883 | -0.005 | -0.044 | 0.965 |
| Marijuana | -0.021 | 3.632 | -0.002 | -0.006 | 0.995 |
| Foot soaking | -0.181 | 0.919 | -0.014 | -0.197 | 0.844 |
| Regular meditation | -1.542 | 4.986 | -0.022 | -0.309 | 0.757 |
| Formal meditation | 0.573 | 1.347 | 0.075 | 0.426 | 0.671 |
| Collmed | 0.294 | 1.242 | 0.070 | 0.236 | 0.813 |
| Social | -0.359 | 0.984 | -0.126 | -0.365 | 0.716 |
| Meeting | -1.000 | 0.927 | -0.084 | -1.079 | 0.282 |
| TA | -0.650 | 0.479 | -0.096 | -1.356 | 0.176 |
| Durnsy | -0.020 | 0.159 | -0.009 | -0.123 | 0.902 |

† Dependent variable: PCS ‡ Sig. = significance

Table 5.33 GLM PCS/MLS.

Dependent variable: PCS.

| Source | Type III Sum of squares | Df | Mean squared | F | Sig.† |
|---|---|---|---|---|---|
| Corrected Model | 14663.293‡ | 39 | 375.982 | 1.840 | 0.004 |
| Intercept | 2514.409 | 1 | 2514.409 | 12.306 | 0.001 |
| TA | 3147.854 | 11 | 286.169 | 1.401 | 0.175 |
| Age | 16.197 | 1 | 16.197 | 0.079 | 0.779 |
| Gender | 10.778 | 1 | 10.778 | 0.053 | 0.819 |
| Relationship | 362.905 | 1 | 362.905 | 1.776 | 0.184 |
| Ethnicity | 32.883 | 1 | 32.883 | 0.161 | 0.689 |
| Education | 172.268 | 1 | 172.268 | 0.843 | 0.360 |
| Salary | 108.763 | 1 | 108.763 | 0.532 | 0.467 |
| Mental illness | 13.110 | 1 | 13.110 | 0.064 | 0.800 |
| Smoking | 175.055 | 1 | 175.055 | 0.857 | 0.356 |
| Alcohol | 147.999 | 1 | 147.999 | 0.724 | 0.396 |
| Marijuana | 15.438 | 1 | 15.438 | 0.076 | 0.784 |
| Foot soaking | 40.280 | 1 | 40.280 | 0.197 | 0.658 |
| Regular meditation | 71.012 | 1 | 71.012 | 0.348 | 0.556 |
| Formal meditation | 0.077 | 1 | 0.077 | 0.000 | 0.985 |
| Collmed | 189.680 | 1 | 189.680 | 0.928 | 0.336 |
| Social | 18.243 | 1 | 18.243 | 0.089 | 0.765 |
| Meeting | 548.997 | 1 | 548.997 | 2.687 | 0.103 |
| Durnsy | 7.429 | 1 | 7.429 | 0.036 | 0.849 |
| Relationship * Ethnicity | 467.294 | 1 | 467.294 | 2.287 | 0.132 |
| Age * Education | 113.240 | 1 | 113.240 | 0.554 | 0.457 |
| Education * Salary | 0.012 | 1 | 0.012 | 0.000 | 0.994 |
| Age * Mental illness | 240.288 | 1 | 240.288 | 1.176 | 0.279 |
| Gender * Mental illness | 45.643 | 1 | 45.643 | 0.223 | 0.637 |
| Relationship * Salary | 44.504 | 1 | 44.504 | 0.218 | 0.641 |
| Education * Mental Illness | 346.502 | 1 | 346.502 | 1.696 | 0.194 |
| Ethnicity * Mental illness | 504.740 | 1 | 504.740 | 2.470 | 0.118 |
| Mental illness * smoking | 193.140 | 1 | 193.140 | 0.945 | 0.332 |
| Mental illness * Alcohol | 181.110 | 1 | 181.110 | 0.886 | 0.348 |
| Age * Durnsy | 22.251 | 1 | 22.251 | 0.109 | 0.742 |
| Error | 40456.64 | 198 | 204.326 | - | - |
| Total | 1622800 | 238 | - | - | - |
| Corrected Total | 55120 | 237 | - | - | - |

† Sig. = significance ‡ R squared = 0.266

To develop an impression of the individual contribution of TA to the PCS score, a GLM was performed with only TA as the independent variable, resulting in an $r^2$ of 0.034. In order to contrast this with the individual contribution of FM, another GLM was performed with FM as the independent variable, resulting in an $r^2$ of 0.019.

To develop an impression of the individual contribution of various constructs to the total variance in the PCS score, a further set of GLMs was applied:

- The contribution of TA to the PCS score, a GLM was applied with only TA as the independent variable, resulting in an $r^2$ of 0.046.
- In order to contrast this with the individual contribution of FM, another GLM was applied with FM as the independent variable, resulting in an $r^2$ of 0.019.

#### 5.4.13.3 MCS regression

A stepwise, forward multiple linear regression was performed using the above factors. The proportion of variance explained by this was small ($r^2 = 0.179$). The only factor that contributed significantly to this variance was TA ($p < 0.01$, $\beta = -1.81$). See Table 5.34.

To further explore the interrelationship between these factors, and to account for potential interactions between factors, a GLM was used. The same factors were used in addition to interactions that were either suggested by the correlation or regression $r^2$ of 0.278.

Table 5.34 Regression MCS/MLS.

a) Correlation coefficient (r) and standard error of the estimate (SEE)

| Model | r | r squared | Adjusted r squared | SEE |
|---|---|---|---|---|
| 1 | 0.423† | 0.179 | 0.115 | 10.512 |

b) Coefficients for dependent variable: MCS.

| | Non-standardized coefficient | | Standardized coefficient | | |
|---|---|---|---|---|---|
| | B | SE | Beta | T | Sig.‡ |
| Constant | 78.975 | 7.277 | - | 10.852 | 0 |
| Age | 0.074 | 0.058 | 0.089 | 1.268 | 0.206 |
| Gender | -0.569 | 1.574 | -0.025 | -0.362 | 0.718 |
| Relationship | 0.897 | 1.585 | 0.037 | 0.566 | 0.572 |
| Ethnicity | 0.641 | 0.502 | 0.084 | 1.277 | 0.203 |
| Education | 1.349 | 0.945 | 0.096 | 1.428 | 0.155 |
| Salary | 1.071 | 0.556 | 0.176 | 1.925 | 0.056 |
| Smoking | -3.650 | 2.506 | -0.155 | -1.457 | 0.147 |
| Alcohol | 3.688 | 2.055 | 0.190 | 1.795 | 0.074 |
| Marijuana | 2.638 | 2.541 | 0.412 | 1.038 | 0.300 |
| Foot soaking | 0.362 | 0.659 | 0.039 | 0.550 | 0.583 |
| Regular meditation | -2.286 | 3.556 | -0.045 | -0.643 | 0.521 |
| Formal meditation | -0.235 | 0.963 | -0.042 | -0.244 | 0.808 |
| Collmed | -0.139 | 0.882 | -0.045 | -0.157 | 0.875 |
| Social | -0.886 | 0.694 | -0.426 | -1.277 | 0.203 |
| Meeting | -0.639 | 0.662 | -0.073 | -0.965 | 0.336 |

† Dependent variable: MCS ‡ Sig. = significance

In the GLM the significant factors were TA ($p$ = 0.047), tobacco consumption ($p$ = 0.04) and alcohol consumption ($p$ = 0.025). These two factors were negatively correlated such that higher tobacco/alcohol consumption was associated with lower MCS score. The interaction between age and education was also significant ($p$ = 0.036). See Table 5.35.

Table 5.35 GLM MCS/MLS.

Dependent variable: MH.

| Source | Type III Sum of squares | Df | Mean squared | F | Sig.† |
|---|---|---|---|---|---|
| Corrected Model | 8194.563‡ | 38 | 215.646 | 2.007 | 0.001 |
| Intercept | 2705.862 | 1 | 2705.862 | 25.178 | 0.000 |
| TA | 2196.792 | 11 | 199.708 | 1.858 | 0.047 |
| Age | 245.405 | 1 | 245.405 | 2.283 | 0.132 |
| Gender | 77.121 | 1 | 77.121 | 0.718 | 0.398 |
| Relationship | 0.725 | 1 | 0.725 | 0.007 | 0.935 |
| Ethnicity | 29.743 | 1 | 29.743 | 0.277 | 0.599 |
| Education | 357.295 | 1 | 357.295 | 3.325 | 0.070 |
| Salary | 42.301 | 1 | 42.301 | 0.394 | 0.531 |
| Smoking | 458.784 | 1 | 458.784 | 4.269 | 0.040 |
| Alcohol | 547.332 | 1 | 547.332 | 5.093 | 0.025 |
| Marijuana | 1.164 | 1 | 1.164 | 0.011 | 0.917 |
| Foot soaking | 17.370 | 1 | 17.370 | 0.162 | 0.688 |
| Regular meditation | 97.187 | 1 | 97.187 | 0.904 | 0.343 |
| Formal meditation | 12.096 | 1 | 12.096 | 0.113 | 0.738 |
| Collmed | 142.696 | 1 | 142.696 | 1.328 | 0.251 |
| Social | 226.368 | 1 | 226.368 | 2.106 | 0.148 |
| Meeting | 110.674 | 1 | 110.674 | 1.030 | 0.311 |
| Durnsy | 7.936 | 1 | 7.936 | 0.074 | 0.786 |
| Relationship * Ethnicity | 2.687 | 1 | 2.687 | 0.025 | 0.875 |
| Age * Education | 481.444 | 1 | 481.444 | 4.480 | 0.036 |
| Education * Salary | 140.178 | 1 | 140.178 | 1.304 | 0.255 |
| Relationship * Salary | 12.419 | 1 | 12.419 | 0.116 | 0.734 |
| Age * Durnsy | 0.855 | 1 | 0.855 | 0.008 | 0.929 |
| Collmed * Social | 49.886 | 1 | 49.886 | 0.464 | 0.496 |
| Social * Meeting | 17.415 | 1 | 17.415 | 0.162 | 0.688 |
| Collmed* Meeting | 1.080 | 1 | 1.080 | 0.010 | 0.920 |
| Meditating * Collmed | 154.535 | 1 | 154.535 | 1.438 | 0.232 |
| Meditate * Social | 81.679 | 1 | 81.679 | 0.760 | 0.384 |
| Meditate * Meeting | 33.373 | 1 | 33.373 | 0.311 | 0.578 |
| Error | 21278.888 | 198 | 107.469 | - | - |
| Total | 1693356 | 237 | - | - | - |
| Corrected Total | 29473 | 236 | - | - | - |

† Sig. = significance ‡ R squared = 0.278

To develop an impression of the individual contribution of TA to the MCS score, a GLM was applied with only TA as the independent variable resulting in an $r^2$ of 0.069. In order to contrast this with the individual contribution of FM, another GLM was applied with FM as the independent variable resulting in an $r^2$ of 0.017.

To develop an impression of the individual contribution of various constructs to the total variance in the MCS score, a further set of GLMs was applied:

- The contribution of TA to the MCS score, a GLM was applied with only TA as the independent variable, resulting in an $r^2$ of 0.069.

- In order to contrast this with the individual contribution of FM, another GLM was applied with FM as the independent variable, resulting in an $r^2$ of 0.017.

## 5.5 Discussion

This is the first study to report a cross sectional survey aimed at assessing health and quality of life in a meditating population. It is also the first study to explore the interrelationship between factors such as meditative experience, meditative practices, the "meditative" lifestyle and health outcomes.

There are several findings worthy of discussion. Obviously one of the most important of these is that long term meditators, in this case SYM practitioners, appear to experience better mental and physical health than the general population. Another is, that the practice of meditation and its associated lifestyle factors are particularly associated with better health scores. Perhaps most importantly is that there appears to be a relatively robust and consistent relationship between the meditative experience of *mental silence* and health, especially mental health. Logically these observations necessarily apply to practitioners of *mental silence*-orientated meditation. Interestingly there is some limited evidence to indicate that *mental silence* meditators may have better health scores than meditators who use methods not directed at *mental silence*.

The fact that the *mental silence* construct, more than any other factor in this survey, correlated positively with a wide range of health measures raises interesting implications in several areas of study. The findings emanating from the research set out above, imply that the notion of *mental silence* and its associated yogic philosophy, may be important in the ongoing development of our understanding of meditation and the various definitions and taxonomies that relate to it. It also provides some new clues for scholars interested in the "essential factors" of religiosity and the question as to why some forms of religiosity are beneficial and others not. Furthermore, it provides empirical data that may help to progress the ongoing debate about the theoretical differences between "religiousness" and "spirituality". Perhaps most important of all they provide empirical evidence of a positive relationship between a well-defined state of consciousness and health and wellbeing. That, it is asserted, constitutes a significant contribution to the nascent field of consciousness research as well as our understandings of health. It implies a nexus between religiosity, consciousness and health that is accessible to measurement. The practical ramifications are that meditation may have a valuable role to play in the promotion of mental health and the prevention of mental illness primarily as a result of the beneficial impact of the *mental silence* experience. These points are discussed in greater detail below.

### 5.5.1 Meditators are healthier than the general population

The difference in scores between the SYM population and the general Australian population is substantial and wide ranging. The differences are particularly large in the measures of mental health suggesting potential as a strategy in both mental health promotion and prevention. These idea are discussed in greater detail in the concluding chapter of this thesis.

### 5.5.2 Strengths and limitations

The apparent positive differences between the SYM sample and the national norms may be the result of confounding factors. For example, it may be that a proportion of the observed health benefits are the result of simply controlling conventional risk factors such as smoking, alcohol, recreational drugs and other risky behaviours. As part of the National Health Survey 1995, the Australian normative data included many respondents who participated in these very lifestyle practices that SYM practitioners avoided. In attempts to control for this, and although somewhat limited by the nature of the Australian National Health Survey dataset, it is evident that even when comparing the health scores of that portion of the population that does not consume tobacco, alcohol, drugs but has the same age profile as the SYM sample the significant differences persist.

The SYM population may well be selected for those who are more motivated to achieve and maintain health. Various surveys have shown that people who use meditation and other forms of complementary and alternative medicine hold strong affiliations with holistic health philosophies and are highly motivated to seek out self-empowering health improvement strategies[186]. It is quite possible that a population of long term meditators would be highly selected for such people. Moreover, those meditators who do not experience positive effects or even experience negative effects, naturally desist from the practice and exit from the meditating population, further improving the mean health scores of the remaining population.

Surveys of this nature necessarily generate a level of expectancy among respondents. The responses of long-term meditators could have been influenced by the prospect of the survey results constituting a validation of their chosen lifestyle and belief system. Nevertheless, the fact that that the overall pattern of response in the SYM population follows a similar pattern to that of the Australian population, provides some reassurance that this was not a major confounder. Furthermore, the data reported here are almost exactly the same as the data obtained in two pilot surveys conducted 12 months prior to this national survey.

### 5.5.3 Association between *mental silence* and better health

The most significant finding emanating from this study, is that a number of items identified as important by the focus groups (and represented in the MLS), particularly the measure of *mental silence* experience, correlated positively with health scores such that more frequent experience of *mental silence* was associated with better measures of health. This was an unexpected finding. Yet it concurs with the philosophy of meditation which suggests that health benefits accrue in proportion to the degree to which the meditator can access the meditative state. The findings are therefore consistent and strongly supportive of this study's central hypothesis.

This raises the question of whether meditation could be responsible for the health advantage that this population appears to experience. The various items that make up the MLS appear to explain approximately 36% of the variance of the SF-36 total score and 27% of the variance in physical health subscore of the SF-36. Looking at the K10, the mental health measure, the MLS accounted for 45% of the variance in mental health. In fact in both measures (SF-36 physical health score or the K10 mental health score) frequency of *mental silence* was the most significant contributor.

As previously described the MLS is an agglomeration of both demographic and meditation-specific factors whose effects are sometimes difficult to separate. For example, alcohol, tobacco and recreational drug consumption are well known to have specific effects on health. Yet, within the context of SYM, factors such as intoxicants are also believed to negatively impact on the meditator's ability to experience *mental silence*. Therefore the lack or avoidance of conventionally recognized risk factors are also important in the context of a successful meditation lifestyle for reasons other than their direct impact on health. In an attempt to separate out the effects of the demographic factors alone, analysis showed that these factors accounted for only 10% of the variance in the SF-36 total score. Similarly, the demographic factors alone account for only 14% of the variance in the K10 score suggesting that the balance of the variance associated with the MLS was directly related to the meditative lifestyle itself.

### 5.5.4 Association between *mental silence* and mental health

The mechanisms by which SYM, or in fact any meditation technique, exerts its claimed effects are unclear. One very popular view, which has become more or less the default explanation of meditation effects is in terms of the physiological changes that characterise the *eRelaxation Response*[245] — that is, reductions in heart rate, blood pressure and respiratory rate and increases in skin temperature, skin resistance and alpha wave activity in the brain. All of these are brought about by reducing activity of the sympathetic component of the autonomic nervous system (ANS) and increasing activity of the parasympathetic components of the ANS. Psychophysiological studies in India certainly appear to confirm that SYM does reduce many parameters of sympathetic activation.

More recently scholars have proposed that since *Mindfulness* and similar styles of meditation necessarily allow participants to become "more aware of thoughts and feelings and to change their relationship to them"[7], therefore somehow "that greater awareness will provide more veridical perception, reduced negative affect and improve vitality and coping"[252]. Then it seems logical that by completely eliminating background mental noise, the meditator would necessarily increase internal and external awareness, possibly to a greater degree than in *Mindfulness*. Perhaps SYM acts via both the autonomic and cognitive pathways. Aftanas' brain studies of SYM meditators[318] also suggest that the effect of SYM on the central nervous system may also offer some explanation.

The observed relationship between SYM practices and mental health are not similarly as strong for measures of physical health. In many ways this might be expected since the intervention is primarily focused on a mental experience with the specific aim of reducing negative affect, thinking patterns and related behaviours. Mood, thoughts and behaviour patterns are in constant flux, much of it reflecting (and influencing) brain electrical activity and other neuro-behavioural phenomena which change from moment to moment. Aftanas has shown that the practice of SYM, and the experience of meditation, is strongly reflected in both brain electrophysiology and mood[318]. This might explain why mental health factors are much more likely to be immediately responsive to such an intervention whereas physical health factors, which rely significantly on anatomical structures and mechanical function, will take much longer to manifest (if at all) and are subject to a vast number of other environmental confounders that may obscure any such relationship.

### 5.5.5 Meditation and prayer

The relationships observed in this study are not entirely unprecedented. Meisenhelder's 2001 survey of Presbyterian ministers[256] using the SF-36 as well as measures of prayer habits, found that the sample had somewhat better health than national norms and, remarkably, that frequency of prayer correlated significantly in the *same subscales* of the SF-36 as that for meditation in this study, as shown in Table 5.36.

Table 5.36 Comparison of SF-36 subscale scores for Meissenhelder and this study.

| | Meissenhelder | | This study | |
|---|---|---|---|---|
| | Frequency of prayer | | Frequency of TA | |
| **Subscale** | **r** | **Significance** | **r** | **Significance** |
| PF | -0.001 | 0.965 | -0.039 | 0.474 |
| RP | -0.010 | 0.715 | -0.099 | 0.067 |
| BP | 0.037 | 0.166 | -0.005 | 0.928 |
| GH | 0.088 | 0.001 | 0.200 | 0.001 |
| V | 0.103 | 0.000 | 0.217 | 0.001 |
| SF | 0.027 | 0.317 | -0.030 | 0.586 |
| RE | 0.039 | 0.154 | -0.097 | 0.077 |
| MH | 0.117 | 0.000 | 0.345 | 0.001 |

Meisenhelder proposed that the relationships observed in her study could at least partly be caused by the relaxation effect of prayer and its consequent ability to ameliorate the effects of stress. This idea is supported by studies such as that by Carlson who studied the autonomic impact of Christian devotional meditation in a RCT design and found that it was as effective, and in some parameters more effective, as conventional relaxation[86].

It is fascinating that Meisenhelder's 2001 findings correspond so closely to those in this study especially because both this study and Meisenhlder's report correlations in the same SF36 subscales suggesting that both prayer and meditation have a generic effect on general health, vitality and mental health. An interesting distinction however is that the experience of *mental silence* has a stronger (approximately twice as strong) relationship with these dimensions.

It is entirely possible that the differing strength of relationship between *mental silence* and health as compared to prayer and health may be an artefact arising from demographic inequalities. Nevertheless, one is tempted to ask whether the differences may be because *mental silence* orientated meditation more effectively elicits relaxation or that perhaps *mental silence* itself works through different but more potent mechanisms as compared to prayer. If the health benefit associated with *mental silence* was primarily a result of its ability to make the practitioner sit quietly and relax then one would expect to see a similar relationship between formal meditation and health scores. In fact relationships between how often a SYM practitioner performed "formal meditation" and health measures were considerably weaker and less frequent than for *mental silence*. Implying that differences between contemplative practices (such as prayer or meditation) that are overtly similar but sometimes experientially distinct (i.e. *mental silence* versus mental activity) have significantly different health implications.

### 5.5.6 SYM and non-*mental silence* meditation

The SYM sample's health scores differ significantly from the comparison group scores. While this finding is both unexpected and potentially significant there are important limitations to this observation. The comparison group's MLS did not contain specific measures of meditation experience or competence (such as TA in the SYM-MLS) because the wide variety of meditation techniques surveyed precluded the development of a single questionnaire that could effectively address this factor. The comparison group is a sample comprised of a far more heterogeneous collection of techniques and individuals than the SYM sample, it is relatively small and the degree to which the sample is truly representative is uncertain. The various restrictions on data collection, albeit beyond our control (as described in the methodology Chapter 4), add to the uncertainty about whether or not the sample is truly representative.

There are also a number of fundamental demographic and other differences that may confound the comparison; these include differences in proportion of genders, ethnicity, education, history of mental illness, consumption patterns of alcohol, tobacco and marijuana.

In terms of meditative practices, the SYM sample appears to be comprised of more intense practitioners; 51.2% of the SYM sample did formal meditation once or twice per day whereas only 16.7% of the comparison sample did the same. Nevertheless, the mean duration of practice for both groups was similar; 13 years for the SYM sample (range 2 to 29 yrs) whereas it as was 10 years for the comparison sample (range 2 to 50 yrs). Differences in frequency of social contact probably reflect differences in the sampling methods for the two populations. Of SYM practitioners, 50% socialize with other meditators at least once per week or more whereas 70.1% of the comparison sample do the same. The SYM sample was obtained by travelling to various meditation centres in major cities as well as to weekend meditation retreats. These locations and events attracted SYM practitioners from both metropolitan and non-metropolitan locations. Practitioners in non-metropolitan and even metropolitan locations with small numbers of SYM practitioners are less likely to be able to establish social connections. The comparison sample was developed by contacting meditation organizations and centres located in metropolitan areas. This preferentially attracted meditators in those areas or meditators who regularly visited these centres. Thus they may have had substantially more opportunities to socialize with other meditators.

Notwithstanding these considerations, the health differences are measurable and significant. Setting aside the question of selection bias, the differences between the SYM and the comparison health profiles nor the absence of correlations between any of the comparison sample-MLS factors and health outcomes in the comparison group might be explained by the possibility that different conceptualizations of meditation preferentially attract people with certain health profiles. This does not however explain the absence of any correlation between factors such as duration of practice and frequency of formal meditation with health scores. In line with the hypothesis of this study one possible explanation for the absence of measurable health score differences between the comparison sample and the Australian norms may be explained by the lack of emphasis on *mental silence*. This tentative notion might also be supported by the fact that even within the SYM sample, the relationship between formal meditation and health measures was very weak. Similarly relationships between frequency of meditation in the comparison group and health measures were not detected.

## 5.6 Conclusion

Epidemiological study of religion is currently dominated by a Western, Judeo-Christian perspective. George and colleagues noted in their discussion about the nature and quality of samples used in surveys and longitudinal studies of religious practices, that more than half of the studies that address the relationship between religion and health are based on samples of older adults (60+ years of age). They further noted that these kinds of studies are usually conducted within limited geographic regions within the US and are thus potentially influenced by regional variations in religious observance (for example Bible Belt states versus West Coast)[319]. In contrast, this study involved a national, representative sample of meditators, the sample group was relatively young (with a mean age of 37) and its outcomes were compared to national, census-based normative data. The fact that it examined non-Judeo-Christian religiosity in a country comparable to, although not geographically connected to the USA, on a sample of respondents who are ethnically similar and yet religiously different, are additional strengths.

Future research involving comparison of SYM practitioners with other populations (controlling for the exclusion of health risk factors and similar lifestyle changes as well as religious and spiritual observances) would be useful to more clearly identify the source of the apparent benefits of that this population appears to enjoy.

# Chapter 6. Meditation Therapy for Hot Flushes and Other Symptoms of the Peri-menopause

## 6.1 Overview

Chapter 5 described a population survey that indicated a significant association between the experience of *mental silence* and health outcomes. An association does not however prove causality. The methodological progression now involves moving from the simple survey design in the previous chapter to the most basic of clinical trial designs: a small, uncontrolled observational interventional trial. This was an exploratory study where SYM was taught to a small group of menopausal women who were experiencing troublesome levels of menopausal symptoms, especially hot flushes. Menopausal symptoms often feature or are worsened by psychological and psychosomatic factors and so may be amenable to meditation. Research into the potential role of psychological interventions, especially meditation, in the management of menopausal symptoms is very limited.

In this study 14 women attended meditation classes twice weekly for 8 weeks and practiced daily at home. A variety of measures were used at pre-, mid-, post- and follow-up time-points — including hot flush counts and widely accepted, validated self-report questionnaires. Participants experienced substantial improvements, much of which was maintained at the follow-up assessment. The most remarkable improvement was in their hot flush frequency, with a responder rate of approximately 80% (that is, 80% of the women manifested a positive response to the intervention, defined here as a 50% or greater improvement in frequency) or simple a mean reduction in frequency of 67%,). Notwithstanding the considerable limitations of the study, the magnitude of the outcome is comparable to more conventional management strategies even though no pharmacological or CAMs were being used. Apart from the clinical implications, the study signalled that, given SYM's focus on the *mental silence* experience, the association identified in the previous survey may be sufficient to justify a more thoroughly designed assessment.

## 6.2 Introduction

The consensus definition of the menopause is "the permanent cessation of menstruation resulting from the loss of ovarian follicular activity. It is recognized to have occurred after 12 consecutive months of amenorrhea, for which there is no other obvious pathological or physiological cause."[320] It therefore occurs with the final menstrual period (FMP) only in retrospect and usually a year or more after the event. There is no adequate biological marker for the onset of the condition. The average age for the menopause in Western countries is 51 years[321]. The peri-menopause encompasses the phase prior to the menopause in which the endocrinological, biological, and clinical features commence as well as the first year after menopause. It is usually about 5 years in duration and can occur in women as young as 40 or as old as 60 years. Menopausal transition is that period of time before the FMP when variability in the menstrual cycle is usually increased. This term can be used synonymously with "pre-menopause," although this latter term has caused some confusion. The post-menopause starts from the FMP, regardless of whether the menopause was induced or spontaneous[320].

Problems caused by symptoms of the menopause are common in Western health care. The most commonly experienced are vasomotor phenomena of which the hot flush is particularly common. Other problematic symptoms, which include poor quality sleep, and a general loss of quality of life, are experienced by an estimated 70% of women for up to several years following the onset of peri-menopause[321].

### 6.2.1 Hot flushes and vasomotor symptoms

Hot flushes are characterized by the sudden onset of a sensation of intense warmth that begins in the chest and may progress to the neck and face. They are often accompanied by anxiety, palpitations, profuse sweating, and red blotching of the skin. They can affect ability to work, social life, sleep patterns and general perception of health[322-324]. The hot flush and vasomotor symptoms generally, can be powerful and sometimes overwhelming. That they can be unexpected and random makes them even more disruptive and detrimental to quality of life[325].

The mechanism of the menopausal hot flush is itself not yet fully understood although a neuroendocrine pathway is thought to have a primary role[326]. It is known that central sympathetic activation is increased in women who experience hot flushes[327] and this explains why clonidine, a centrally acting alpha adrenergic agonist, can be clinically useful in controlling these symptoms[328]. Shanafelt proposes that oestrogen withdrawal leads to a decrease in endorphin and catecholamine levels which culminates in increased hypothalamic norepinephrine and serotonin release. He reasons that the change in these 2 factors then lowers the set point in the thermoregulatory nucleus, which allows heat loss mechanisms to be triggered by alterations in blood flow to the periphery, thereby resulting in the hot flush and associated vasomotor phenomena[329].

### 6.2.2 Conventional management

Women with severe menopausal symptoms often seek pharmacological management. The most widely accepted strategy is hormone replacement therapy (HRT). Despite its effectiveness, however, many women are concerned about potential side effects[330], which can be short term (such as vaginal bleeding), or long term (such as increased risks of certain cancers). Recent revisions of menopausal management guidelines mean that HRT is now only recommended for the short to medium-term management of moderate to severe menopausal symptoms[331]. Furthermore, media attention describing the risks of long term HRT has led to a considerable reduction in consumer demand for HRT[332] and a concomitantly increased demand for more "natural" options. For instance, a North American Menopause Society survey of women aged 45 to 60 found that 80% of respondents had used non-prescription therapies to manage the short-term disturbances or prevent the long-term consequences of menopause[333]. Interest seems particularly strong among women in whom HRT is contraindicated as a cause for instance, of breast cancer[334].

### 6.2.3 Complementary and alternative therapies

Complementary and alternative medicine (CAM) options for menopausal symptoms include herbs, vitamin and nutritional supplements as well as behavioural therapies[326 335]. The latter are particularly attractive to both consumers and clinicians as they are non-invasive and do not involve the consumption of exogenous agents, thus significantly reducing the likelihood of dangerous adverse reactions.

As part of the preliminary assessment for an interventional study (described in further detail below), Hunter and Liao surveyed menopausal women who were seeking help for menopausal symptoms and found that 60% of respondents preferred psychological treatment to HRT. The reasons for this included: wanting to avoid the side effects of HRT, a desire to use a "natural option," an interest in gaining broader skills in managing stress and in order to enhance self-efficacy[336].

### 6.2.4 Lifestyle modification

Simple lifestyle changes directed at modifying the physiological environment can be effective. For example, there is evidence that regular exercise[337], elimination of smoking[338] and the avoidance of stress can reduce the impact of hot flushes[339, 340].

A study by Casper reports cessation of hot flushes immediately upon exposure to a cool environment[341]. This supports the idea that hot flushes may be due to irregular hypothalamic regulation of core body temperature and consequently strategies such as taking cold drinks, reducing the intake of spicy foods and providing room air circulation, may also be helpful in ameliorating vasomotor symptoms, especially hot flushes.

### 6.2.5 Behaviour therapy

In general behaviour strategies focus on moderating the impact of illness by modifying cognitive appraisal of the symptoms, ameliorating negative mood states and/or reducing physiological arousal (sympathetic activation) associated with stress. They include: breathing exercises, relaxation, cognitive behavioural therapy and biofeedback. Meditation may also appropriately be included in this category.

#### 6.2.5.1 Review of behaviour therapy research

In order to develop an understanding of the potential efficacy of relaxation strategies and other behaviour therapy methods in the management of menopausal symptoms, the evidence in the peer-reviewed literature was examined. Computer databases were searched and other sources sought out, including: MEDLINE, PsycINFO, CINAHL, EMBASE, Current Contents and Biological Reports, the Internet and hardcopy reports. Search terms included “menopausal symptoms”, “behaviour therapy”, “relaxation” and “hot flushes”. Nine trials were found. Four were uncontrolled, with very small sample sizes, 2 were controlled but did not use randomization, and 3 were RCTs, but with relatively small sample sizes. These are summarized in Table 6.1, and what follows is a brief descriptive review.

Table 6.1 Review of behavioural therapy trials for menopausal symptoms.

| Author, year | Design† | n‡ | Duration (weeks) | Main intervention | Change in HF frequency§ | Other measures |
|---|---|---|---|---|---|---|
| Stevenson, 1983 | UT | 4 | 12 | Multi-component | 70% | Nil |
| Germaine, 1984 | RCT | 12 | 6 | PMR | 54% | Nil |
| Freedman, 1992 | RCT | 33 | 8 | Paced respiration | 39% | Nil |
| Hunter, 1995 | NRT | 61 | 6–8 | CBT | 50% | Mood Anxiety |
| Irvin, 1996 | RCT | 33 | 10 | *Relaxation Response* | 35% | STAI, POMS, HF intensity |
| Wijma, 1997 | UT | 6 | 12 | AR | 56% | Kupperman MOOD, SCL50 |
| Younos, 2003 | UT | 14 | 4 | Hypnosis | 65% | QOL, fatigue |
| Allan, 2005 | CR | 2 | 10 | Multi-component, PMR, CBT, lifestyle modification | 41%, 88% | MENQOL, HAM-D, HAM-A |
| Carmody, 2006 | UT | 15 | 7 | *Mindfulness*-based Stress reduction (Multi-component) | 34% | MENQOL, HFRDS, WHI Insomnia Scale, SCL90R, PS |

† Design categories: **CR** = Case Reports, **UT** = Uncontrolled Trial or Case Series, **NRT** = Non-Randomized Trial, **RCT** = Randomized Trial

‡ n = number of trials

§ HF frequency change at end of the intervention period

## 6.3 Menopausal research

### 6.3.1 Uncontrolled studies

Allan reported on 2 cases of multi-component management strategy for menopausal hot flushes comprising progressive muscle relaxation (PMR), lifestyle modification and 10 sessions of cognitive behavioural therapy (CBT). Both women experienced substantial and clinically meaningful improvements in their hot flush frequency and other measures of quality of life and mood state. The improvements were maintained at the 6 month follow-up[342].

Younus assessed the effect of hypnosis on hot flushes (HF) and overall quality of life in 10 healthy volunteers and 4 breast cancer patients (an unspecified number of whom were taking Tamoxifen) with HF symptoms. They were treated with 4 hour-long sessions of hypnosis weekly. All participants recorded frequency, duration, and severity of HF as well as quality of life and fatigue scores. Although the mean scores were not specifically reported, it appears that the treatment group experienced a 65% improvement in HF frequency and similar improvements in duration and severity. Quality of life improved significantly. The participants enjoyed better sleep and had less insomnia. "Current fatigue" levels improved significantly but not "total fatigue" levels. Neither mean nor raw scores were provided for scrutiny[343].

Wijma trialled "applied relaxation" (AR) in a group of 6 women over 12 weeks. The AR program comprised an hour-long group instruction per week over a 12 week period. The aim of the treatment was to enable participants to cope better with sudden attacks of hot flushes, thereby reducing symptom severity and increasing wellbeing. The authors reported good clinical effects which were maintained 24 weeks after the intervention period. At the end of the intervention period, all 6 participants experienced reduction in hot flushes in excess of 50%, and at 6 months follow-up this improvement was maintained. Additionally, menopausal measures on the Kupperman Index indicated an average improvement of 44.4% by post-intervention. Although the outcomes were promising, the trial was limited by the small sample size[344].

Stevenson and Delprato investigated a multi-component self-control strategy that was based on reducing both stress and body temperature and involved the use of measures aimed at keeping body temperature from fluctuating and precipitating a hot flush. These measures included sipping cool drinks, avoiding spicy food and alcohol and providing for room air circulation. In combination with these measures, a number of behaviour therapeutic techniques (relaxation, self-suggestion of cool thoughts and images, “marital contingency contracting”, and temperature biofeedback) were taught. The intervention period was 12 weeks in duration and involved 10 sessions of instruction. Results immediately post-intervention indicated that the four participants experienced 41%, 75%, 76% or 90% reduction in hot flush frequency which was maintained at 6 month follow-up. Although this study was similarly limited by small sample size and absence of controls, the outcome suggests a potent effect that warrants further investigation[345].

Of particular relevance is a study by Carmody[346] in which *Mindfulness*-based stress reduction (MBSR) was taught to 15 women. Participants experienced a reduction of approximately 40% in the frequency of hot flushes. The MBSR is a multi-component strategy that includes: coaching in certain mental attitudes and beliefs about the relationship between thoughts and feelings, the mind and sense of self as well as other exercises[251]. As part of the MBSR, *Mindfulness* meditation (MM) i taught. Questions remain as to whether or not this is a meditation technique, a relaxation method or a more complex form of cognitive behavioural therapy. Furthermore, from a research perspective, the multi-component nature of MBSR makes it difficult to determine which clinical effects are specific to *Mindfulness vis-á-vis* the other therapeutic components of the package. This final point is of considerable relevance to the ongoing debate about whether or not meditation has a specific effect[346].

### 6.3.2 Non-randomized controlled trials

In 1996, Hunter and Liao recruited 61 menopausal women (aged 35–71) who reported hot flushes at least once a week. In this study the authors included “night sweats” within their definition of hot flush. Participants were allocated to their treatment of choice (HRT, cognitive behaviour therapy, or no treatment) with random allocation only for those expressing no preference. While this novel approach to subject allocation may introduce certain selection biases, the researchers argue that the design is particularly suitable for evaluation of treatments that rely heavily upon patient motivation and may better reflect "real world" outcomes more closely than simple randomization. Notably, probably as a result of this kind of allocation strategy, the HF frequency rates were substantially higher in the sample of women in the HRT group (42.9 per week) in comparison to those in the cognitive behaviour therapy (CBT) group (28.1 per week). The CBT consisted of 4 hour-long individual sessions spaced over 6 to 8 weeks and comprised daily training in "muscular relaxation", information about hot flushes, including the possible role of stress and a general discussion about menopause. CBT was reported to reduce HF by 50.2% whereas HRT brought about a 68.5% improvement in frequency. However, HRT did not improve mood, anxiety or the perception of hot flushes as a problem, whereas the CBT treatment did. The CBT-induced improvements were maintained at the 6 month follow-up. No significant improvements were observed in the no-treatment group. Interestingly, no significant between-group differences were observed in hot flush frequency after intervention. Furthermore, at follow-up the CBT group had only 25% of participants free of hot flushes and yet 91.5% of participants in the CBT group rated themselves as having improved significantly. While in the HRT group 50% were free of hot flushes, only 50% rated themselves as having improved significantly. This highlights the clinical importance of addressing not only the patho-physiology of the hot flush but also the psycho-social dimension of the problem[347].

Anarte provides an interesting counterpoint in a study which compared the effect of HRT alone to a combination of HRT and psychological support. The outcome measures were the Kupperman's Index and the Granada Gynaecological Questionnaire. Surprisingly, the combined strategy was less effective than HRT alone in controlling vasomotor symptoms, whereas it was more effective in controlling non-vasomotor symptoms such as insomnia, anxiety and fatigue. Neither HRT nor the combination approach appeared to be effective in controlling arthromyalgia or headache[348].

### 6.3.3 Randomized controlled studies

Germaine conducted a small RCT in which 12 participants were allocated to either progressive muscle relaxation or alpha EEG biofeedback (considered a placebo control). The researchers used a laboratory induced hot flush response to heat as their major endpoint. Increased finger skin temperature and tachycardia along with subjective report of HF occurrence were the criteria by which the flushes were objectively assessed. After 6 weeks of weekly instructional sessions, the intervention group experienced a 50% improvement (measured as an increased latency to exhibit a laboratory-induced HF) and this was maintained at the 6 month follow-up phase[349].

In an attempt to separate out the effects observed in Germaine's study, Freedman and Woodward compared "muscle relaxation", "paced respiration" (deep abdominal breathing, 6–8 breaths per minute applied when a woman feels that she anticipates HF about to occur), and "alpha wave electroencephalogram (EEG) biofeedback" (again described as a placebo condition) in 33 postmenopausal women. After 8 weeks of twice weekly individual therapy sessions, "paced respiration" was associated with a significant 39% reduction ($p < 0.02$) in the HF frequency. Significant changes did not occur in the other groups and no between-group comparisons were reported. The investigators hypothesized that the slow, deep breathing exercises acted to reduce central sympathetic activity and thereby reduce the HF frequency[350].

Finally, Irvin conducted a RCT of *Relaxation Response* versus both a "reading control" and a "charting control" with 33 peri-menopausal women. Women received 3 one-hour instructional lessons over a 10 week period in "*Relaxation Response*" and were then instructed to practice it twice daily at home for a further 7 weeks. There was no significant reduction in HF frequency. The study did however report significant reduction in HF intensity, as well as in some general psychological measures of mood and anxiety. No between-group comparisons were conducted[112].

## 6.4 Some conclusions about behaviour therapies

In summary, relaxation and behaviour therapies for menopausal HFs appear promising, although the interpretation of the findings are limited by methodological shortcomings within most of the extant trials. In fact the degree of change in average HF frequency was quite variable, ranging from 35% to 70%. Moreover, degree and scope of changes in ancillary symptoms also seemed to vary from trial to trial. Both Stevenson's and Wijma's studies discussed above, although severely limited by sample size and lack of control, reported very promising outcomes with relaxation-orientated interventions. Smaller studies have greater sampling error, thereby increasing the likelihood of selecting for those sympathetic to behaviour therapy. This, among other factors, may explain why the mean effect reported in the RCTs was substantially less than that reported in the observational studies.

It is important to also consider the role of the placebo effect, regression to the mean, demand and expectancy and other non-specific factors. It is well recognized that these can be potent factors in psycho-physiological symptoms such as the vasomotor phenomena associated with the peri-menopause. For example, Clayden, Bell and Pollard reported that flushing responded to suggestions of improvement[328]; and a number of other reviews[329] suggest that placebo effect can be substantial for vasomotor symptoms. For example, Mclennan conducted a systematic review of oestrogen versus placebo effects for the management of menopausal symptoms and found that, while

HRT was clearly more effective than placebo, participants in the placebo groups experienced up to 50% improvement in HF frequency from baseline to the end of the study[351].

Nevertheless, the positive outcomes of RCTs such as Germaine's and Freedman's[349] provide a more reassuring impression of the potential of behaviour therapies. Hunter's reported outcomes contribute further promise although limited by the quasi-randomization methodology[347]. On the other hand, Hunter's study highlights the importance of selecting a therapy to which the subject is favourably disposed in order to maximize therapeutic benefit. Bearing this in mind, along with the fact that the studies reporting the greatest effects on HF frequency are multi-component stress management strategies[345] and hypnosis[352] conducted on small groups of patients, as well as the fact that both of these trials use interventions with little similarity, suggests that non-specific effects play a significant role in the outcome. Thus although intense relaxation programs may be promising, there is still a need for more robust information about the specific role or clinical effect that might be expected from each specific strategy.

Importantly, no studies have evaluated meditation as a singular behavioural intervention for menopausal symptoms. While it may be argued that since the abovementioned studies have used relaxation techniques and that since meditation and relaxation are extremely similar, the findings of these studies could be reasonably extrapolated to predict the effect of meditation. As discussed in Chapter 3 however, while meditation and relaxation are overtly similar, a strong argument can be made to distinguish SYM, with its emphasis on the *mental silence* experience, from forms of meditation aimed at reducing physiological arousal or modifying cognitive behavioural patterns.

Further, Carmody's study of the MBSR[346] might also be interpreted as a sufficiently heuristic assessment of the potential of meditation. As described in Chapter 2 however, the MBSR is a multi-component strategy and therefore teasing out the specific contribution of meditation to the study's outcomes, is difficult. Given that the literature makes it clear that non-specific effects are the primary confounder in meditation research, this is an important issue that needs addressing.

As far as *Mindfulness* itself is concerned, the SYM approach has some important similarities to *Mindfulness*, in that it also emphasizes awareness of the present moment and the idea of disengaging attentional processes from the flow of internal and external events (rather than reduction of physiological arousal). A critical difference however is that this state of "present moment awareness/passive observation" constitutes only the prelude to a more important and specific experience of *mental silence — nirvichara Samadhi*[239]. Thus while SYM is a specific experience that can be preceded, if not facilitated by, present-moment observation and other *Mindfulness* methods, the *sine qua non* feature — elimination of thought activity — distinguishes it from MM. Similarly, *mental silence*-orientated meditation can be distinguished from MM-orientated meditation since the former focuses on the notion of "non-thought" while the latter emphasizes the notion of "passive, non-judgemental observation of mental activity". Given these theoretical considerations, the extant literature does not feature data that can be reasonably extrapolated to *mental silence* orientated meditation. Therefore a separate assessment of the clinical potential of SYM is warranted. The aim of the following exploratory study was therefore, to describe and explore the effects, suitability and safety of SYM as a management strategy for menopausal symptoms, particularly HFs.

## 6.5 Methodology

### 6.5.1 Participants and design

The study was approved by the South Eastern Area Health Service Ethics committee. A specifically designed program conducted at the Sydney Menopause Centre, Royal Hospital for Women, Sydney, Australia, attracted 14 participants.

### 6.5.2 Inclusion and exclusion criteria

Inclusion criteria for this trial were:

- last menstrual period over 6 months previously
- no other treatment for menopausal symptoms, whether natural or conventional, undertaken over the past 8 weeks
- no history of breast cancer
- age between 40 and 60
- no history of any significant psychological or physical illness
- non-smoker
- intake of less than 2 standard alcohol drinks per day.

Participants needed to be experiencing a minimum of 5 HFs a day, as measured by a HF diary.

Exclusion criteria were:

- current use of HRT
- use of herbal or nutritional supplements within the last 6 weeks

- any major systemic illness (e.g. diabetes, congestive cardiac failure, hypo- or hyperthyroidism, liver or kidney disease)
- any major psychiatric/psychological disorder
- having undergone surgically/medically induced menopause
- unwillingness to comply with treatment guidelines of the study.

During their first visit, participants filled in a battery of self-report questionnaires. These included the Kupperman Index, Greene's Score, MENQOL, POMS and STAI. Participants also filled out a baseline HF diary that indicated the number of HFs per day over a 7-day period.

The questionnaires and HF diaries were filled out at baseline, in Week 4, Week 8 (post intervention) and in Week 16 (8 weeks post intervention).

### 6.5.3 Measurement instruments

#### 6.5.3.1 Flush count diary

This is a standard menopausal assessment tool. Participants are asked to tally each HF episode as they occur. This measure has been found to be reliable and have validity compared to daily monitoring[353].

#### 6.5.3.2 Kupperman Index of menopausal symptoms

This is a menopause-specific symptom measure which uses a scale from 0 (none) to 3 (marked) to sum the menopausal symptoms and yield a total menopause symptom index[262, 263]. This is the oldest of self-report instruments and focuses primarily on symptomatic relief.

#### 6.5.3.3 Menopause-specific quality-of-life questionnaire (MENQOL)

This is a validated quality of life questionnaire[264]. It assesses the impact of menopausal symptoms on quality of life using 29 questions, each with a 7-point severity scale. It was designed to detect changes in quality of life as a result of treatment.

#### 6.5.3.4 State trait anxiety index (STAI)

This uses two, 20 item self-report scales to measure anxiety proneness (trait) as well as the current level of tension and apprehension (state)[265]. The STAI is easily administered and scored and is widely used in a variety of research settings. It is particularly useful for research on anxiety reduction.

#### 6.5.3.5 Greene Climacteric Scale

This is a 21 item self-report scale designed to measure the severity of common menopausal symptoms[266]. Symptoms are based on 3 broad categories: psychological, somatic, and vasomotor. These symptoms have been confirmed by other factorial studies as having a statistically significant factor loading. The scale can also be used to identify menopausal women who are possibly clinically depressed.

### 6.5.4 Treatment

The meditation group attended the Sydney Menopause Centre 2 evenings per week for 8 weeks. Each instructional session lasted one-and-a-half hours. All participants began the program simultaneously. Attendance rolls were kept and the participants were encouraged to practice the techniques learned in the instructional sessions on a 15-minute, twice-daily basis at home. Instructional audiotapes were supplied together with written guidelines of how to cultivate the meditation experience.

The instructor was a health professional with expertise in SYM instruction. Each class began with the calling of the attendance roll followed by a brief talk on the principles of meditation to be learned that day. Questions were taken to help clarify any difficulties being experienced by the participants. Following this, 2 guided meditation sessions with a short break in between, were conducted. This was followed by a brief question-and-answer session. Participants were encouraged to practice what they had learned during that session, at home.

Participants were introduced to the idea that most menopausal symptoms could be spontaneously corrected by the practice of regular meditation. The idea that the state of *mental silence* was the crucial, therapeutic component of the experience, was impressed upon them.

### 6.5.5 Statistical analysis

Of the 14 people enrolled, 4 dropped-out prior to the end of the intervention and another prior to follow-up assessment. The most conservative approach in the handling of missing values was taken, with no attempt being made to estimate missing values, and each analysis used all available scores.

Non-parametric analysis was the most appropriate way to handle the data because of the small sample size. These results are presented in Table 6.2. Response rates were compared between pre-intervention, post-intervention and at the follow-up stages to determine any change in HF frequency. Table 6.3 summarizes the percentage change for each measure.

## 6.6 Results

### 6.6.1 Vasomotor symptoms

There was a clear improvement in vasomotor symptoms, particularly HFs. Maclennan argues convincingly that hot flush frequency is best assessed by determining responder rate, with a reduction of 50% or more regarded as a positive response[351]. Eight out of ten participants exhibited a positive response, and this response was maintained at 16 weeks follow-up. By post-treatment, HF frequency was at an average 67% below baseline, and at follow-up it was still 57% below baseline. Non-parametric analysis of HF frequency across the entire study showed that the changes were significant.

A reduction of 50% or greater in HF frequency is considered a clinically significant response. Of the 10 participants who filled out post intervention HF diaries, 8 experienced a positive response at the end of the intervention period. At the 8 week follow-up, 9 participants completed HF diaries and 6 of these continued to experience a positive response.

The Kupperman Index fell to a level 58% below baseline, with only some loss of benefit at the follow-up assessment, (compared to Wijma's average 43% reduction in severity scores, which however, was maintained at follow-up). Non-parametric analysis showed the changes in the Kupperman's score to be significant. Similarly, the vasomotor subscale of Greene's Climacteric Scale improved by an average of 71% post-treatment. At follow-up, scores returned to 53% below that of baseline. Analysis of this subscale showed these changes to be significant. The MENQOL's vasomotor subscale scores were 53% better at post-treatment and remained unchanged at follow-up; however on statistical analysis these changes were not significant. Informal feedback from participants indicated that most did not continue meditating with the same intensity after cessation of the program.

### 6.6.2 Other symptoms and QOL domains

Non-vasomotor symptom scores did not change as impressively. For instance, the psychometric and depression subscales of the Greene's Climacteric Scale and the physical subscale of the MENQOL, despite their impressive changes at post intervention, were not maintained at follow-up. Consequently, analysis showed that these changes were not significant across the full duration of the study.

Table 6.2 Non-parametric repeated measures Friedman test.

| **Measure** | **n** | **Baseline Mean rank** | **Post-treatment Mean rank** | **Follow-up Mean rank** | **Friedman $\chi^2$, 2df** | ***p*** |
|---|---|---|---|---|---|---|
| **HF frequency** | 10 | 2.89 | 1.50 | 1.61 | 11.7 | 0.003 |
| **Kupperman** | 8 | 2.88 | 1.31 | 1.81 | 10.5 | 0.005 |
| **Greene:** | | | | | | |
| Vasomotor | 9 | 2.89 | 1.33 | 1.78 | 14.9 | 0.001 |
| Somatic | 9 | 2.50 | 1.28 | 2.22 | 8.9 | 0.012 |
| Anxiety | 9 | 2.67 | 1.22 | 2.11 | 10.1 | 0.006 |
| Psychometric | 9 | 2.56 | 1.22 | 2.22 | 9.2 | 0.010 |
| Depression | 9 | 2.33 | 1.50 | 2.17 | 4.7 | 0.097 |
| **MENQOL:** | | | | | | |
| Vasomotor | 9 | 2.28 | 1.72 | 2.00 | 1.5 | 0.469 |
| Psychosocial | 9 | 2.33 | 1.11 | 2.56 | 10.9 | 0.004 |
| Physical | 8 | 2.50 | 1.75 | 1.75 | 3.0 | 0.223 |
| Sexual | 9 | 2.56 | 1.56 | 1.89 | 7.0 | 0.030 |
| **STAI-state** | 10 | 2.50 | 1.80 | 1.70 | 4.0 | 0.135 |
| **STAI-trait** | 10 | 2.50 | 1.60 | 1.90 | 4.4 | 0.110 |

Table 6.3 Descriptive summary of changes, baseline to post-intervention, baseline to follow-up.

| Measure | Post-intervention % change | Follow-up % change |
|---|---|---|
| HF frequency | 67.2 | 56.2 |
| Kupperman | 58.2 | 40.4 |
| Greene: | | |
| Vasomotor | 71.1 | 52.4 |
| Somatic | 80.8 | 29.3 |
| Anxiety | 77.5 | 32.9 |
| Psychometric | 74.3 | 21.4 |
| Depression | 69.1 | 2.1 |
| MENQOL: | | |
| Vasomotor | 46.7 | 46.7 |
| Psychosocial | 45.9 | 37.2 |
| Physical | 53.0 | 31.7 |
| Sexual | 56.2 | 33.3 |
| STAI-state | 25.8 | 26.6 |
| STAI-trait | 26.4 | 23.0 |

To facilitate qualitative discussion, the mean scores for the various outcome measures are graphically illustrated below in Figures 6.1–6.11.

### 6.6.3 HF frequency

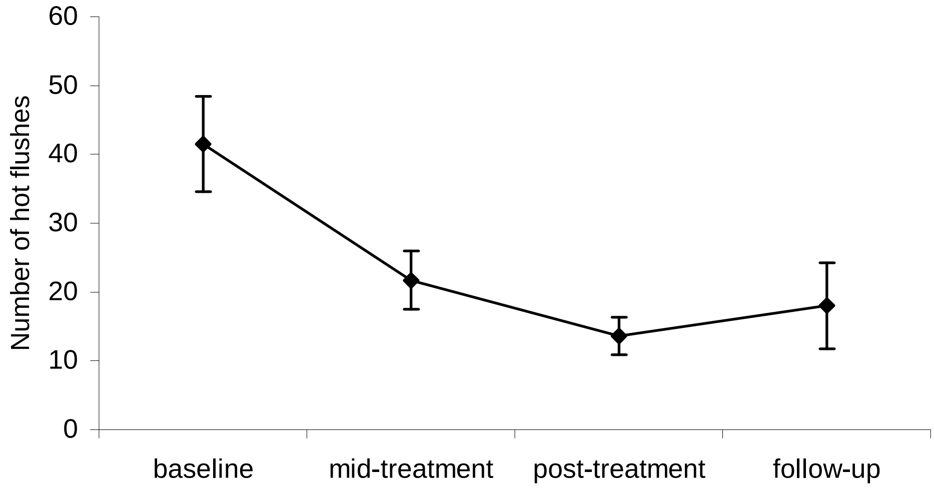


Figure 6.1 Mean frequency and associated standard errors of HF count at each of the 4 test times.

### 6.6.4 Kupperman index of menopausal symptoms

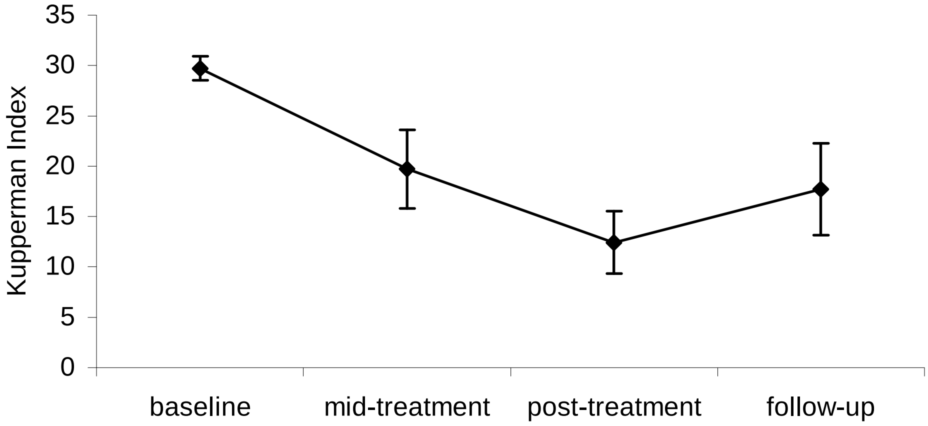


Figure 6.2 Mean scores and associated standard errors for the Kupperman Index of menopausal symptoms at each of the 4 test times.

### 6.6.5 Greene's Climacteric Scale

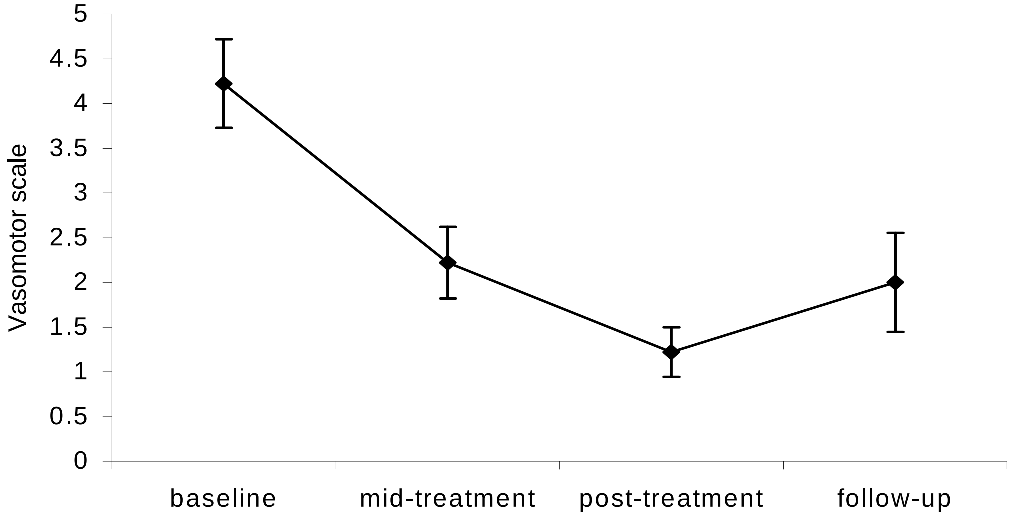


Figure 6.3 Mean scores and associated standard errors for the vasomotor subscale of Greene's Climacteric Scale.

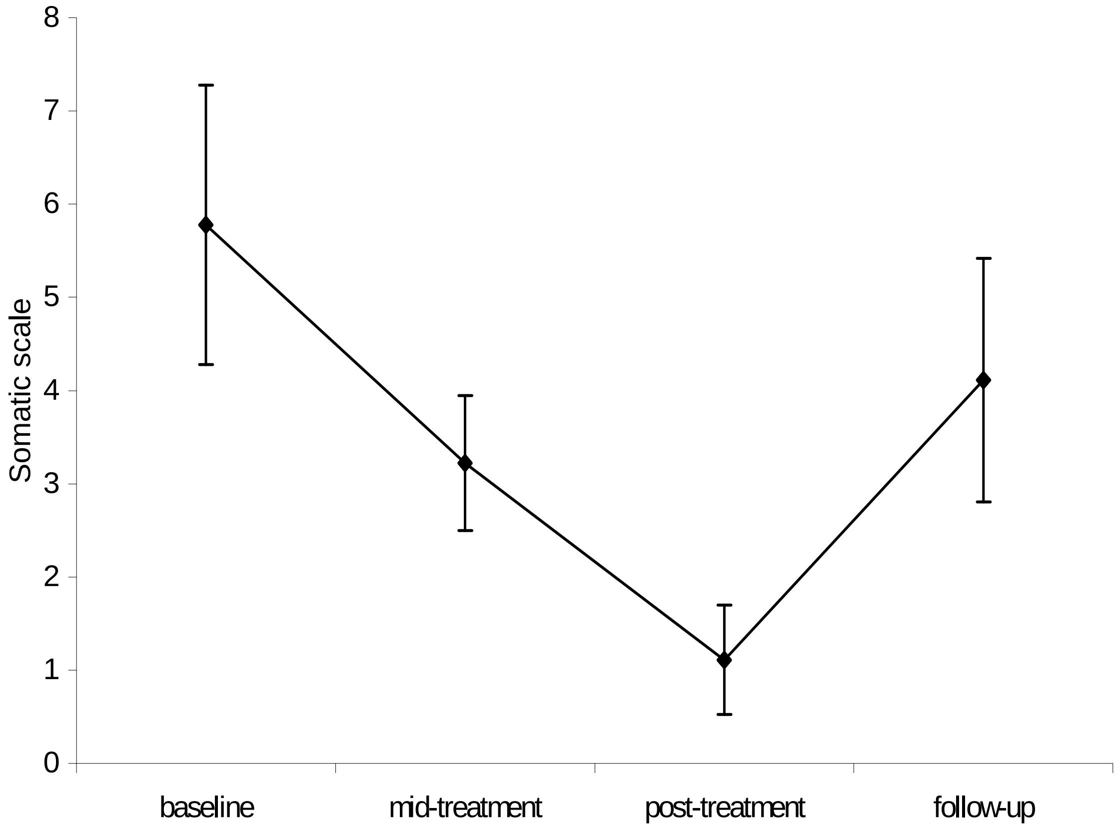


Figure 6.4 Mean scores and associated standard errors for the somatic subscale of Greene's Climacteric Scale at each of the 4 test times.

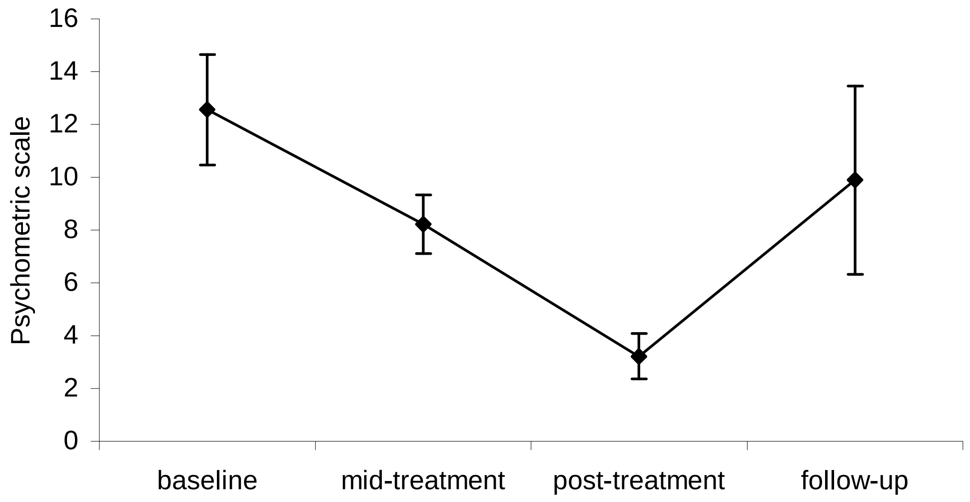


Figure 6.5 Mean scores and associated standard errors for the psychometric subscale of Greene's Climacteric Scale at each of the 4 test times.

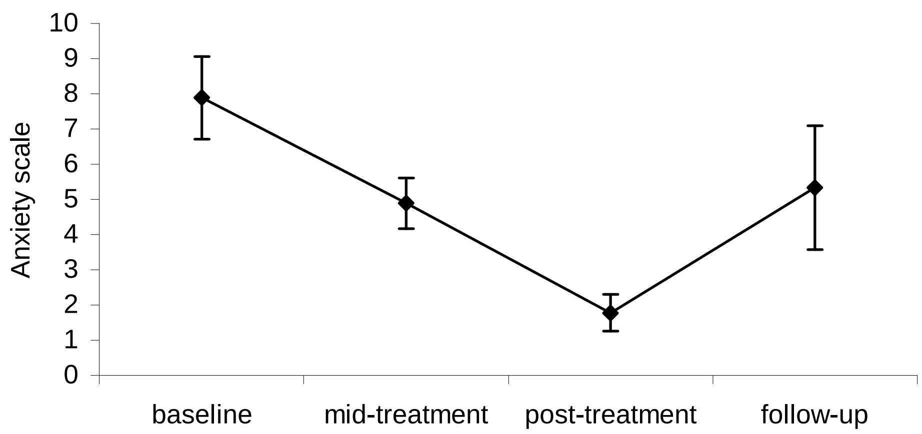


Figure 6.6 Mean scores and associated standard errors for the anxiety subscale of Greene's Climacteric Scale.

### 6.6.6 Menopause Quality of Life Questionnaire (MENQOL)

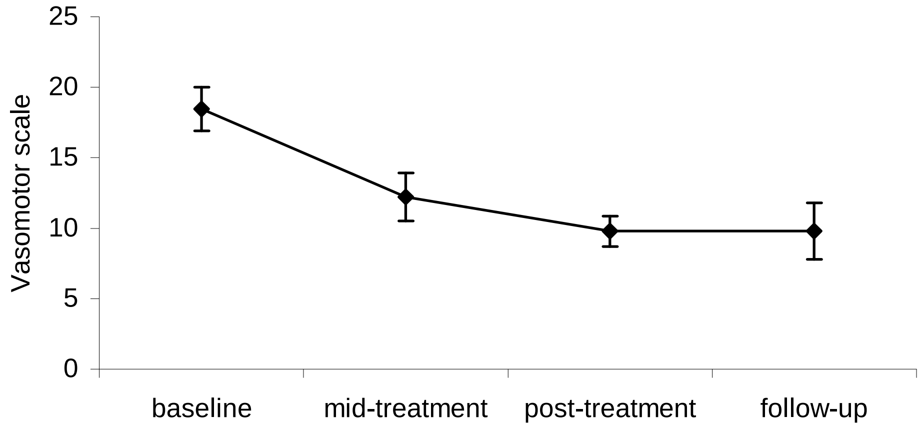


Figure 6.7 Mean scores and associated standard errors for MENQOL vasomotor subscale.

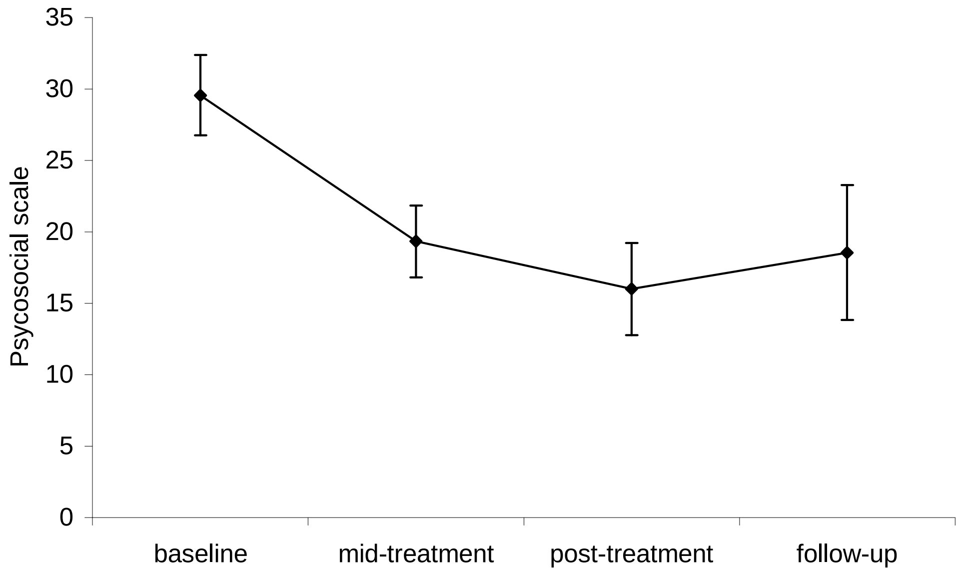


Figure 6.8 Mean scores and standard errors for MENQOL psychosocial subscale.

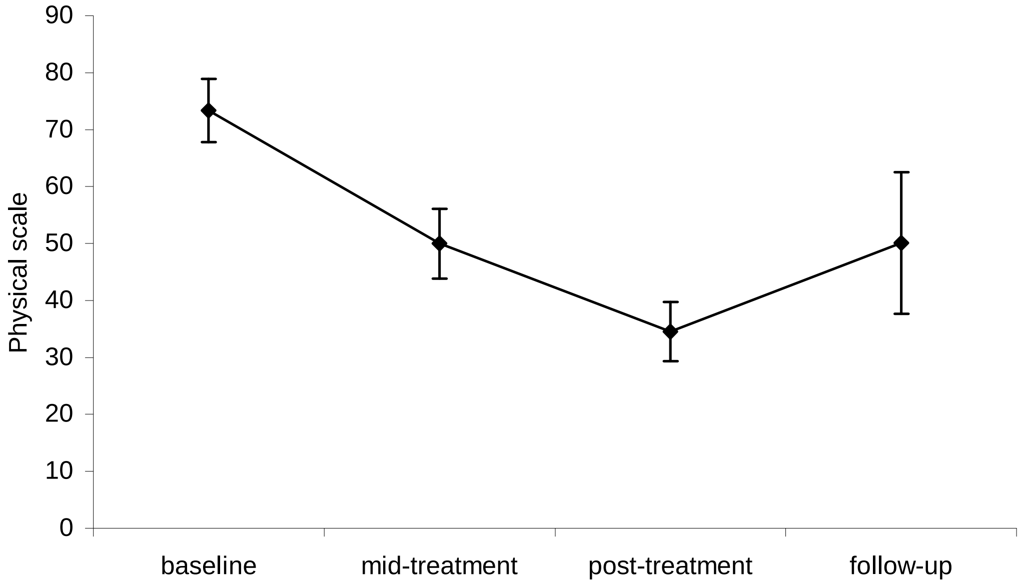


Figure 6.9 Mean scores and associated standard errors for MENQOL physical subscale at each of the 4 test times.

### 6.6.7 State trait anxiety index

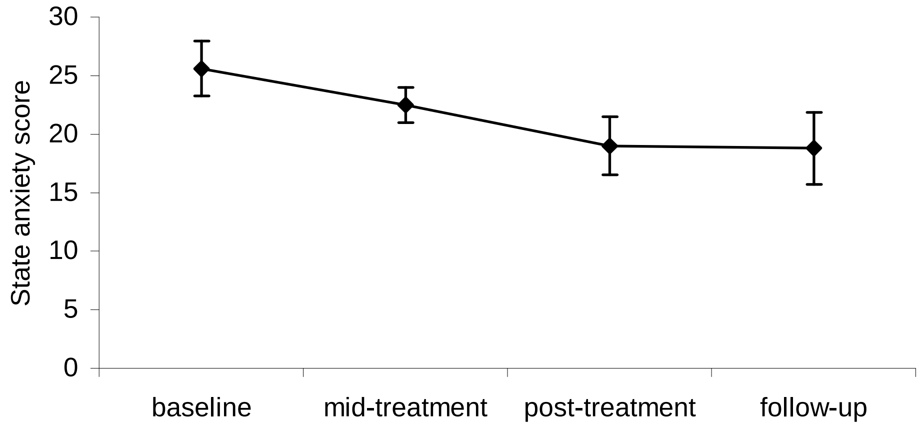


Figure 6.10 STAI mean state anxiety scores and associated standard errors at each of the 4 test times.

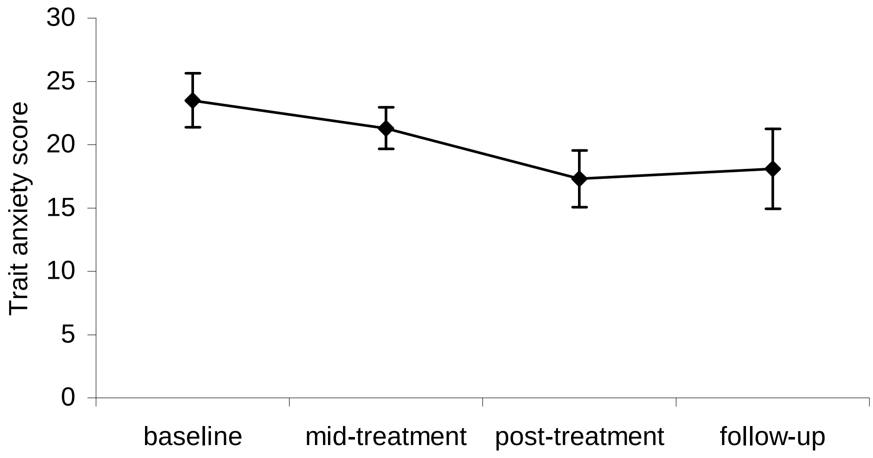


Figure 6.11 STAI mean trait anxiety scores and associated standard errors at each of the 4 test times.

## 6.7 Discussion

Notwithstanding the obvious limitations of this small, uncontrolled trial, those participants who completed the program and were followed up appeared to experience substantial improvements in a wide range of symptoms. The most remarkable response was related to vasomotor symptoms, particularly HFs. Analysis by either frequency or responder rate indicated that the improvement was both statistically and clinically significant and more or less sustained even at the follow-up phase. There was no significant change in frequency in the follow-up phase, indicating that, even without professional supervision and formal classes, participants were able to maintain the health advantage that they achieved in the formal phase of the treatment program.

Clinically significant improvements also occurred in a number of the other measures, many of which were also statistically significant. The Kupperman Index, the vasomotor, somatic and anxiety subscales of the Greene's Climacteric Scale and the psychosocial and sexual subscales of the Menopause Quality of Life Questionnaire, all exhibited statistically significant changes across the entire assessment period. This is not to say that the other changes seen in the other scales, such as in both state and trait subscales of the STAI or the vasomotor subscale of the MENQOL, were negligible. In fact Table 6.3 shows that the changes in these measures were substantial; however the power of the analysis was limited by the small sample size. More fine-grained analysis, say, between baseline and post intervention, was deemed inappropriate, given the small sample size and exploratory nature of the study.

The loss of benefit indicated in the above figures in some of the scales at follow-up may be explained by reduced compliance in the follow-up phase. By the same token, this also suggests that even partial compliance with the treatment program may be sufficient to maintain some benefits.

The improvements reported here compare favourably with previous studies (see summary Table 6.1) suggesting that the SYM approach may be more effective than a simple relaxation approach, but may not necessarily be more effective than multimodal approaches.

### 6.7.1 Putative mechanisms

SYM may be helpful in mitigating the experience of HFs via a number of possible pathways. First, like many other forms of meditation, SYM has been shown to reduce arousal in laboratory experiments. An interesting study on stress-induced HFs however, suggests that simple reduction of arousal may not be the only explanation. Swartzmann[339] used objective measuring strategies and found that menopausal women exposed to various experimental stressors, experienced not only greater sensitivity to pre-existing symptoms, but also more episodes. Unexpectedly however, the additional HFs neither occurred in acute association with the stressor nor were they directly associated with elevated sympathetic arousal. Rather, the data suggested that the effects were mediated by a mechanism that is considerably slower than the sympathetic adreno-medullary system. This implies that a neuro-endocrine pathway may be involved in reducing central sympathetic activation. SYM may exert its effect by disrupting that part of the HF mechanism which is associated with increased central sympathetic activation.

For instance, it is known that central opioid and noradrenergic influences may be modulated by stress and that these changed levels can then influence hypothalamic thermoregulatory centres. Interestingly, the practice of meditation has also been shown to change the levels of circulating catecholamines and opioids. Rai demonstrated a reduction in urinary catecholamine metabolites with SYM[354], while a pilot study of SYM conducted by Mishra[355] demonstrated increased endorphin levels in association with meditation. A study of experienced meditators undertaken by Harte in which SYM practitioners comprised most, but not all, of the entire cohort, demonstrated substantial reductions in the cortisol releasing factor, clearly suggesting a central neuroendocrine effect[356]. This preliminary evidence suggests that SYM might act to mitigate the magnitude of either or both of endorphin withdrawal or central sympathetic activation, thereby asserting a relatively direct effect on hypothalamic temperature regulation.

The negative emotions of stress are processed in the limbic system, and some experiments involving stimulation of the hippocampus have been shown to change thermosensitivity of preoptic neurons[329]. This might explain why stress potentiates rather than precipitates hot flushes and why meditation might be effective not only in reducing the severity of hot flushes, but also in preventing them.

Finally, Borkovec and other researchers have found that a CBT intervention led to the reduction in physiological and psychological elements of anxiety in normal populations as well as in clinical populations[357]. This suggests that the clinical effect of meditation may arise as a result of reducing negative perceptions and cognitions about symptoms rather than symptoms *per se*. Mirroring this notion, Chapter 9 describes a RCT of SYM for the management of occupational stress in which SYM was significantly more effective in reducing stress than other approaches to meditation. This improvement was associated with significant changes in the way in which participants perceived the demands in their work environment despite the fact that meditation classes did not involve any formal or informal cognitive therapy or other kind of counselling. This suggests that SYM may reduce stress not only by reducing physiological arousal but also by altering cognitions, therefore acting to reduce negative perception of symptoms. In the present study however, more robust effects were observed in scales assessing physical rather than psychological symptoms, suggesting that SYM's primary effect was via alteration of physiological function rather than cognition and that the significant changes in psychological measures may actually be secondary to changes in physiological activity.

### 6.7.2 Strengths and limitations of this study

With a small sample, this study demonstrated significant changes in the frequency of HFs in a group of menopausal women who were recruited into a SYM program. At the end of 8 weeks of intervention, HF frequency was 67% below baseline and at follow-up it was still at a level 57% below that at baseline. These results are both statistically and clinically significant, particularly because the women were not using any other form of management, conventional or otherwise, for this condition.

Due to the small sample size it is possible that small, but real treatment effects were not identified and this may explain why some of the changes in psychological measures failed to reach significance. Further studies using larger samples would be needed to explore this issue.

Of the 14 participants for whom baseline measures were taken, only 10 continued with the study. This represents a drop-out rate of almost 30%. Selection bias may have inflated the apparent effect of the intervention. On the other hand, the drop-out rate is similar to that seen in psychotherapy (discussed briefly in the systematic review, Chapter 2) and similar drop-out rates would be probably also occur in real life. As Hunter and Liao[336] found, not all women are interested in lifestyle modification and so the drop-out phenomenon, while introducing statistical bias by selecting for those most motivated, does not necessarily invalidate the potential practical relevance of the findings since it also selects that part of the population that is most likely to choose such treatments and therefore benefit from them. This is a process that occurs in daily clinical practice whenever a clinician offers a patient a choice of treatment options.

The absence of a control group makes it difficult to identify the magnitude of the placebo and other effects of non-specific factors such as expectancy, demand, practice effect, and regression to the mean. In our study, the responder rate was 80% and the mean reduction in HFs was 67%. Based on previous studies and reviews, it seems that the observed effect is unlikely to be due to placebo and other non-specific factors alone. The fact that HFs, rather than affective phenomena such as anxiety or depression improved to a greater degree implies that the intervention's effects were more prominent in the physiological rather than affect-orientated domains thereby suggesting that observed effect is not simply due to a change in subjective perception.

While it is possible that the participants may have simply experienced an unrelated, spontaneous improvement as part of the condition's natural history the time span for such regression to the mean would usually be several years whereas the improvements in this study occurred over several weeks and were maintained for some months afterwards.

Although SYM has been shown to reduce sympathetic activation[52], increase EEG alpha power[138, 358, 359] and reduce psychological parameters associated with stress[354], there are some aspects of SYM that do not support the idea that it is simply one of a number of strategies aimed at reducing physiological arousal. For example, consistent and significant skin temperature reductions (the opposite that would be expected in a *Relaxation Response*) have been reported in association with SYM[52]. Preliminary trials support this finding (see Chapter 10).

Interestingly, physiological studies report that increased finger temperature and increased heart rate are strongly associated with the onset of the menopausal HF[349]. Similarly the physiology of generic relaxation is associated with increased skin temperature and reduced heart rate. These phenomena are the opposite of what has been reported to occur during the practice of SYM, suggesting that the physiological effects of SYM might specifically oppose the patho-physiological phenomena of the HF. This may explain why the observed reduction in HF frequency was comparatively better than that observed in most other relaxation oriented trials.

Another feature that potentially differentiates SYM from generic relaxation/meditation is the fact that EEG changes include pronounced midline frontal theta activity in addition to the increased alpha levels that one would expect to observe during relaxation alone[358]. further suggesting that the central effects of SYM might be different to those occurring in association with non-*mental silence* forms of meditation.

The aim of the present study was to describe and explore the effects of SYM on women seeking non-pharmacological treatment for menopausal HFs and other symptoms. It appears that ongoing practice of SYM may be helpful for several kinds of menopausal symptoms, particularly vasomotor phenomena. Future evaluation should involve RCT methodology in conjunction with a credible and active control method in order to exclude non-specific effects with more certainty.

# Chapter 7. Meditation for Attention Deficit Hyperactivity Disorder — An Exploratory Clinic

## 7.1 Overview

The previous chapter (Chapter 6) described a small, uncontrolled trial of *mental silence* orientated meditation for the treatment of menopausal hot flush symptoms. The outcomes of uncontrolled trials are subject to all manner of confounding effects and their outcomes can therefore be misleading. As part of the methodological progression, the study described here corresponds to a larger exploratory study, using a cohort waiting for admission as a control. This occurred within the context of an experimental clinic for children with attention deficit hyperactivity disorder (ADHD). ADHD is characterized by a symptom triad of inattention, hyperactivity and poor impulse control. Meditation is precisely directed at developing the opposite features, that is, stable attention, calm and measured behaviour and the ability to contain one's impulses. The use of complementary and alternative medicines and other non-pharmacological strategies as a treatment for children diagnosed with ADHD is widespread, but little is known on the effectiveness of many such therapies. This study investigated SYM as a family treatment method for children with ADHD. Parents and children participated in a six-week program of twice-weekly clinic sessions and regular meditation at home. Pre- and post-treatment assessments included parent ratings of children's ADHD symptoms (a mean reduction of 35%), self-esteem and child–parent relationship quality. Results showed improvements in children's ADHD behaviour in both respects. Children described benefits at home such as better sleep patterns and diminished feelings of anxiety and also at school, reporting that they felt more able to concentrate and experienced less conflict with peers and teachers. Parents reported feeling happier, less stressed and more able to manage their child's behaviour. Indications from this preliminary investigation are that SYM may offer families an effective management tool for family-oriented treatment of childhood ADHD.

## 7.2 Introduction

### 7.2.1 What is ADHD?

Core symptoms of childhood ADHD, according to the DSM-IV[267], are inattention, impulsivity, and hyperactivity. Associated, probably secondary symptoms, are academic underachievement and impaired self-esteem[360, 361]. The typical pattern is thus one of a highly energetic, impulsive, delay averse, unfocused and behaviourally poorly controlled child who demands constant attention and redirection. The central problem of the disorder is difficulty in self-regulating own behaviour[362, 363].

The prevalence of ADHD in the US is reported at between 3% and 10% of children and 1% and 6% of adults, with girls much more affected than boys[364]. The breadth of impairment and chronicity leading to its classification by the Center for Disease Control and Prevention as a serious public health problem[365]. Children with ADHD often have significant learning and language problems leading to academic impairment in over 90% of children with the diagnosis[366]. They also experience social and emotional impairment, resulting in difficulties with parent-child, sibling and peer relationships. ADHD is a condition which demands the expenditure of greater financial outlays on medications and outpatient treatments compared to children with other chronic illnesses such as asthma[367]. A cohort study conducted by Leibson[368] showed that children with ADHD are more likely to have more inpatient and outpatient hospital and emergency department admissions, to incur more major injuries and to suffer more from asthma. The healthcare costs of children and adolescents with ADHD were double those of children and adolescents without the diagnosis. Thus children with ADHD are likely to suffer from its direct and indirect consequences throughout their life[369].

No single etiological factor has been identified for ADHD and there is no objective diagnostic test. Like all neuropsychiatric conditions, ADHD is thought to be caused by a complex combination of environmental, genetic and biological factors. Specifically identified contributing factors include pre- and peri-natal, genetic and neurobiological deficits which presumably combine differently in every individual[370]. For instance, smoking and alcohol consumption during pregnancy, independent of whether the mother has ADHD, increased the risk two to three times, while a parent who themself suffered or has suffered from ADHD, increased the risk eight times[371]. In fact twin studies indicate that ADHD has a heritability of between 0.60[372] and 0.91[373] (i.e. 60–91% of the aetiology is genetic). This compares with heritabilities of 0.39 for depression, 0.27 for breast cancer and 0.39 for asthma. Genetic studies suggest that ADHD is associated with defects in dopamine[374] and catecholamine regulation[375] with up to 60% of ADHD sufferers carrying the defect associated with the D4 dopamine receptor[376].

Neuro-physiological and electro-physiological studies have pointed to structural and functional deficits in the brain as correlates of poor regulatory control in hyperactive children[377, 378]. Abnormalities in the frontal cortex are consistent with findings in ADHD[379]. Functional imaging studies have associated abnormal activation of frontal brain areas with deficits of inhibitory and attentional control[380-382]. Neurotransmitter abnormalities such as dopamine dysregulation have also been linked to ADHD[383]; notably, that dopamine transporter levels are elevated in the striatum of children[384] and adults with ADHD[385].

In an attempt to explain ADHD in terms of psychological aetiologies, authors have looked to transactional models that explain poor self-regulatory behaviour within the wider context of family dynamics and parent-child relationships. Certainly, research shows that an ADHD child may unduly strain these relationships. Cara[360] noted that parents often feel frustrated, anxious, and angry that parenting techniques which are effective for other children appear useless in the case of a child with ADHD, who seems not to understand the consequences of inappropriate behaviour or to learn from punishment. When oppositional, noncompliant behaviour is characteristic, parents may be less appreciative of their children's efforts, less willing to reward them, and more negative, directive and controlling[386].

An alternate interpretation suggests that deficits in self-regulation may be related to insecure parent-child attachment relationships[387, 388], which are usually characterised by a pattern of conflicted, angry parent-child interchanges[389]. To date, few studies have examined attachment status in children with ADHD.

### 7.2.2 Management

The most commonly used treatment for ADHD in North America and Australia continues to be psychostimulant medication[383, 390, 391]. The drugs, methylphenidate and dexamphetamine, have been found to improve the core behavioural and cognitive features of ADHD, such as behavioural inhibition and concentration, as well as co-morbid symptoms such as poor academic achievement, in about 80% of the children who take them[360, 363, 392]. In the last 10 years, there has been a 5-fold increase in methylphenidate prescription and consumption, with as many as 30–40% of children in some American schools receiving stimulant medication[393]. Similar trends are evident in Australia. From 1990 to 2000, the rate of children receiving stimulant medication for ADHD increased in the order of 9 times[394].

### 7.2.3 Pharmacological treatment

Pharmacological treatment of ADHD, while at the moment more effective than any other treatment option, is still considerably limited in its usefulness. For instance, although stimulants act for only a limited period, symptoms are continuous. Thus stimulants must be given several times per day (or at least daily in the case of sustained release formulations) with concomitant compliance issues.

Common physiological short term side effects of stimulant include insomnia, appetite loss, stomach-aches, dizziness and daytime drowsiness in addition to emotional and motor symptoms, such as mood lability and tics[391]. Psychostimulants can produce abuse and dependency[390] and the potential long-term side effects of lengthy treatments are not unknown[395]. For example, it has been shown that 6% of children treated with stimulant medication developed psychotic side effects[396].

As such information becomes more widely available, it is not surprising that large numbers of parents seek out complementary and alternative medicine (CAM) therapies[397, 398] as a response to their "concern about the physiological and psychological effects that the drugs may have on their children"[362].

Support for CAM has also come from clinicians who argue that an emphasis on medical therapy alone draws attention to the control of symptoms, rather than attending to the need for children to acquire important behavioural and social skills[399]. Researchers have been compelled to explore other treatment options by concerns relating to the escalating use of stimulants in the management of ADHD symptoms. Other issues include treatment acceptability, side effects, compliance, potential long-term effects, the danger of drug abuse and dependency and consumer and parent preference of non-pharmacological treatment.

### 7.2.4 Psychosocial interventions

Nonmedical interventions for ADHD include a variety of behavioural treatments, such as behaviour therapy, cognitive behaviour therapy and intensive contingency management. There is considerable evidence for the efficacy of reward/punishment strategies in laboratory and classroom settings for improving various aspects of ADHD behaviour. There is less consistent evidence for the efficacy of behavioural strategies administered by parents at home. While some such do demonstrate immediate beneficial effects, these can wane after withdrawal of active enforcement. This suggests that while external modification of behaviour makes the child more socially acceptable, it is probably not addressing the underlying neuro-biological abnormalities that are generating the behaviour[400]. According to Rice and Richmond[386], the most promising interventions are those which work with the whole family system and which use medication in association with nonmedical interventions.

Recenty completed, the MTA study was a landmark project designed to assess the effects of best practice behavioural training for children with ADHD at the more severe end of the spectrum and compare it to:

- best practice medication management
- a combination of the two
- “real world” community-based treatment.

Interestingly, while best practice medication management by research clinicians was superior to best practice behaviour therapy, the latter was still more effective than community-based treatments (which for most participants was medication). The combination approach was particularly effective for certain subgroups. Importantly, consumers expressed greater satisfaction with behavioural and combined strategies[401]. The MTA study's initial findings were very influential in convincing clinicians that medication rather than behaviour therapy was the best option for children with ADHD. However, recent follow-up data from the MTA study has led to a significant revision of that opinion and a re-emphasis on behavioural management.

### 7.2.5 Complementary and alternative treatments

Despite an absence of reliable evidence, complementary and alternative treatments are rapidly increasing in popularity in the treatment of ADHD. They include dietary modification, the use of nutritional supplementation (such as essential fatty acids, zinc, magnesium, amino acids, megavitamins) and herbs (such as ginseng and ginkgo). Also important are environmental therapies (which involve eliminating pollutants such as lead, and manganese from the environment), biofeedback, relaxation training, and meditation[402]. Arnold's review of alternative approaches to the management of ADHD noted that meditation was one of a number of promising strategies and warranted further systematic assessment. However, so far there have been only two unpublished dissertations suggesting that in children with ADHD, meditation may mitigate tendencies to impulsiveness both at home and in the classroom[403].

The EEG studies of Aftanas & Golocheikine[318, 358] suggest that meditation might influence those parts of the brain that govern attention. Furthermore, anecdotal feedback from teachers and meditation practitioners has indicated that meditation could help to focus attention, enhance concentration and memory and improve children's performance at school[239]. Given the background of neurological, physiological, and psychological research as well as practical experience, it seemed reasonable to evaluate the potential of meditation as a useful alternative treatment for children with ADHD.

## 7.3 Methodology

The present study sought to assess the contribution of SYM as an adjunct in the management of children with ADHD. The SYM programme was designed as a family practice in which parents were encouraged to meditate regularly with their child. It was expected that SYM would be an adjunct to children's on-going medical therapy and would provide a means of working with the whole family. The aims of the program reflected the goals for appropriate treatment identified by the American Academy of Paediatrics[360] which was to:

- improve core symptoms of ADHD, such as short attention spans, hyperactivity and impulsivity
- reduce associated symptoms, such as anxiety and poor self-confidence
- improve functional outcomes such as relations with parents.

These aims were tested in a voluntary clinic provided at the Royal Hospital for Women in Sydney, Australia, by the researchers and a team of experienced instructors of SYM.

### 7.3.1 Ethics

The programme was approved by the SESAHS ethics committee.

### 7.3.2 Recruitment

The SYM trial treatment program was publicised through a newspaper article and the presentation of an introductory lecture open to parents of school-age children diagnosed with ADHD. Interested parents were invited to participate, together with their child, in a 6-week SYM program consisting of bi-weekly teaching sessions. Inclusion criteria were that the child had a formal diagnosis of ADHD, that is, that the case met the DSM-IV criteria as assessed by a paediatrician or child psychiatrist[268], and scored above threshold for ADHD (i.e. a score of 15 and over) on the Conners Parent-Teacher Questionnaire[269] (see Assessment Procedures - Child Assessment Measures: Parent Report in Appendix 4).

### 7.3.3 Participants

Following publicity in the local news media, parents interested in participating contacted the Natural Therapies Unit of the Royal Hospital for Women. General information on the children's age, diagnosis of ADHD, medication status and availability for bi-weekly sessions was collected prior to the commencement of the meditation training.

Forty-eight children (41 boys, 7 girls), including 4 sets of siblings, met the criteria for inclusion in the program. All were above the criterion for ADHD on the Conners Parent-Teacher Questionnaire — scores ranged from 15 to 30, $M = 22.65$; $SD = 4.36$. The majority of children ($n = 31$) were receiving medication, 14 were not medicated, and medication information was not provided for the other three children (and so were excluded).

Demographic information collected from participating adults showed that the 44 participating families represented a diverse population. About three-quarters were in couple relationships and one-quarter comprised single parents or guardians. Adult participants who provided personal data included 38 mothers, 22 fathers and one grandmother. Mothers ranged from 27 to 50 years of age ($M = 38.8$; $SD = 5.9$); fathers were slightly older than mothers (range = 35 to 55 years; $M = 43.1$; $SD = 5.2$). Education levels for both mothers and fathers ranged from less than secondary school to doctoral studies, with the majority having completed tertiary level studies (mothers, 62%; fathers, 73%). Parental ethnicity was less diverse: 95% of participants identified themselves as White/Caucasian.

Because of the large number of interested families and the requirement for individualised training in the SYM program, it was necessary to separate the children into two groups and run a two-stage treatment program. The first session, Study 1, involved older children and was comprised of 19 boys, one girl. Their ages ranged from 8 to 12 ($M = 10.1$, $SD = 1.1$). There was also a 6-year-old female sibling in this group. The program began at the end of the January summer holidays and continued into the first term of school. The second session, Study 2, began in April was run in both school holidays and school time. Children invited to participate in Study 2 were more diverse in age: range = 4 to 12 years ($M = 7.4$ years; $SD = 2.0$). Participants for Study 2 included 16 "wait-list" children whose parents had attended the initial recruitment session in January, and a further 11 children whose parents expressed an interest in joining the second program.

### 7.3.4 Meditation program

The intervention was conducted over a 6-week period and consisted of twice-weekly 90-minute clinics, held in large meeting-rooms at the hospital. For the first three weeks, the clinic consisted of guided meditation sessions, with parents attending one group and the children another. Meditation instructors, experienced in SYM techniques, conducted these sessions. The meditation process involved practising techniques which helped participants to achieve a state of thoughtless awareness. Instructors directed participants to become aware of this state within themselves by becoming silent and focusing their attention inward. Parents were also asked to conduct shorter meditation sessions at home twice a day.

In the clinic, there were usually two periods of meditation of 5 to 15 minutes each, supplemented by information on how to meditate and also a sharing of experiences. The parent sessions had one to two instructors, but the child sessions had a higher instructor-to-child ratio (normally, one instructor for every three children). From weeks 4 to 6, one of the weekly sessions was conducted as a joint parent-child meditation. This enabled instructors to train parents in guiding their children's meditation. Children and parents were asked to meditate regularly at home and to record their progress in a diary, which was checked each week to encourage compliance.

### 7.3.5 Assessment procedures

Children and parents contributed to a range of data collection procedures, which drew on child self-report questionnaires and parent-rated questionnaires. Child data included information on ADHD symptoms, medication status, feelings of self-esteem, cognitive testing and perceptions of the meditation program. Child-parent relationship quality was also assessed. Parents were asked to give their views on what they felt about the effectiveness of the program both for their children and themselves. ADHD symptoms (parent rating), medication consumption and perceptions of the programme are reported below. Assessments were conducted at three points: at recruitment or commencement of the meditation program (week 1), at the midway point (week 3), and at the end of the program (week 6). The full schedule of assessments was completed for the Study 1 sample. Study 2 assessments were only completed at the commencement and end of the program.

#### 7.3.5.1 Connors' Parent-Teacher Questionnaire

ADHD symptoms were assessed via parent-report, using the Connors Parent-Teacher Questionnaire. Connors' parent-rated checklists, which are shorter versions of the 93-item original, are commonly-used tools in research and clinical practice (reviewed in

Connors et al. 1998[269]). The measure chosen for the present study presents 10 behavioural descriptors (e.g. excitable/impulsive, fails to finish things/short attention span) that parents rate on a 4-point scale (0 = not at all, 1 = just a little, 2 = pretty much, 3 = very much), and one overall question "How serious a problem do you think the child has at this time?" (0 = none, 1 = minor, 2 = moderate, 3 = severe). These 11 items achieved a high level of internal reliability. Coefficient alphas ranged from 0.74 to 0.86. Ratings on the 11 items were summed to give a total score for ADHD symptoms at each assessment point (minimum = 0; maximum = 33).

#### 7.3.5.2 Perceived outcomes for the child

At the mid and endpoints of the program, parents were asked to complete a short questionnaire asking whether they felt the meditation had benefited the child, and whether it had changed their relationship with the child. Simple 5-point rating scales were used to obtain information on the level of benefit (1 = little benefit; 5 = a lot of benefit) for the child in the areas of emotions (less anxious, less angry, more able to manage negative feelings, less conflict, more cooperative), self-esteem (more confident), attention (improved memory, more able to settle down), and sleep (improved sleep patterns). Additional questions were included at the final point about the perceived benefits of the meditation program for the child's schoolwork. These included attitudes to school (being positive about going to school), social relations (having less difficulty with the teacher and other children), and attention to work (being more able to manage schoolwork and homework).

#### 7.3.5.3 Psycho-stimulant medication

The SYM treatment program did not ask or advise parents to reduce their child's pharmacological treatment for ADHD, but it was clear from comments made by a number of parents at recruitment that they were looking for alternatives to medication.

For example, some parents said that they did not use medication during the school holiday period and that during school terms, they felt pressured by teachers to medicate their child. Therefore, at the mid and endpoints of the program, parents were asked about any changes they had made to their child's level of medication. They were asked: "Have you been able to reduce your child's level of medication and still maintain an acceptable level of behaviour?" If medication had been reduced, parents were asked to report on the proportion; that is, less than half, half, or more than half.

#### 7.3.5.4 Perceived outcomes for the parents

Parents were asked by means of a short questionnaire presented at the mid and final points of the program, to report on their own experiences of the meditation program and whether they felt it had been beneficial to them. Parents were asked to rate on a 5-point scale (1 = little benefit, 5 = a lot of benefit), the extent to which they felt happier, less stressed, more able to manage stress, less angry, and more able to manage anger. At the end of the program, parents were also asked to provide written examples of recent positive and negative interactions with their child.

## 7.4 Results

Results are presented in two sections. First, baseline ADHD data for child participants, demographic characteristics, and SYM program retention and completion rates are reported for Study 1 and Study 2. Second, the impact of SYM on changes in the primary problem areas of ADHD symptoms, along with medication status and perceived child outcomes are examined drawing on data from the combined Study 1 and 2 samples.

### 7.4.1 Baseline ADHD symptoms – Demographic factors and SYM program retention

Baseline information on ADHD symptoms was provided for 48 children (41 boys, 7 girls) at the initial recruitment or commencement stage of the SYM program. Comparisons of mean scores, using *t*-test analyses, were conducted to assess the effects of child and family demographic factors. There were no differences between groups of children allocated to Study 1 versus Study 2 ($M = 23.00$ and 22.37, respectively, $t = 0.24$, *ns*) or between boys and girls ($M = 22.59$ and 23.00, respectively, $t = 0.05$, *ns*). Children from couple-families had significantly lower ADHD symptom scores ($M = 21.25$, $SD = 3.88$) than children from single parent families ($M = 25.58$, $SD = 3.68$), $t = 11.19$, $p = 0.002$, and children whose parents had completed tertiary education had lower scores ($M = 21.23$, $SD = 4.34$) than non-tertiary educated parents ($M = 24.13$, $SD = 4.09$), $t = 5.17$, $p = 0.029$.

Parents' marital status and level of education were not associated. Older mothers were more likely to have completed tertiary studies, $r(26) = 0.55$, $p < 0.01$, and to be in a couple rather than single parent families, $r(26) = 0.36$, $p = 0.07$. There was also a trend for maternal age to be related to child ADHD scores, with older mothers reporting less problematic symptoms, $r(26) = -0.35$, $p = 0.08$.

Retention rates for the two 6-week SYM programs were reasonably good, especially considering that many families travelled long distances (in some cases more than 200 kilometres per session) to attend the hospital clinic and that children had to attend school and extra-school activities that may have competed with the clinic times and home meditation expectations.

In Study 1, 16 of the 21 children completed the full six-week program — a retention rate of 76%. In Study 2, the delay between the introductory meeting in January and the second six-week SYM program resulted in some problems for sample retention. When the second session commenced in April, some of the families wait-listed in January were no longer available. New children were recruited and Study 2 began with 27 children. Of these, 19 completed the full six weeks — a retention rate of 70%. Unfortunately, due to organisational problems in the final week, endpoint data was only available on 10 of these children. Combining the Study 1 and Study 2 samples provided commencement and endpoint data for 26 children. Comparisons of mean AHDH scores, using *t*-test, showed there were no differences between the participants who provided complete data ($n = 26$) and the participants who did not ($n = 22$) on any of the demographic measures (child's age and sex, mother's and father's age and education, family marital status). There was also no difference in the proportion of children receiving and not receiving medication.

The two-stage administration of the SYM program provided an opportunity to assess ratings of ADHD symptoms for wait-listed children on two occasions prior to the treatment program. Twelve children provided data at the initial recruitment stage in January and several months later at the commencement of Study 2 in April. Analyses showed that children's ADHD scores were consistent across these two occasions, $r(12) = 0.68$, $p = 0.015$, and had remained at a similar level ($M_1 = 22.08$, $SD = 4.72$; $M_2 = 21.17$, $SD = 4.69$), $t = 0.84$, *ns*. Because the waitlisted children's pre-treatment scores did not differ, a mean score was computed to provide as a baseline ADHD level for use in subsequent analyses.

### 7.4.2 Change to ADHD-related symptoms—pre- and post-meditation program

Results for the 26 children who provided commencement and final data showed a marked improvement in ADHD symptoms as measured on the Connors Parent-Teacher Questionnaire over the course of the meditation program. Mean scores dropped from

$M_{pre}$ = 22.54, $SD$ = 4.61, to $M_{post}$ = 14.62, $SD$ = 5.15. The average mean drop in reported ADHD symptoms was 7.91 points, $SD$ = 4.91 (range = 0 to 19), which represented an average improvement rate of 35%. Statistical analysis using paired samples $t$-test showed that the difference in pre- and post-treatment scores was highly significant, $t(1,25) = 8.23$, $p < 0.001$.

Because of concerns that the improvement in behaviour may have been due to the medical treatment children were receiving rather than the SYM program, further comparisons were made to assess whether medication status may have contributed to this change. Results presented in Table 7.1 (lines 1 and 2) show a similar reduction in ADHD symptoms for the 20 children who were receiving medication compared to the six children who were not receiving medication at commencement of the program. The mean reduction scores were 7.83, $SD$ = 5.15, and 7.95, $SD$ = 4.97, respectively. ANOVA comparison of means showed there was no significant difference in the scores for these two groups, $F(1,25) = 0.00$, *ns*. This data suggests that the reduction in ADHD symptoms was not related to children's pharmacological treatment. It was also noteworthy that, in a number of cases, parents stated that they had been able to reduce their children's medication during the course of the SYM program. Of the 20 children who were receiving medication when they started the program, 11 had reduced the dose during SYM treatment — 2 by less than half, 6 by half, and 3 by more than half, while 9 did not change the dose. Table 7.1 (lines 3 and 4) presents the change in ADHD symptoms data for these two subgroups. Comparison of means using ANOVA indicated that the improvement in the level of ADHD symptoms was significantly greater for the 11 children who had reduced their medication ($M_{reduction}$ = 10.18, $SD$ = 4.79) compared to the 9 who had maintained the same level of medication ($M_{reduction}$ = 5.22, $SD$ = 3.83), $F(1,19) = 6.31$, $p = 0.022$. These findings suggest that SYM treatment not only contributed to the reduction in children's ADHD behaviour scores, but also had the added benefit of helping children manage their own behaviour with a reduced level of medication.

Table 7.1 Children's ADHD symptoms during the meditation programme by medication status. ADHD symptoms were measured using the Conners Parent-Teacher Questionnaire.

| Medication status† | Commencement (Week 1) | | | Final point (Week 6) | | | Symptom change (Week 1–6) | | |
|---|---|---|---|---|---|---|---|---|---|
| | n | $M_{pre}$ | SD | n | $M_{post}$ | SD | n | $M_{reduction}$ | SD |
| No medication | 6 | 22.33 | 5.57 | 6 | 14.50 | 1.52 | 6 | 7.83 | 5.15 |
| Receiving medication | 20 | 22.60 | 4.45 | 20 | 14.65 | 5.86 | 20 | 7.95 | 4.97 |
| *t*-value‡ (*p*) | | -0.12 (ns) | | | -0.06 (ns) | | | -0.50 (ns) | |
| Reduced dosage†† | 11 | 24.00 | 4.90 | 11 | 13.81 | 7.11 | 11 | 10.18 | 4.79 |
| No change of dose | 9 | 20.89 | 3.33 | 9 | 15.67 | 4.03 | 9 | 5.22 | 3.83 |
| *t*-value‡‡ (*p*) | | 1.62 (ns) | | | -0.69 (ns) | | | 2.51 (0.02) | |

† Medication status as reported by parents at week 1 of the treatment programme.

‡ *t*-Test analysis compared mean scores for the 20 children receiving medication with the scores for the 6 children not receiving medication.

†† Of the 20 children who were receiving medication at week 1, 11 reduced the dose over the 6-week programme and 9 did not change.

‡‡ *t*-Test analysis compared mean scores for the 11 children who reduced dosage with the scores for the 9 children who did not change dosage.

Post-treatment responses from children were positive. A child who had stopped his medication completely said he "felt great", adding "I used to hate having to be on my medication." The children identified a number of other benefits of SYM, not only during meditation itself, which was described as "easy," "relaxing," and like being "in your own bubble, where no-one else can stop you from doing what you're doing at the time," but also in other situations at home or at school. One child said that meditation "helps me with my headaches;" another said he was "getting into less of a panic;" another that meditation "gave him more energy, but not energy to get 'hyped-up'." Many children said they were able to get to sleep more easily. Benefits at school included being more able to attend to school tasks; for example, children commented that "it keeps me focused on my work;" "it's made me smarter; I seem to be able to concentrate more;" "if my friends are talking around me, now I can bring my mind straight back to my work." Children also mentioned having fewer social problems at school, such as "not getting into trouble" or being able to ask the teacher for help instead of retaliating when children were teasing them. A number of children remarked that prior to involvement in the programme, they were aware that their behaviour was not constructive and often alienating but that they were unable to prevent themselves from following certain behaviour patterns. They said that the meditation techniques gave them the ability to control their behaviour.

Parent perceptions of the outcomes of SYM for their child were also generally positive. Most (92%) felt their child had benefited from the SYM program. Particular benefits for the child that were rated highly (over 3 on a 5-point scale) by parents were "more confident in him/herself" ($M = 3.35$, $SD = 0.93$), "improved sleep patterns" ($M = 3.27$, $SD = 1.42$), and "more cooperative" ($M = 3.18$, $SD = 1.01$). Parents also gave high ratings for benefits related to school, including "less difficulty with the teacher" ($M = 3.64$, $SD = 0.92$), "more able to manage schoolwork" ($M = 3.56$, $SD = 1.03$), "more able to manage homework" ($M = 3.47$, $SD = 1.33$), and "positive about going to school" ($M = 3.43$, $SD = 1.09$).

Certainly the benefits of the SYM program seemed convincing to the participants; however, it was possible that the improvements in child ADHD behaviour and related symptoms were due to factors other than SYM, such as child or parent characteristics, which could have contributed to the outcome. Repeated measures analyses were used to test the contribution of three child factors (sex, age, medication status) and three family factors (mother's age, secondary versus tertiary education, single parent versus couple families). Tests were conducted with each of the 6 child and parent covariates entered separately. Results showed that none of these child or family factors contributed significantly to the model. This suggests that the reduction in children's ADHD behaviour scores was attributable to the SYM treatment rather than to medication status, child, or family characteristics.

### 7.4.3 Changes in ADHD-associated symptoms—pre and post-SYM program

Post-treatment scores showed that the SYM program was associated with significant improvements in all of the parent-rated measures. Results are presented in Table 7.2. For each measure, mean pre and post-treatment scores were compared using paired sample *t*-test analysis. ADHD symptom scores at the mid-point and final point were significantly lower than the baseline score, $M_{pre} =$ 22.62, $M_{mid}$ = 15.94 and $M_{post}$ = 16.25, $t$ = 5.81 and 5.65, respectively, $p < 0.001$.

Table 7.2 Changes in child outcomes and parent-child relationship quality during the meditation programme.

| | **Start (Week 1)** | | **Mid-point (Week 3)** | | **Final point (Week 6)** | | **Paired samples *t*-value** | |
|---|---|---|---|---|---|---|---|---|
| **Measure** | **M** | **SD** | **M** | **SD** | **M** | **SD** | **Time 1–3** | **Time 1–6** |
| **Child outcomes** | | | | | | | | |
| *Parent rated:* | | | | | | | | |
| ADHD symptoms† | 22.62 | 4.06 | 15.94 | 4.99 | 16.25 | 5.48 | 5.81*** | 5.65*** |

*** $p < 0.001$;

### 7.4.4 Parent responses to SYM

The SYM intervention was designed as a family treatment program, which was expected to impact on parents as well as children. At the end of the program, 92% of parents agreed that the program had been personally beneficial. The overall benefit was rated at 4 ($M$ = 3.91, $SD$ = 0.92) on a 1 (low) to 5 (high) scale. Specific benefits rated highly (over 3 on a 5-point scale) were "more able to manage stress" ($M =$ 3.79, $SD$ = 0.93), "less stressed" ($M =$ 3.67, $SD$ = 0.96), "happier" ($M =$ 3.45, $SD$ = 1.01), "more able to manage anger" (*M* = 3.37, *SD* = 1.25), and "less angry" (*M* = 3.29, *SD* = 1.23).

Parents were also asked to rate the extent to which they felt that SYM had benefited the relationship with their children. Mean scores on a 5-point scale showed a consistent pattern of benefit, specifically for "more open communication" (*M* = 3.83, *SD* = 0.72), "less exhausting" (*M* = 3.50, *SD* = 0.91), "more able to manage conflict" (*M* = 3.42, *SD* = 0.67), and "less conflict" (*M* = 3.33, *SD* = 0.78). A number of parents commented that participating in the program had made a positive change to their relationship with their child. A father mentioned his pleasure at being able to laugh with his son for the first time in years. One mother wrote: "I truly understand how meditating and becoming more relaxed have helped my son 150% because he feeds off a calmer mum." Parents also said they had used meditation at home to help deal with difficult situations. One mother commented: "I'm now able to get N...to calm down (using meditation). He is then able to focus and carry on with his day." Another wrote about how she dealt with a difficult time: "We had a good meditation and he went off to bed quite calm and relaxed and went straight to sleep."

## 7.5 Discussion

The results of this trial program indicate that SYM has potential as an adjunctive therapy for children with ADHD when offered via a family treatment approach and in combination with existing medical treatment. Although results were limited by the small number of children for whom complete data was available, the consistency of the findings, which drew on different measures of child outcomes, different groups of children and both parent and child respondents, along with the significance of the results, points to the positive potential of this approach.

Core symptoms of ADHD were improved. Parent ratings on the Connors Parent-Teacher Questionnaire, which assesses attention, hyperactivity and impulsivity, were significantly reduced over the course of the program. Children also reported that they felt calmer, less panicky, and more relaxed. Parents reported that the children's approach to school and homework had improved during the SYM program, while the children themselves said that they were more able to concentrate at school. Improved sleep was another positive outcome reported by parents and children.

Evidence for the effectiveness of the SYM intervention, over other possible contributors was provided by the group of "wait-list" children whose baseline ADHD scores remained the same over two pre-treatment assessment points. It consequently dropped significantly over the 6-week SYM program.

It was not possible in this initial investigation of the efficacy of SYM for managing ADHD, to include the design features of a clinical trial, which would allow allocation and comparison of treatment groups such as SYM in combination with pharmacological treatment and SYM alone. The children who entered the program also varied in the severity of their ADHD symptoms and use of medication. Three-quarters of the children were receiving psychostimulant drugs at the commencement of the program and combined this with the SYM treatment, while the non-medicated children only used SYM. Although the numbers in the latter group were very small, it was noteworthy that the observed reduction in ADHD symptoms did not differ according to the children's initial medication status. Further evidence that the improvements were attributable to the SYM intervention (and not to medication) comes from the fact that over half of the children taking prescribed medication had been able to reduce it during the course of the treatment. Furthermore, these children showed significantly greater improvements in

ADHD-related behaviours than the children who maintained their initial level of medication.

The fact that the SYM effects occurred regardless of concurrent medication suggests an interesting corollary to the findings of the Multimodal Treatment (MTA) study of children with ADHD, which reported that "intensive behavioural treatments are a viable alternative to medication in treatment of ADHD"[404]. The current study was not behavioural but intensive in design, involving as it did parents and children in twice daily meditation sessions at home and regular clinic sessions with trainers. However, similar to the MTA findings, the SYM results are encouraging for parents and communities seeking ways to minimise child medication. Therefore health care consumers are likely to be more satisfied with a program such as this which incorporates the efficacy of medication while at the same time, by using a family-based strategy, reduces the amount of medication needed. It also enhances participants' sense of control, provides an environment likely to foster better relationships and represents an important step toward a more holistic management strategy, in line with the bio-psychosocial model of health.

Despite these promising results, the study is not without its limitations. The small sample size has been mentioned. A study using larger numbers of participants will be essential to replicate the observed findings. That the control group was not randomly allocated raises the possibility of selection bias. The use of self- report measures, especially within a trial design where the participants were aware of the hypothesis, introduces the possibility of demand bias. However, it is significant that post-intervention interviews with the children provided many examples of the benefits they had experienced from the SYM program, giving further support to the accuracy of their parents' ratings and comments.

Questions remain about the underlying processes that may account for the success of the SYM intervention. Improvements in child-parent relationships suggest that at least some benefits occurred as a result of psychological changes. The observed interrelationship between ADHD symptoms and more conflict in the child-parent relationship is consistent with Keown and Woodward's[405] finding that "boys who experienced less synchronous interactions (which are characteristic of insecure relationships) with their mothers were 8 times more likely to be hyperactive than comparison children" (p549). Interactional synchrony, they argue, is more likely when parents are more able to manage their child's behaviour. Because the benefits of the SYM treatment reported by parents included being more able to manage stress, feelings of anger and conflict in relationships with their child, it is not implausible to suggest that an important outcome of the meditation program was the parents' sense of being more relaxed and able to deal with their child's ADHD-related problems. Relationship benefits may also be linked to the nature of the intervention, which provided direct instruction to parents in SYM techniques as well as training in how to supervise their child's meditation at home.

On a neuro-biological level, SYM claims to reduce sympathetic nervous system arousal by activating parasympathetic-limbic pathways that relax body and mind[239]. Direct physiological effects of SYM include indicators of increased parasympathetic activity such as decrease in blood pressure as well as in heart, respiratory and pulse rates and an increase in galvanic skin resistance (an indicator of decreased sympathetic activity)[406]. Recent modern functional imaging studies have shown that the reduction of thoughts in the meditation process reduces activity in frontal and other cortical brain regions (believed to originate thought processes), while increasing activation in limbic brain areas[407, 408]. High resolution EEG studies have shown that SYM leads to increased alpha and theta power over anterio-frontal and fronto-central brain regions and to reduced complexity of EEG patterns[318, 358]. This appears to be because decreased complexity of the EEG from fronto-cortical regions is correlated with increased attentional control over cognitive processing[409], whereas poor attention[410] is correlated with increased complexity over fronto-central brain regions. It has been suggested that reduced complexity of EEG patterns during meditative experience in SYM may reflect switching off irrelevant networks in order to maintain focused internalised attention and inhibit inappropriate information[358]. It has been shown that alteration of beta/theta waves by means of biofeedback correlates with improvement of ADHD symptoms (for an overview see Ramirez, Desantis, & Opler, 2001[411]). It is thus possible that the causal mechanism underlying the positive effect of SYM on the improvement of ADHD symptoms occurs via changes on frontal brain activation during meditation. Since frontal dysfunction is the most consistent finding in ADHD[383], a change in frontal brain activation during the 6 weeks practice of SYM may well have been the cause of the symptom improvements.

Other possible, yet unexplored mechanisms of action, could be a balancing effect of meditation on neurotransmitter systems. In fact, a recent study using positron emission tomography has shown that meditation increases endogenous levels of dopamine in the striatum by as much as 65%, which correlated with an increase in EEG theta activity[412]. As ADHD has been associated with elevated dopamine transporter levels[384, 385, 413], a meditation-induced change in endogenous striatal dopamine levels could be a plausible hypothetical mechanism for the amelioration of ADHD symptoms. Further research using modern imaging techniques will be necessary to explore the mechanisms of action of SYM.

In summary, this is the first study investigating the effect of SYM as treatment for ADHD behaviours. The study aimed to investigate SYM as an additional family-oriented treatment which could be practiced in conjunction with conventional medical treatment being administered to the children. The study was not designed to compete with or substitute medication treatment. Preliminary findings provide evidence of the benefits of SYM in alleviating the behavioural symptoms of children diagnosed with ADHD. This was confirmed through parent report and the evidence of participating children. These benefits extended beyond the immediate environments of the home and into the classroom.

Future directions in SYM research would be well served by larger studies involving teachers as well as parents in following the progress of children afflicted by ADHD. Furthermore, the fact that confirmatory analyses provided evidence that medication did not add significantly to the changes observed with SYM, means that it may be worthwhile comparing the effects of meditation on both medication-free and medicated children, or even comparing SYM with other treatments for ADHD such as behavioural programs.

In studies of psychiatric disorders in adults, when SYM was applied to patients with depression, it was seen significantly to reduce the depressive symptoms in adult patients compared to control patients treated with behavioural therapy[414]. Clinical trials, conducted under more controlled conditions and with a larger sample than was possible in the present study, would be needed to provide the necessary rigour to assess the relative effect of SYM as an alternative or complementary treatment for ADHD. However, the indications are that SYM may offer families an effective management tool for family-oriented treatment of childhood ADHD.

# Chapter 8. Randomised Controlled Trial of Meditation versus Stress Management in the Management of Moderate/Severe Asthma

## 8.1 Overview

The studies reported in previous chapters, have suggested that there is a health effect associated with the practice of SYM which has been imputed as to the experience of *mental silence*. Much of the apparent effect however, could equally be explained as arising from the result of non-specific factors common to any behavioural intervention and not necessarily due to *mental silence* or even meditation. So as part of the methodological progression of this dissertation, a more rigorous experimental design was conceived in order to control for these non-specific effects: A parallel group, double blind RCT was designed into order to compare SYM with a recognised stress management intervention in the management of asthma. The study was designed in such a way that while enabling both groups to learn a credible strategy and techniques to reduce stress, one group would receive skills in achieving and maintaining the *mental silence* experience whereas the other would not. All non-specific aspects of the two interventions were matched as closely as possible.

Asthma was selected as it is, colloquially and otherwise, regarded as a disease state that may be significantly influenced by psychosomatic factors. Asthma sufferers who were symptomatic despite maximal conventional therapy, were selected using rigorous selection criteria. Among the measures assessed at the pre-, post- and follow-up time-points were asthma-related quality of life, mood state, level of airway hyper-responsiveness to methacholine (AHR), a proxy measure of the patho-pysiological disease process that underlies asthma. At post-intervention, a number of significant improvements were detected that suggested a specific effect of meditation in AHR, mood and a trend for improvement in asthma-specific quality of life. These findings are remarkable in the context of the rigorous design and clinical severity of the patients' conditions and the fact that no other relaxation or meditation study had demonstrated significant changes in RCTs. Although not sustained at follow-up, the outcomes did indeed suggest a specific effect, providing important insights for the next stage of scientific exploration.

## 8.2 Introduction

Asthma is a multifactorial disease in which environment, pathogens, allergens, genetics and psychology all play a part. The prevalence of asthma in industrialized countries is rising quickly with some studies showing that more than 10% of current school children in developed countries are affected by the disorder[415]. Asthma is a major cause of absenteeism from school and work and may disrupt social relationships, future prospects and overall quality of life[416, 417]. Consequently, living with asthma generates a vulnerability to worry, anxiety, panic and depression[418]. The notion that asthma might be a stress related illness is not new and there is a long history of both psychosomatic theories for the aetiology of this condition[419] and of investigations into the role of anxiety and emotional states in outcomes of this disease[420, 421]A bidirectional causal interaction between asthma and stress would be a vicious circle, affecting the management of asthma and patients' quality of life. Some researchers claim that the increase of asthma morbidity and mortality in the Western world has been related to increasing levels of stress and emotional strain associated with modern life[422].

There is some empirical evidence suggesting that emotional stress can trigger or worsen acute and chronic asthma[423]. Moreover there is a widespread perception among health professionals that stress is a contributor to asthma, although most mainstream authorities believe that its contribution is probably a minor one[424]. Empirical studies have shown that while stress causes a reduction in airway resistance in non-asthma participants, the opposite is the case for asthma sufferers[425, 426]. Similarly, while exercise can bring about broncho-dilation in non-asthma participants it can induce broncho-constriction in those with asthma[427].

On the whole, the evidence for the role of emotions in asthma is by no means consistent, with many inconclusive and poorly designed studies, leading Goreczny and coworkers to conclude:

> To date, no study has satisfactorily measured the changes in asthma severity as they relate to acute changes in stress and anxiety. Thus, a temporal relation between stress/anxiety and asthma symptoms has never been demonstrated.[428]

This position is supported in more recent reviews of the evidence[429].

In terms of potential explanatory mechanisms, the current understanding of the autonomic nervous system and the lung does not adequately explain why psychological stress should worsen asthma or why reduction of stress might be beneficial. This is because the clinical effects of psychological stress are thought to increase sympathetic tone. Yet increased sympathetic activation leads to increased levels of circulating catecholamines which then act on the distal bronchial tree to induce broncho-dilation (there are no sympathetic nerve fibres in the distal bronchial tree). Obversely, relaxation methods bring about their clinical effect by reducing sympathetic (S) tone and increasing para-sympathetic (PS) tone. Yet greater PS tone should lead to broncho-constriction, as should a reduction in S tone. Yet psychological stress, which usually involves release of catecholamines, should induce broncho-dilation, is commonly clinically associated with broncho-constriction. Moreover, prolonged stress should trigger cortisol release with a reversing effect on bronchus constriction[430]. Interestingly, a study by Ritz reported that stress-induced respiratory function changes in asthma sufferers appeared to be independent of both autonomic and ventilatory activity[431]. This and other data suggest that the asthmatic lung has a somewhat different physiology compared to a normal one and that explanations focusing on sympathetic–para-sympathetic shifts in autonomic physiology, are probably inadequate.

The impact of emotions on immunological and inflammatory mediators is a promising alternative explanation. It is well known that stress can cause alterations in immune response. Acute stress activates the sympatho-adrenal medullary system (SAMS) leading to changes in hormones and peptides that influence the CNS-based control mechanisms on the immune system[424]. For example, cytokine production, which has an important role in inflammation, can change within minutes of the onset of a stressor[432-434]. Cytokines have also a key role in chronic asthma. Therefore stress may influence asthmatic reactions through direct alterations in cytokine levels, granular leucocyte activity or perhaps even indirectly through increased general susceptibility to asthma[424]. However, empirical data on the direct relationship between stress and asthma and the meditating role of immunological factors, is relatively scarce. Other more mundane explanations might include the impact of emotions and stress on breathing patterns and subjective impressions of symptoms such as dyspnoea[429].

Clearly part of the challenge in answering this question is to develop empirical methodologies that can effectively tease out the relationship between a fluid, subjective phenomenon like emotions and the asthmatic condition that is itself intertwined with subjective perceptions and responses. As Borkovec points out, human behaviour and health:

> …are nonlinear, dynamic systems involving processes like attention, thought, imagery, memory, emotion, physiology, and behaviour, all constantly interacting in response to changing interpersonal and non-interpersonal environments and based on developmental and biological history”.[435]

As a result of these and similar notions, various behavioural interventions have been trialled in patients with asthma, including Buteyko breathing, relaxation exercise, yoga, and meditation, all of which have produced evidence of mild benefit[436]. These various strategies are discussed below.

### 8.2.1 Breathing exercises

#### 8.2.1.1 Buteyko breathing

This is a method of controlled breathing which has attracted a good deal of attention in Australia. Its application has produced enough level II evidence to suggest it has beneficial effects. For instance, a small RCT showed marked reduction in asthma drug consumption among patients[437]. A further trial, based on the use of a training video also demonstrated its effectiveness in reducing ß2-agonist use[438]. More recently an RCT conducted in New Zealand, compared conventional asthma education and relaxation exercises (n = 38) to the Buteyko technique and found that it produced a significantly greater reduction in consumption of inhaled steroids (ICS) and bronchodilators than was the case in the control group[439].

#### 8.2.1.2 Yogic exercises

Buteyko is not the only breath control strategy that has been trialled for asthma. For instance, Singh *et al*. have reported on a simple device designed to regulate breathing patterns in accordance with *pranayama yoga* principles. The Pink City Lung Exerciser “imposes slowing of breathing and 1:2 inspiration/expiration duration ratio equivalent to *pranayama* breathing methods”. In a small RCT (n = 23) with mild (defined as no use of inhaled corticosteroids) asthma, the device brought about statistically significant improvements in airway hyper-responsiveness (0.96 doubling doses) and some non-significant improvements in symptoms scores and medication consumption after two weeks of use[440].

Recently, Cooper compared the PCLE with Buteyko and a sham-PCLE in a reasonably sized RCT (n = 90) using a six-month treatment phase. There were no significant differences in airway hyper-responsiveness either within or between groups comprised by the 69 participants who completed. However, there were significant improvements in symptoms and bronchodilator consumption in the Buteyko group compared to the others[441].

### 8.2.2 Relaxation exercises

A recent systematic review of relaxation therapies for asthma[436] identified 15 RCTs but only 9 compared outcomes between groups. The overall methodological standard was considered poor (Jadad scores of generally 1 or 2), reflecting a general trend in behaviour therapy trials[442], and similar to the findings in the systematic review reported in Chapter 2. While 2 trials demonstrated significant results, the remainder of the trials failed to do so (3 of relaxation based methods[443-445], 2 of biofeedback[446, 447], one of autogenic training[448] and one of hypnotherapy[449]).

In one of the 2 positive trials, Alexander compared Jacobsonian relaxation to simply sitting quietly in a group of 44 children. A significant improvement in peak flow was observed in favour of the intervention, although the degree of improvement (11%) was not clinically significant[450]. Hock also used Jacobsonian relaxation and compared it to assertiveness training in a sample of 20 boys. No significant differences were observed at post-intervention (8 weeks) but there was a significant difference in forced expiratory volume ($FEV_1$) at the follow-up assessment (12 weeks from baseline assessment), although it is unclear to what degree this translated into clinical benefits[451].

The reviewers concluded that at best only minor, inconsistent improvements could be achieved by relaxation therapies. Methodological weaknesses were a major concern, with only one RCT scoring 3 on the Jadad scale. Of particular concern was selection of control methods that would adequately exclude non-specific effects. Deter's trial exemplifies this issue — it comprises autogenic training, systematic relaxation and a waiting list control as an adjunct in the management of asthma in a 3-arm RCT. Despite the 12-month intervention period no differences were found between the groups[448].

Consequently, the reviewers concluded that while there may be some potential for conventional relaxation methods as part of a comprehensive asthma management plan, the evidence for their efficacy was weak.

### 8.2.3 Yoga and meditation

As outlined in Chapter 2, meditation research to date has been plagued by conceptual and methodological problems. One of the most significant difficulties involves developing control strategies involving interventions which blinded participants might consider plausible, that have no specific therapeutic effects. Randomization and management of other sources of bias is another area of concern; a large number of controlled trials have used non-randomized, dissimilar cohorts.

In addition, defining meditation for research purposes is a challenge. Conceptual definitions of meditation vary widely but generally lack empirical confirmation. Many reviewers and researchers practically assume that all processes labelled "meditation" are similar, an assumption which could well be flawed. These issue, along with the idea that modern and traditional notions about meditation may be fundamentally different are discussed extensively in the cultural review in Chapter 3.

In order to develop an understanding of the potential efficacy of meditation in the management of asthma I reviewed the RCT evidence in the peer-reviewed literature. Computer databases, including MEDLINE, PsycINFO, CINAHL, EMBASE, Current Contents and Biological Reports. I also searched the Internet, hardcopy reports and other sources of "grey literature". Search terms included "asthma", "meditation" and "randomized trial". Three studies were found.

#### 8.2.3.1 Transcendental Meditation

In the first of these, Wilson conducted a single low quality trial of TM, which was listed in Huntley's review but was not assessed because it failed to make between group comparisons. In this trial, 25 stable asthma sufferers were randomized to either TM or reading about relaxation. After 12 weeks, they crossed over without a washout phase. Airway resistance was significantly reduced in both groups after TM (52% and 59%, $p < 0.05$) but FEV remained unchanged and no significant changes occurred in the control group. Critical limitations of this trial include the use of an implausible control and the fact that at least half of participants continued TM after crossover, invalidating the post-crossover analysis[170].

#### 8.2.3.2 Yoga

Vedanthan conducted a small RCT of 17 American college students with asthma. The intervention comprised a multimodal yoga package involving exercise, breathing methods and meditative practices, used over a 16 week period. Results in the intervention group were compared with those of students on a waiting list. The participants were blinded to the design and hypothesis of the trial. Assessments included symptoms diaries, medication consumption and spirometry. Despite using a completely inactive comparator, no significant between-group differences were observed post-intervention[163].

### 8.2.3.3 SYM

The above results contrast with those of the data which emerged from a small trial of SYM reported by Rai in New Delhi, India. In an RCT, 18 female sufferers of severe asthma were allocated either to a SYM or a waiting list/standard treatment control group[52, 452]. Rai's reports were based on a doctoral thesis by Chugh[51]. The study was not published in the peer-reviewed literature, so this data was not included in the review in Chapter 2. Nevertheless, in the context of this chapter, the study warrants attention. Unlike Vedanthan's trial, Chugh focused exclusively on meditation. In 9 patients randomized to the intervention group, the $FEV_1/FVC$ ratio increased from 48% at baseline to 66% at the conclusion of the 4-month intervention. Over the same period the spirometric ratio did not change in 9 control participants ($p < 0.001$). Participants in the intervention group had an average of 5.8 "acute attacks" during the treatment period, compared with 12.9 "acute attacks" over the same period in the controls ($p < 0.001$).

In addition to asthma-specific outcomes, Chugh also assessed psycho-physiological measures of stress. He observed differences in serum lactic acid, urinary VMA, percentage alpha activity in occipital EEG leads, GSR, HR, RR, and ST (see glossary of abbreviations). In consideration of the available data, Chugh's trial outcomes seem promising since significant differences were observed in more than one variable and a number of them were also clinically significant. Unlike Alexander's trial, in which changes in asthma specific measures were not corroborated by changes in subjective measures of relaxation, the changes reported by Chugh in asthma profile were reflected in altered psycho-physiological variables.

### 8.2.4 Conventional asthma management

The optimal management of patients with asthma who remain symptomatic on moderate to high dose inhaled steroids, remains undefined. Pharmacological alternatives include addition of long-acting ß2-agonist, a further increase in the dose of inhaled steroids, or the introduction of leukotriene receptor antagonists. The role of non-pharmacological therapies, including psychological and physical techniques in this context, has not been well established by existing trials.

For this study, an attempt was made to assess the effectiveness of SYM, a non-pharmacological intervention, as an adjunctive tool in the management of asthma in adult patients who remained symptomatic on moderate to high doses of inhaled steroids. The examination sought to establish the effect of SYM on asthma-related quality of life and level of airway hyper-responsiveness. A diary-card based score reflecting symptoms, bronchodilator usage and peak expiratory flow rates, was used. A further aim was to compare the effect of this approach with that of more orthodox, pre-existing stress reduction programs designed for asthma sufferers.

## 8.3 Methods

### 8.3.1 Study design

A parallel group, double-blind, randomized controlled trial was conducted. After a 2-week baseline assessment period, participants were randomly divided between an SYM and a placebo control intervention group. Both required the participants to attend a 2-hour session once per week for 4 months. Participants were informed that the project aimed to assess the relative effectiveness of two alternative relaxation techniques for the management of asthma. Outcome assessments were undertaken at the conclusion of the 4-month intervention period and again 2 months later. The study protocol was approved by the Institutional Ethics Committees of the South Western Sydney Area Health Service and the Central Sydney Area Health Service. Informed consent was obtained from participants prior to randomization. The study design is summarized in Figure 8.1.

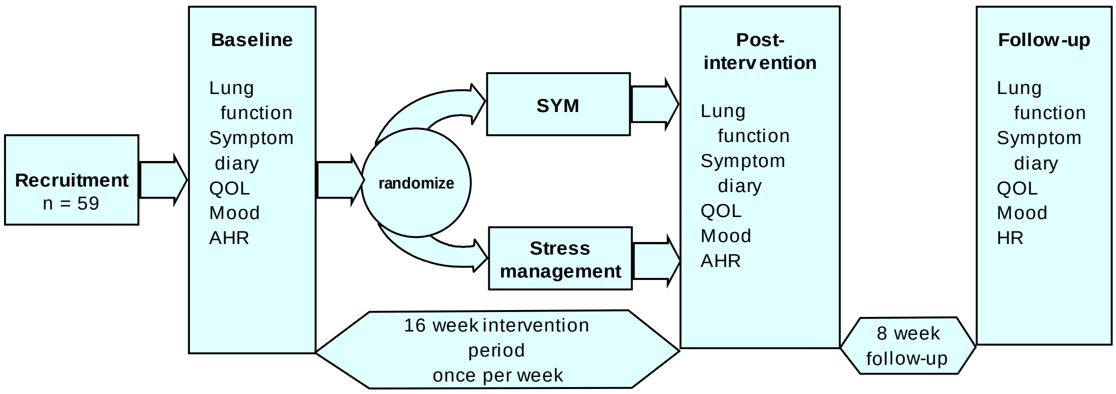


Figure 8.1 Study Design.

### 8.3.2 Subject selection

The aim was to select adult patients with asthma who remained poorly controlled on moderate to high doses of inhaled steroids and who were amenable to the idea of a non-pharmacological, stress management intervention.

Participants were recruited by newspaper advertisement, from general practitioners and hospital asthma clinics. Newspaper advertising produced a major response, from which 850 patients were screened. Another 200 were recruited from the asthma clinic records, and 30 from GP referrals. Of the 120 people who satisfied phone-screening criteria, 59 met the eligibility criteria after completion of baseline diary card, lung function and methacholine challenge and were therefore randomized into the study. Participant flow is summarised in the CONSORT diagram in Figure 8.2.

People with asthma were eligible for inclusion if they were aged 16 or over and had a history of asthma symptoms for a least one year. Other inclusion criteria were: at least moderate to severe asthma, as evidenced by a combined asthma score of ≥ 7 out of 12 (see below); airway hyper-responsiveness ($PD_{20}FEV_1$ < 12.2μmol methacholine) or > 15% $FEV_1$ bronchodilator response; daily inhaled treatment with ≥ 1500μg beclomethasone, 1200μg budesonide or 750μg fluticasone for at least the preceding 6 weeks; and stable asthma treatment for the preceding 6 weeks.

Exclusion criteria were: a history of an asthmatic exacerbation of or respiratory tract infection during the preceding 6 weeks, being a current smoker, being pregnant or lactating, inability to communicate in English, and resistance to stress management intervention.

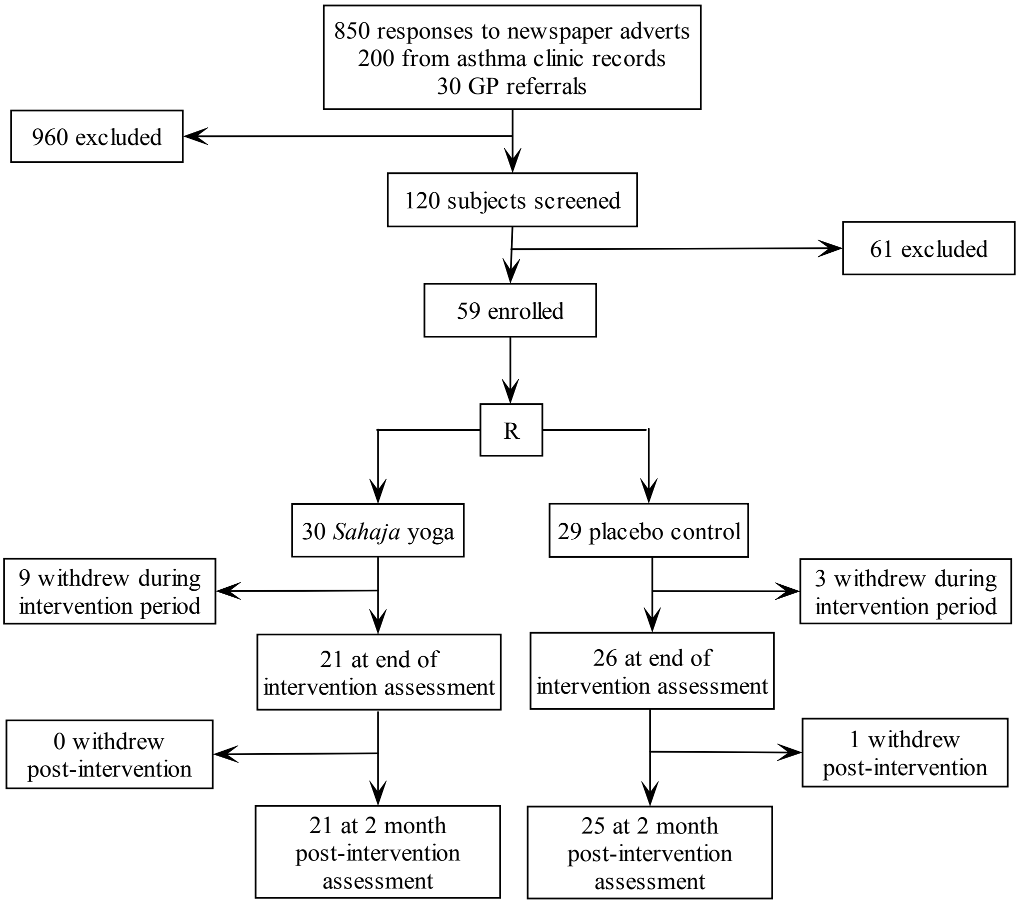


Figure 8.2 CONSORT diagram.

### 8.3.3 Randomization

Allocation to groups was by randomized permuted blocks with a block size of 4, generated by computer. The allocation for each successive subject was contained within a sealed envelope. Allocation was done at a distance by an assistant who was not an investigator. The subject's identification was disclosed only to the relevant group instructor who then contacted the subject.

8.3.3.1 Blinding

Participants and instructors were:

blinded to the complete hypothesis of the trial were not informed about what methods were being used in the comparison groups

were instructed not to disclose information about the methods used in their classes to other trial participants or the investigators.

The investigators, data entry personnel, scorers and statistician were also blinded to group allocation.

8.3.3.2 Non-specific effects

The two meditation interventions were structured identically so that non-specific factors such as credibility, expectation and demand characteristics were matched as closely as possible. Classes for both intervention groups were conducted at the same institutional location, in similar rooms, at the same time of day, with similar support materials; instructional sessions were of equal duration with equivalent periods between interventions.

**8.3.4 SYM intervention**

The SYM session was conducted by an experienced instructor. Participants were taught how to achieve a state of *mental silence* by the use of silent psychological affirmations. They were encouraged to achieve this state twice each day for a period of 10 to 20 minutes. The sessions were held on a weekly basis at the local hospital in the evening. Each session lasted 2 hours and involved meditation, instructional videos, personalized instruction and discussion of problems in relation to improving the experience of meditation.

The key experience of *mental silence* was crucial for the assessment of any potential beneficial effects on physical and psychological health to be experienced. All instructional sessions and the advice given in those sessions was directed at facilitating and enhancing that experience.

### 8.3.5 Comparison intervention

In an attempt to control non-specific effects, the comparison sessions were structured in such a way as to replicate the intervention sessions as exactly as possible, thereby accentuating the emphasis on *mental silence* as the major difference between the two groups. The sessions were held on a weekly basis at the same venue, and at the same time in the evening. The duration of the sessions was the same and the participants were encouraged and in fact required to practice at home twice daily for the same amount of time that was recommended in the meditation group.

The method used in the control sessions was a combination of relaxation methods, group discussion and CBT-like exercises. The programme was highly plausible as a meditation-like programme. Relaxation methods involved positive affirmations such as "I can breathe easily and without restriction", progressive muscle relaxation and visualisation (focusing on seeing their lungs breathing easily). Group discussion was semi-formal and enabled participants to share experiences and develop a sense of community. The CBT-like exercises were designed to give the subject insight into the way in which their thoughts, feelings and reactions to stress influenced the severity and perception of their illness. This approach was based on a workbook on relaxation and stress management techniques called *Learn to Unwind* produced by the Health Media and Education Centre, of the NSW Department of Health[271].

Although the comparison group may itself have some clinical effect, this was necessary not only to control for specific effects, but also to ensure subject compliance. The crucial difference between the two groups was that the SYM meditation method focused primarily on the experience of *mental silence* while the comparison group clearly did not.

### 8.3.6 Outcome measurements

Outcome assessments at baseline, the end of the intervention and two months after the end of the intervention, were undertaken by an investigator who was blinded to the group allocation of the participants.

#### 8.3.6.1 Diaries

Participants kept written diary cards to record, twice daily, peak expiratory flow rates, symptoms, and bronchodilator use for two-week periods at each assessment. Each of these was scored as shown in Table 8.1. The combined asthma score [270] the sum of these 3 components, was then calculated for each subject for each assessment period. The possible range of scores was 0 to 12. In addition average morning peak flow (a.m. PEF) and lowest peak flow as a percentage of the highest peak flow (low/high %) were calculated for each diary card.

#### 8.3.6.2 Self-report measures

At each assessment, participants completed a battery of questions to assess, for the preceding one month period, the need for urgent doctor visits, time off work and changes in medication and progress in terms of psychological, quality of life and symptom parameters compared to baseline. This included:

**AQLQ**

This disease-specific Asthma Quality of Life Questionnaire[272] (AQLQ, devised at the University of Sydney**) is** a standardized and validated self report instrument. It is used to measure mood states, total AQLQ scores and subscale scores for breathlessness, mood disturbance, social disruption and concerns for health were calculated on a scale of 0 to 4 (no impairment of quality of life –maximum impairment).

**POMS**

The Profile of Mood States[273] (POMS), a standardized and validated self report measure of mood was also administered.

8.3.6.3 Lung Function

**Spirometry and airway hyper-responsiveness**

Spirometric function was measured at least 4 hours after the last dose of short-acting bronchodilator and 12 hours after the last dose of long-acting bronchodilator. In those whose $FEV_1$ was greater than the 60% predicted[274]and who did not have a big breath effect (that is a 10% or greater fall after saline), a methacholine challenge test was performed to assess airway responsiveness. The rapid, hand-held dosimeter method was used[275] with a maximum cumulative dose equal to 12.2 µmol. The provoking dose required to cause a 20% reduction in $FEV_1$ from the post-saline value ($PD_{20}FEV_1$) was measured by linear interpolation on a log-dose response curve or by linear extrapolation to a maximum of twice the final dose administered. All extrapolated values greater than this were assigned a value of twice the final cumulative dose. In participants with low lung function ($FEV_1$ < 60% predicted[274]) or "a big breath effect", the response to inhalation of salbutamol 200 µg was assessed. For the purpose of measurement of change in airway responsiveness as an outcome measure, these participants were assumed to have severe airway hyper-responsiveness and were assigned a $PD_{20}FEV_1$ value of 0.1 µmol. Values of $PD_{20}FEV_1$ were log-transformed for analysis. Change in $PD_{20}FEV_1$ was expressed in units of doubling doses.

**Daily peak flow**

As mentioned above, the diary card included an average morning peak flow (a.m. PEF) and lowest peak flow as a percentage of the highest peak flow (low high %) were calculated for each diary card. Scoring system for the diary card is summarized in Table 8.1.

Table 8.1 Scoring key for diary card recordings of symptoms, bronchodilator usage and peak expiratory flow rates.

| Score | Symptoms | Bronchodilator usage | Min morning PEF as % of best† |
|---|---|---|---|
| 0 | Nil | Nil | > 93% |
| 1 | No night symptoms, but<br>Daytime symptoms ≤ 2 times (in 2/52) | Used on ≤ 2 days<br>(in 2/52) | 85–93% |
| 2 | No night symptoms, but<br>Daytime symptoms > 2 times but<br>≤ 10 times (in 2/52) | Used on > 2 days<br>but ≤ 10 days<br>(in 2/52) | 78–85% |
| 3 | Night symptoms ≤ 2 times (in 2/52)<br>OR<br>Daytime symptoms > 10 times in (2/52) | Used on > 10 days,<br>average 1–2 times/day | 70–78% |
| 4 | Daytime symptoms every day<br>OR<br>Night symptoms > 2 times (in 2/52) | Used on > 10 days,<br>average ≥ 3 times/day | < 70% |

† "Best" includes clinic spirometry and all PEF records

### 8.3.7 Analysis and sample size

Analysis was by intention-to-treat. Primary outcome variables were the combined asthma score, the AQLQ (total) score and $PD_{20}FEV_1$. All other outcomes were secondary outcome variables.

All outcomes measured at the conclusion of the intervention and 2 months later were expressed as changes from baseline. Between-group differences in these changes were calculated, together with 95% confidence intervals. The changes were compared by 2 sample t test. For non-normally distributed data, Wilcoxon's non-parametric test was used to check the results of the parametric analysis.

### 8.3.8 Compliance

Details of participants' record of attendance at the SYM and placebo control sessions were quantified to assess compliance.

### 8.3.9 Sample size calculation

It was estimated that a sample size of 25 in each group would allow for the detection of a one doubling dose difference between groups in $PD_{20}$ with 80% power ($\alpha = 0.05$). This sample size would also be sufficient to detect a clinically meaningful difference in AQLQ scores between groups. To ensure 25 participants are available for evaluation, it was planned to randomize 30 participants into both groups.

## 8.4 Results

### 8.4.1 Participants

Of 840 people screened for the study, 59 eligible participants were randomized: 30 to the SYM intervention and 29 to the placebo control arm. Nine participants randomized to the yoga intervention and 3 participants randomized to the placebo control group withdrew prior to the end-of-treatment assessment. No outcome data are available for these participants. The reasons for withdrawal are shown in Table 8.2.

Table 8.2 Reasons for withdrawal of participants from the study.

| Reason for withdrawal | SYM | Placebo control |
|---|---|---|
| Social/work changes | 4 | - |
| Illness unrelated to intervention | 2 | 1 |
| Disliked the intervention | 1 | - |
| Changed management regime | 2 | 2 |

Differences at baseline between randomization groups and between those who did complete the end-of-treatment assessment and those who did not, are shown in Table 8.3. Participants in the SYM group had slightly higher (worse) scores on the mood subscale of the AQLQ and higher values for peak flow (low/high %) than those in the control group. Five participants in each group were using long-acting ß2-agonists and one subject in each group was taking theophylline.

Of the 21 participants in the SYM group who had the end-of-treatment assessment, one did not have a valid measure of AHR at the end of treatment and 2 did not have valid measures of AHR at end of the 2 month follow-up period. Of the 26 control group participants who had the end-of-treatment assessment, one was lost to follow-up before the 2 month follow-up assessment, one did not complete the diary cards or questionnaires at the end of the treatment or the 2 month follow-up period, one had did not have a valid measure of AHR at the end of the treatment period and 3 did not have valid measures of AHR at the end of the 2 month follow-up period.

### 8.4.2 Compliance

Twenty of the 21 participants in the yoga intervention group who had the end-of-treatment assessment, attended at least 8 of the 16 yoga sessions. Seventeen of these attended 12 or more sessions and 5 attended all 16 sessions. In the control group, 19 of the 26 who had the end-of-treatment assessment attended at least 8 sessions, 17 attended 12 or more sessions and 12 attended all 16 sessions.

Table 8.3 Baseline demographic and clinical characteristics.

| Characteristic | SYM | | Control | | *p* for comparison | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | SYM vs control | | Complete vs DNC | |
| | Randomized | Complete† | Randomized | Complete† | Randomized | Complete | Yoga | Control |
| n | 30 | 21 | 29 | 26 | - | - | - | - |
| Mean age (years) | 36 | 37 | 36 | 37 | 0.98 | 0.9 | 0.3 | 0.15 |
| Female | 14 | 11 | 17 | 15 | 0.5 | 0.9 | 0.6 | 0.9 |
| Ex-smokers | 10 | 7 | 11 | 10 | 0.9 | 0.9 | 0.9 | 0.9 |
| Duration of asthma (years) | 25 | 25 | 22 | 22 | 0.2 | 0.2 | 0.7 | 0.7 |
| Mean inhaled steroid dose (µg) †† | 2458 | 2274 | 1927 | 1918 | 0.07 | 0.15 | 0.16 | 0.9 |
| Mean FEV1 % predicted | 75% | 76% | 76% | 73% | 0.8 | 0.7 | 0.6 | 0.07 |
| Mean FEV1/FVC ratio | 0.70 | 0.71 | 0.75 | 0.74 | 0.1 | 0.3 | 0.5 | 0.3 |
| FEV1 < 60% predicted | 8 | 5 | 7 | 7 | 0.9 | 0.9 | 0.9 | 0.7 |
| Mean AQLQ total score | 1.7 | 1.5 | 1.5 | 1.5 | 0.3 | 0.9 | 0.2 | 0.3 |
| Mean AQLQ breathlessness score | 1.5 | 1.4 | 1.5 | 1.5 | 0.99 | 0.5 | 0.4 | 0.15 |
| Mean AQLQ mood score | 1.7 | 1.8 | 1.3 | 1.3 | 0.03 | 0.04 | 0.6 | 0.7 |
| Mean AQLQ social score | 1.4 | 1.2 | 1.4 | 1.5 | 0.8 | 0.4 | 0.04 | 0.3 |
| Mean AQLQ concerns score | 1.9 | 1.7 | 1.6 | 1.7 | 0.4 | 0.9 | 0.08 | 0.6 |
| GP visits ‡ | 0.5 | 1 | 0 | 0 | 0.8 | 0.8 | 0.3 | 0.5 |
| Days missed work‡ | 0.5 | 0 | 0 | 0 | 0.4 | 0.6 | 0.7 | 0.9 |
| Mean morning peak flow | 369 | 372 | 365 | 363 | 0.9 | 0.8 | 0.8 | 0.8 |
| Mean evening peak flow | 377 | 378 | 375 | 371 | 0.9 | 0.8 | 0.9 | 0.6 |
| Peak flow: low % high | 76% | 77% | 72% | 70% | 0.1 | 0.04 | 0.7 | 0.07 |
| Av. daytime symptom score (max 4)‡ | 1 | 1 | 1 | 1 | 0.3 | 0.7 | 0.1 | 0.7 |
| Av. night symptom score (max 4)‡ | 1 | 0 | 0 | 0 | 0.2 | 0.6 | 0.04 | 0.6 |
| Av bronchodilator score (max 2)‡ | 1 | 1 | 1 | 1 | 0.08 | 0.4 | 0.01 | 0.8 |
| Combined asthma score (max 12)‡ | 10 | 10 | 10 | 10 | 0.9 | 0.5 | 0.5 | 0.1 |

† These are the participants who had outcome assessments performed at the end of the treatment period.

†† Daily dose of inhaled steroids in beclomethasone µg equivalents. These were calculated on the assumption that beclomethasone 2000µg = budesonide 1600µg = fluticasone 1000µg.

‡. Median numbers are shown. Comparisons are by Wilcoxon's two sample test. Other comparisons are by chi square (for categorical variables) or by two sample t test (for normally distributed, continuous variables).

Table 8.4 Change from baseline in outcome measures.

| | End-of-intervention | | | | Two months post-intervention | | | |
|---|---|---|---|---|---|---|---|---|
| | **SYM** | **Control** | **Difference† (95% CI)** | **p** | **SYM** | **Control** | **Difference (95% CI)** | **p** |
| Combined asthma score, (max score 12) | 2.90 | 2.00 | 0.90 (-0.9 to 2.7) | 0.30 | 2.00 | 2.50 | -0.50 (-2.2 to 1.2) | 0.60 |
| AQLQ (total) (max score 4) | 1.05 | 0.65 | 0.41 (-0.04 to 0.86) | 0.07 | 0.88 | 0.63 | 0.25 (-0.21 to 0.72) | 0.30 |
| $PD_{20}FEV_1$ (doubling doses) | -1.48 | 0.32 | -1.80 (-3.1 to -0.4) | 0.012 | -1.16 | -0.01 | -1.20 (-2.6 to 0.3) | 0.11 |
| $FEV_1$ % pred. | -4.20 | 0.60 | -4.80 (-13.1 to 3.5) | 0.30 | -0.90 | -1.90 | 1.00 (-8.1 to 10.1) | 0.80 |
| $FEV_1$/FVC ratio | -0.008 | 0.003 | -0.011 (-0.047 to 0.024) | 0.50 | -0.033 | -0.002 | -0.031 (-0.085 to 0.023) | 0.30 |
| Morning PEF (L/min) | 1.70 | 2.40 | -0.70 (-18.4 to 17.0) | 0.90 | 1.60 | -1.40 | 3.10 (-13.0 to 19.1) | 0.70 |
| PEF: low % high | -6.70 | -6.50 | -0.10 (-6.1 to 5.8) | 0.97 | -4.50 | -8.50 | 4.00 (-3.4 to 11.4) | 0.30 |
| AQLQ breathless (max score 4) | 0.90 | 0.43 | 0.46 (-0.04 to 0.97) | 0.07 | 0.65 | 0.66 | -0.01 (-0.52 to 0.50) | 0.97 |
| AQLQ mood (max score 4) | 1.14 | 0.51 | 0.63 (0.06 to 1.20) | 0.03 | 0.93 | 0.36 | 0.58 (-0.05 to 1.20) | 0.07 |
| AQLQ social (max score 4) | 0.92 | 0.75 | 0.17 (-0.36 to 0.70) | 0.50 | 0.84 | 0.71 | 0.14 (-0.43 to 0.70) | 0.60 |
| AQLQ concerns (max score 4) | 1.16 | 0.90 | 0.25 (-0.25 to 0.76) | 0.30 | 1.03 | 0.76 | 0.28 (-0.27 to 0.82) | 0.30 |
| POMS total mood | 33.2 | 14.8 | 18.4 (0.2 to 36.5) | 0.05 | 31.7 | 14.4 | 17.3 (-6.7 to 41.3) | 0.2 |

† Change in SYM group – Change in Control group, differences tested by 2 sample *t* test

### 8.4.3 Airway hyper-responsiveness

At the end of the treatment period, the level of airway hyper-responsiveness had improved by 1.5 doubling doses in the SYM intervention group and had worsened by 0.3 doubling doses in the placebo control group ($p$ = 0.01 for between-group difference). The difference between the groups was no longer significant at two months post-intervention (Table 8.4 and Figure 8.3). The improvement in AQLQ score at the end of the treatment period, was 0.41 units greater in the SYM group than the control group. This difference just failed to reach statistical significance ($p$ = 0.07). There was no between-group difference in change in AQLQ scores 2 months after the intervention was completed (Table 8.4 and Figure 8.4). There was no difference between the SYM and control groups in the combined asthma score, either at the end of the treatment period or at the 2 month follow-up assessment.

### 8.4.4 Secondary outcome measures

8.4.4.1 AQLQ

Examination of the subscale scores from the AQLQ reveals that the major impact of the meditation was on the *mood* subscale. At the end of treatment, there was a significantly greater improvement in this subscale in the SYM group compared to the control group. A slightly lesser difference, which just failed to reach statistical significance, was still evident at 2 months post-intervention. The *breathless* subscale tended to reflect greater benefits from the yoga intervention than the *social* or *concerns* subscales. See Figure 8.5.

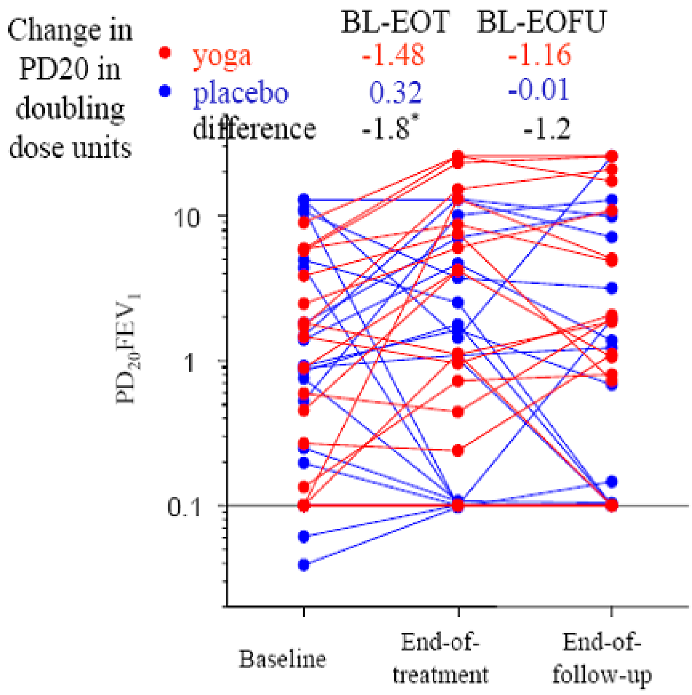


Figure 8.3 Change in airway hyper-responsiveness.

Change in PD20 in doubling dose units. Airway hyper-responsiveness ($PD_{20}FEV_1$) at baseline, end-of-treatment, and end-of-follow-up. Yoga group shown in red, control group shown in blue. Participants with $FEV_1$ < 60% predicted were assigned a $PD_{20}FEV_1$ value of 0.1 (shown as solid, reference line).

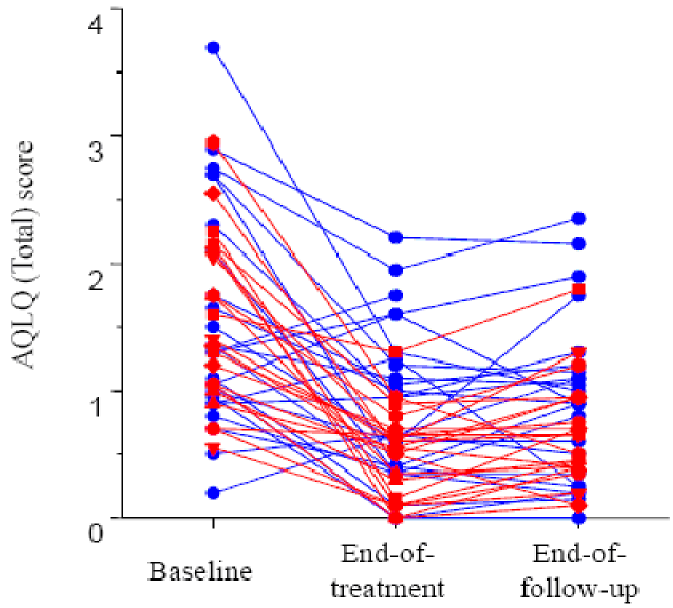


Figure 8.4 Change in quality of life scores.

AQLQ (Total) score at baseline, end-of-treatment, and end-of-follow-up. Yoga group shown in red, control group shown in blue. Scores range from 0 (no impact on quality of life) to 4 (most severe impact on quality of life).

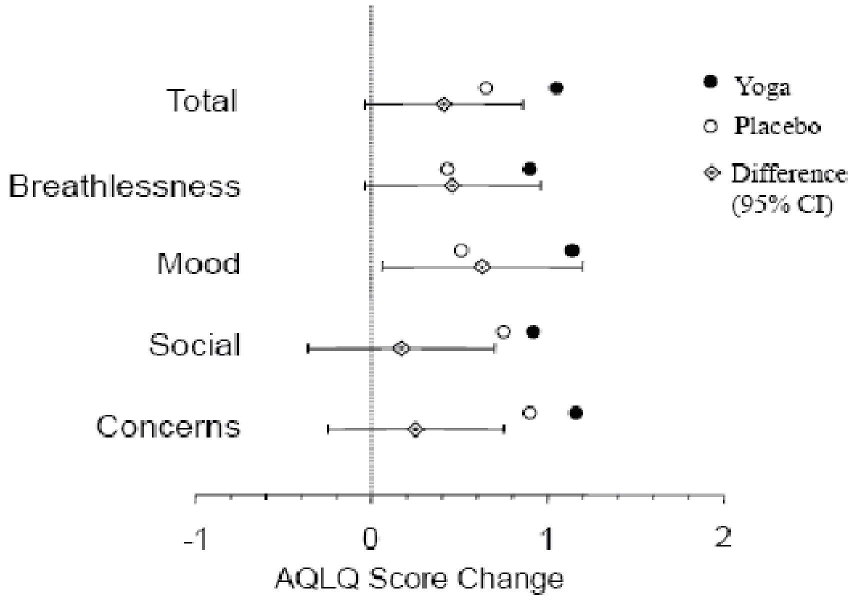


Figure 8.5. AQLQ subscales.

The plot shows changes in the subscales from baseline to end of intervention for the yoga and placebo groups.

8.4.4.2 Lung Function

There were no significant changes in lung function as measured by spirometry during clinic visits or as measured by peak flow at home.

8.4.4.3 POMS

The meditation group improved their POMS total score more than the control group.

See Figure 8.6.

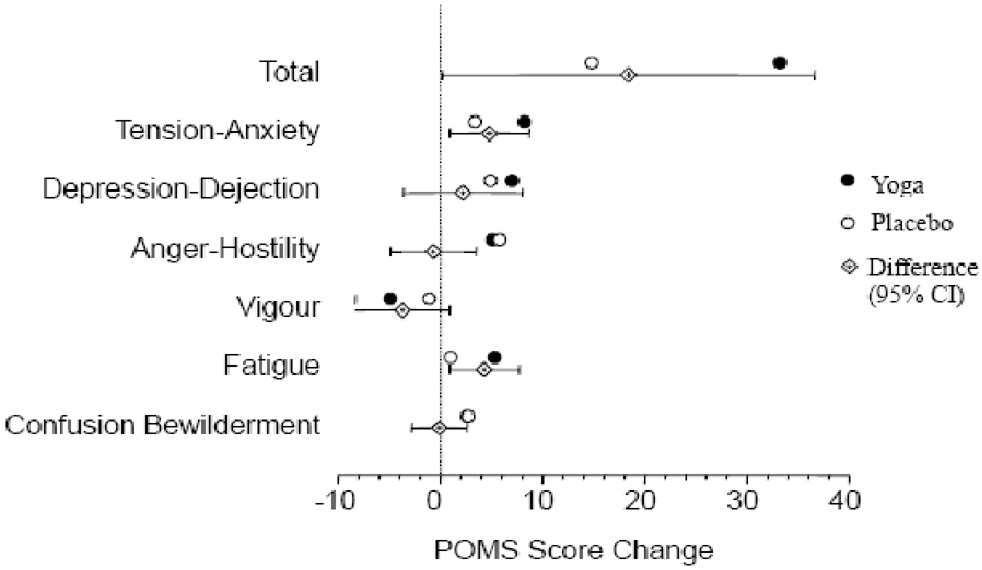


Figure 8.6. POMS score.

The plot shows changes in the subscales from baseline to end of intervention for the yoga and placebo groups.

## 8.5 Discussion

SYM improves airway hyper-responsiveness, general mood state and some aspects of impairment of asthma-related quality of life in patients with asthma who remain symptomatic despite treatment with moderate to high dose inhaled steroids for at least 6 weeks. These improvements are not accompanied by changes in lung function or symptoms recorded by diary card and appear to wane over a period of 2 months follow-up after the intervention ceases.

The conclusions of this study can be generalized to participants with symptomatic asthma who express interest in non-pharmacological therapies such as meditation. The conclusions of this trial may not be applicable to patients who are antipathetic to this form of treatment.

It is important to note that the role of SYM was assessed as an adjunctive treatment. All participants had been taking the equivalent of beclomethasone 1500 µg/day for at least 6 weeks prior to randomization and they continued on this treatment throughout the intervention and follow-up period. Hence, the benefits of meditation are additional to the benefits of inhaled steroids. We have not tested the role of SYM as a replacement for inhaled steroids and cannot deduce whether the beneficial effects of SYM require the simultaneous use of inhaled steroids.

There was a larger than expected loss to follow-up in the SYM treatment group. The availability of outcome data on only 21 participants in this group was less than the 25 estimated in the sample size calculations. This left the study slightly "under-powered" and hence the failure to detect a significant treatment effect on AQLQ (total) score may be a Type II error. The higher than expected drop-out rate introduces a potential problem with bias due to selective withdrawal of participants who were not benefiting from the intervention. However, most of these withdrawals occurred soon after randomization and hence are unlikely to be related to the effectiveness of the intervention. Treatment group instructors indicated that much of this related to participants' perception of meditation as culturally foreign. This is partly due to the recruitment method which advertised for volunteers for a trial of "stress management methods" for asthma. The wording was selected so as to attract potential volunteers who recognized the potential of stress management strategies for asthma while at the same time not disclosing the specific differences between the two conceptually and operationally divergent interventions in order to minimize the effect of expectancy.

Interestingly, the SYM instructors who conducted the intervention classes, felt that participants with less severe asthma would be easier to teach and would probably experience its purported benefits more quickly. Moreover there was a greater preponderance of asthma sufferers with milder symptoms, thus probably making it easier to achieve larger recruitment levels, sample sizes and hence more powerful statistical inferences and more generalized outcomes.

Among those who did reach the end-of-treatment assessment, compliance with the SYM regimen and control treatments was good. Most participants attended most of the sessions. However, there is no quantitative data on adherence to meditation practices between the actual sessions or during the post-intervention follow-up period. The findings reported here lend some support to the conclusions of a previous small randomized controlled trial of the effectiveness of SYM in the management of asthma in adult women[452]. In 9 patients randomized to the intervention group $FEV_1/FVC$ ratio increased from 48% at baseline to 66% at the conclusion of the 4 month intervention. Over the same period the spirometric ratio did not change in 9 control participants ($p < 0.001$). Participants in the intervention group had an average 5.8 "acute attacks" during the treatment period, compared with 12.9 "acute attacks" over the same period in the controls ($p < 0.001$).

There are a number of ways in which the observed effect may be explained. Many yoga and meditation practices include exercises designed to alter the pattern of breathing. Participants in this study were given no explicit instructions about controlling their breathing pattern and we did not measure ventilation. However previous studies have shown that tidal volume and frequency may be reduced during and following a period of meditation. Mild hypoventilation has a number of physiological consequences which could have affected the outcomes. Proponents of the Buteyko breathing technique claim that asthma is associated with chronic hyperventilation and subsequent hypocapnia, and propose that exercises which reduce minute ventilation are likely to be beneficial. In the only published controlled trial of the Buteyko breathing technique, asthmatics receiving active treatment had significant reductions in ß2-agonist use, suggesting that the breathing exercises reduced asthma symptoms. However, the breathing exercises had no effect on end tidal $CO_2$, suggesting that the mechanism of the effect is unlikely to be via a reduction in hypocapnia.

An alternative hypothesis may be that altering the pattern of breathing alters AHR via a direct effect on airway smooth muscle dynamics. Recent observations have led to the suggestion that the shortening velocity of airway smooth-muscle may be an important determinant of AHR. In addition, there is *in vitro* evidence which suggests that airway smooth-muscle shortening velocity may be affected directly by the volume of tidal breathing[453]. In this model, decreasing tidal volume decreases the amplitude of force fluctuations acting on the smooth muscle and leads to reductions in actin-myosin cross-bridge cycling rates and shortening velocity of the muscle, with a subsequent reduction in the amount of airway narrowing for a given stimulus. This model has not been tested in human participants, but provides a plausible explanation whereby changes in breathing pattern might alter AHR. Yet, Cooper's study of both Eucapnic Buteyko and the PLCE, both of which employ substantial alterations of breathing pattern, found no significant changes in AHR after 24 weeks of practice[441]. Singh's study of the PLCE reported mild changes in AHR after 2 weeks of practice suggesting that changes in the contraction dynamics of smooth muscle may be transient, if there are any at all, thus implying that support for this notion as an explanation of the changes in AHR in this study, observed after 16 weeks of instruction, is weak[440].

The effect may have been achieved as a result of reduced anxiety or psychological stress. It is widely perceived that relaxation techniques can be of clinical benefit in diseases which involve chronic inflammatory processes[454]. Moreover, relaxation techniques may facilitate the release of mediators that attenuate the inflammatory reaction[424]. A number of studies have demonstrated the relationship between stress and susceptibility to common infections such as viral upper respiratory tract infections[455]. Hence the application of a stress reduction technique may improve resistance to such infections and therefore reduce the likelihood of asthma occurring as a result of perhaps subclinical infection. Current interest in the role of *Chlamydia pneumonie* in the aetiopathogenesis of asthma lends some credence to this idea. It might be hypothesized that the same reduction in airway hyper-responsiveness was not observed in both groups because the improvement in emotional status between the two groups was also much higher (approximately double) in the SYM group.

The placebo group essentially employed a relaxation process which focused on achieving the conventional understanding of relaxation (rest) whereas the SYM group focused on attaining the meditative experience which is hypothesized to involve not only relaxation but also a spontaneous therapeutic process said to be activated in the state of "thoughtless awareness".

There are some interesting observations in the literature about the impact of suggestion and expectation on lung function and asthma symptoms. When Luparello, in a single blind study, gave nebulised saline to asthmatics and suggested that it was an allergen/irritant, he observed that about 50% of participants manifested significant increases in airway resistance. The changes were reversed when the same saline was introduced with the suggestion that it was therapeutic[39]. In a double blind RCT crossover trial, Luparello supplied participants with a bronchodilator agent (isoproterenol) telling them: "This is broncho-dilator, a substance that will open up your airways and make it easier for you to breathe", which created a positive expectation in the subject. When the same agent was given with a statement intended to create a negative expectation ("This is a broncho-constrictor, a substance that will tighten up your airways and make it harder for you to breathe") the negative expectancy condition led to a significant attenuation (by almost 50%, $p < 0.02$) of the broncho-dilator's effect. A broncho-constrictor (carbachol) was then supplied with the same set of opposing statements to create two different expectations. The positive expectancy condition significantly attenuated the broncho-constrictive effect of the carbachol by almost 40%, $p < 0.05$).

This raises a question about the mechanism of suggestion. McFadden conducted further trials that reported broncho-constriction in response to a suggestion and that intravenous atropine blocked this response[40]. Neild conducted an experiment which utilized suggestion to bring about broncho-constriction using warmed and humidified saline. In those participants who responded to the suggestions, the broncho-constrictive effect (up to 15% reduction in FEV1) was significantly mitigated by administration of inhaled ipratropium bromide at normal dosage levels[41]. Thus the findings of Luparello, Macfadden and Neild's indicate that the effects of suggestion may be vagally mediated and are negated by anticholinergic agents. It can be confidently argued that the two intervention groups in this study were equally matched in terms of plausibility and credibility, as interventions and thus subject expectations would have been very similar. Nevertheless, it may be that the positive effects of SYM somehow exploited the potential demonstrated by the experiments above to bring about changes in patho-physiology.

An explanation of the observed effect using the conventional understandings of stress and its influence on the ANS, has a number of difficulties. Some have endeavoured to explain that the improvement of asthma symptoms with relaxation/stress reduction techniques is a result of reduced S tone and increased PS tone. While this may explain some of the general physiological phenomena associated with the PS response and the experience of relaxation, this represents a paradox with regard to some of the observed changes in asthmatics. Interestingly, Luparello's impressive outcomes have, to date, not been replicated[429].

Although both groups demonstrated an improvement in diary card scores, there was no significant difference between the two groups. The similar effect may have been a result of variables which influenced both groups equally, such as seasonal changes. This may have occurred because intervention and control techniques may be similarly effective in changing the perception of asthma symptoms, although by different methods. The SYM group may have achieved its effect by a mechanism that influences airway hyper-responsiveness and therefore disease activity itself, while the control group may have achieved its effect simply by modifying the perception of symptoms.

It can be argued that the effects demonstrated by this trial are superior to those of relaxation-orientated studies. Of the two known positive trials of relaxation, significant differences occurred in peak expiratory flow rate (PEFR) or forced expiratory volume in 1 second ($FEV_1$). Neither trial used a control method that plausibly resembled a relaxation-based self guided daily practice, so it can be argued that non-specific effects were not adequately controlled for. This trial of SYM manifested two significant changes, one in the relatively reliable outcome of AHR and the other using a well-validated, self-report scale for mood. Asthma-specific quality of life showed near-significant changes for the total score ($p = 0.07$) with two symptom subscales showing significant changes (mood and breathlessness, $p < 0.05$). That the control group used a meditative practice and drop-out rates as well as informal feedback from participants, suggests that participants in the placebo group did not feel that they were receiving a non-meditative intervention.

In broader terms this study also represents important progress in the refinement of SYM research methodology. As previously discussed, the major issues affecting the validity of meditation research are the use of adequate control strategies and the need for a clearer conceptualisation of what meditation is. By using a highly plausible control and a randomised design, not only are confounding non-specific effects minimised, but the effect of orthodox stress management/relaxation have been excluded. Thus it can be assumed for the sake of argument, that whatever the significant differential in effect between the two groups, this is the result of the purportedly unique dimension of meditation—thoughtless awareness. Given that very few trials have demonstrated a major significant difference between various "relaxation-meditation" methods, the emergence of the observed differences between the "relaxation" oriented control group and the *mental silence* oriented SYM group lends support to the *mental silence* conceptualisation of meditation.

Methodologically speaking this study represented an important step forward in terms of quality and rigour. Many of the common shortcomings as identified in the systematic review in Chapter 2 were addressed. Extensive steps were taken to control for non-specific effects by using a highly plausible, active control strategy. Common sources of bias were tackled by use of appropriate randomisation methods, blinding of investigators, participants and instructors. Widely accepted, orthodox and appropriate statistical design and analysis strategies were used within a highly conservative intention to treat model. The sample size, although relatively small was considerably larger than most RCTs reported in the literature and was derived based on appropriate sample size and power calculations.

## 8.6 Conclusion

The meditation technique yielded a number of improvements that were significantly better than those seen in the control group. The two main areas of improvement were airway hyper-responsiveness and mood state. This suggests that SYM does in some way attenuate the severity of the disease process. This effect that was not seen in the control group. The significant improvement in mood state was associated with a strong, larger trend toward improved quality of life. The methodological features of this study represent an important step forward in terms of overall quality and hence reliability of findings. Nevertheless, this study appeared to lack sufficient power to conclusively demonstrate the clinical significance of the quality of life improvements. Further evaluation is necessary to determine the clinical relevance of this kind of intervention as an adjunct to the normal management of asthma. It does appear that SYM, and hence its defining feature of *mental silence*, may have a specific effect.

# Chapter 9. Two Different Approaches in using Meditation for Management of Work Stress

## 9.1 Overview

Preceding chapters describe data suggesting an effect that appears to be associated with the *mental silence* dimension of SYM (and hence its main distinguishing feature, the *mental silence* experience). The RCT in the previous chapter, despite shortcomings, provides the most reliable evidence for a specific effect so far, particularly with regard to mood. It compared SYM to stress management as a treatment for asthma; this was important since stress management is an accepted adjunctive management strategy for asthma treatment. This study develops on the observations made in the previous study by positing that SYM or any meditative technique that elicits the *mental silence* experience, is likely to generate specific effects, whereas meditation techniques that emphasise constructs other than *mental silence*, such as relaxation, are less likely to do so. As part of the methodological progression aimed at testing this final part of the hypothesis, an RCT of meditation for the management of stress was designed comparing SYM to a non-*mental silence* form of meditation and a waiting list control.

Work stress is a growing health problem relevant to organizations, health professionals and society in general. It is recognized world-wide as a major challenge to workers' health and the healthiness of organizations. Workers who are stressed are likely to be less healthy, motivated, productive and safe at work. The organizations for which they work are less likely to be competitive or successful[456]. Participants experiencing work stress were recruited from the general community, the final cohort having had psychological stress levels significantly higher than established population norms. Accepted and validated self-report psychological measures of stress, anxiety and depression were used at pre- and post- time points. The program for both groups was identical in almost every aspect other than the emphasis on *mental silence*. After 8 weeks of twice weekly meditation classes and daily practice, participants in the SYM group demonstrated significant improvements compared to the other two groups. Post hoc analysis indicated that while both active interventions reduced somatic arousal, the SYM group also appeared to alter participants' cognitions and perceptions, suggesting that changes in the way in which they thought and felt contributed, to their reduction in stress. Although relying on self-report measures, albeit highly validated and accepted, this study provides further, stronger proof for a specific effect associated with *mental silence* beyond that of the non-specific effects commonly associated with contemplative/meditative interventions.

## 9.2 Introduction

### 9.2.1 What is stress?

*Stress* was first proposed by Selye to describe the subjective experience of an individual who is faced with demands and circumstances that challenge their ability to deal with them. He later revised his own definition and agreed that the term *strain* more closely represents the experience while stress more correctly refers to the circumstances that lead to it[457, 458].

In the context of work, the stress construct (or strain as the more academically correct term) is founded on a core set of operational notions. These include:

- Karasek's idea of "demand-control imbalance" or "job strain"; jobs are stressful if they combine high demands with a lack of ability to control the situation. In other words, the perception of low control is put forward as the main source of work stress. There is data that indicates a relationship between low control and poor health outcomes[459].

- Siegrist's idea of "effort-reward imbalance"; the demands of a job, and the coping capacity that is required to do it become stressful if the rewards, whether they be remuneration, job satisfaction, status or other, are not reciprocally matched[460].

- Johnson's idea of "support"; having the right tools and infrastructure for the job and supportive relationships in the workplace[461].

The way in which these notions can be used to develop an explanatory framework by which different occupations and environments cause stress, how various stress management strategies exert their effect, how stress might impact on health and how meditation might be conceptualized within this context, are explored as part of this chapter.

### 9.2.2 Frequency of stress

Overseas studies estimate that up to 40% of patients presenting to general medical practitioners (GPs) are psychologically distressed[462-464]. In the US it has been estimated that 50–70% of general practice consultations feature stress related issues[465]. Medical practitioners, especially GPs, are the first point of contact for most people who are psychologically distressed[466].

In Australia, the Bettering Evaluation and Care of Health (BEACH) project was initiated 10 years ago to continuously collect information about the clinical activities in general practice in Australia. The programme is overseen by the Family Medicine Research Centre in collaboration with the Australian Institute of Health and Welfare. A sub-study from the BEACH project, supported by the Commonwealth Department of Veteran's Affairs assessed the prevalence of stress and anxiety issues among patients of GPs. An analysis of 100 GP encounters with 3,684 patient encounters, found that 40% of respondents (i.e. 1, 470 patients) reported experiencing a period of anxiety or stress lasting 2 weeks or more in the previous 12 months. Of this group, 75% sought help from professionals and 58% from their GP[467 468]. Similar results were found in a study of Australian patients by Cohen et al.[469], clearly indicating that medical practitioners need to understand the aetiology and management of this widespread problem.

### 9.2.3 The workplace as a major source of stress

Work stress in organizations is an increasingly common and widely acknowledged phenomenon[470]. Stress related disorders are becoming the most prevalent reason for worker disability[471] manifesting as absenteeism, workforce turnover, loss of productivity and disability pension costs[472 473].

A 1991 survey found that 27% of workers in the US rated their jobs as the most stressful factor in their lives, even more so than divorce or death[474]. In the Netherlands stress related disability pensions increased from 21% to 30% between 1981 and 1994 and individuals with a diagnosis of adjustment disorder had the lowest rate of return to work[475].

A number of key studies on work stress have been conducted in the UK which provide a useful overview of the character of the problem. The Health and Safety Executive (HSE) is the UK body responsible for policy and operational matters related to occupational safety and health. It estimates 50% of absenteeism to be work-stress related[476]. In fact, the household survey from the Self-reported Work-related Illness study (SWI 01/02)[476] data released by the HSE reinforces the perception of work stress as a major drain on workplaces, business and national health expenditure. The survey found that the 2 commonest work related illnesses were musculo-skeletal disorders (affecting 1.126 million workers) followed by work-related stress, depression or anxiety (affecting 563,000 workers). Thus in Great Britain 1.3% of people in work felt that they were experiencing stress, depression or anxiety either caused or worsened by current or past work. Interestingly, 47% of these sufferers had first become aware of their work-related stress, depression or anxiety within the previous 12 months.

Furthermore, although stress, depression and anxiety were the second most prevalent work related illnesses, these actually caused more loss of work days than musculo-skeletal disorders. For example, each sufferer of a musculo-skeletal disorder took an average of 19.4 days off work, whereas the average sufferer of stress, depression and anxiety took an average 29.2 days off in the same 12-month period. This translates to 12.3 million working days lost for musculo-skeletal disorders whereas 13.4 million working days or 0.6 days per worker were lost due to stress, depression or anxiety made worse or brought on by work.

Within the reference period, the incidence rate of stress, anxiety or depression was 50% higher for women than men and the days lost per female worker was double that of male workers (0.8 days lost versus 0.4 days, respectively). Higher rates of stress, depression and anxiety were reported in higher status jobs. The highest rate was in the lower managerial and professional grouping while the lowest was in routine occupations. The highest incidence occupations were teaching and research professionals, protective service, health and social welfare professionals, business and public service and administrative occupations.

The most recent HSE data indicates that the prevalence of musculoskeletal disorders from 1990 to 2007 had reduced significantly, as in fact the prevalence of all work related illnesses when taken as a single group. Yet, the prevalence of work related stress and related (mainly heart) conditions had increased significantly by a factor of approximately 2 In fact, work related stress, depression or anxiety in 2007 appears to be as prevalent as work related back pain and is significantly more prevalent than work-related lung or hearing problems[477]. As part of a major initiative aimed at tackling work stress, the HSE developed a taxonomy of factors that influence work stress. These are:

- *Demands*: including issues such as workload, work patterns and the working environment.

- *Control*: how much say the person has in the way they do their work.

- *Support*: which includes the encouragement, sponsorship and resources provided by the organization, line management and colleagues.

- *Relationships at work*: including promoting positive working practices to avoid conflict and to deal with unacceptable behaviour.

- *Work-roles*: whether people understand their role within the organization and whether the organization ensures that the person does not have conflicting roles.

- *Change*: how organizational change (large or small) is managed and communicated in the organization[478].

**9.2.4 The cost of work stress**

In 1993, the United Nations International Labour Organisation claimed that stress-related absenteeism, disability and lost productivity cost in the region of US$200 billion per year. The cost of stress to the workplace has been estimated at US$17 billion in the US alone[479].

More recently the HSE concluded that work related stress, anxiety or depression costs UK employers in the UK in the region of £370 million and the general society approximately £3.7 billion[480]. Since these calculations were done, the estimated number of days lost due to stress has more than doubled[476]. On this basis, the HSE identifies work related stress, anxiety and depression as a major health concern and argues that effective reduction of stress will lead to significant benefits for organizations. Recently organizations have become legally required to address these issues.

## 9.3 Work stress and health

### 9.3.1 Effects of work stress on health

The role of stress in the development of psychological disorders, disease and disability is becoming better defined and more widely accepted[471, 481]. A 1998 survey of more than 46,000 US employees indicated that medical care costs were 70% higher for those who reported being depressed and 46% higher for those who reported being stressed. While 2% of the sample reported being depressed, 18% of the sample reported being stressed[482].

The Bristol work stress study assessed 17,000 workers and found that approximately 20% of respondents experienced very high or extremely high levels of stress at work[483, 484]. A related cohort study suggested that this stress may influence physiology, mental performance and hence “cognitive failures” that then lead to risk of workplace accidents[485]. The landmark Whitehall large-scale prospective epidemiological studies of more than 10,000 British civil servants described clear associations between demands of work, employees’ sense of control, available support and physical and mental health outcomes[486]. Similar research in other developed countries produced results which correspond with the findings for the UK. Importantly, work stress appears to be especially prevalent among health professionals and in health care organizations[487].

This and other research indicate that stress is strongly associated with common health problems including hypertension[488, 489], heart disease[490], substance abuse[491], anxiety, depression[492] and gastrointestinal disorders[493].

There is epidemiological data to implicate each of the work related factors (demands, control, support, relationships, role ambiguity, change) identified by the HSE, in the development of health problems.

For instance, researchers using the Whitehall data found that competitiveness, over-commitment and a tense and hostile atmosphere in the workplace coupled with low opportunities for promotion and career development, were associated with a doubling in the risk of new coronary heart disease[494]. They also found that high job demands predicted poor health functioning and higher scores on the GHQ30, a screening tool designed to detect prodromal changes associated with the development of mental illness[495]. Low control was moderately associated with risk of alcohol dependence. In contrast, social support in the workplace and a sense of control over work, had a protective effect on mental health and health functioning and reduced illness related absenteeism[496]. Head et al. in a follow-up study on the Whitehall data, reported that high job demands, low decision latitude and effort-reward imbalance, were all related to higher rates of coronary heart disease, despite controlling for conventional risk factors such as smoking or blood pressure[497]. Similarly, high job strain, high demands and reduced decision latitude were associated with the highest risk of coronary heart disease[486].

For these reasons, Karasek's[459] demands-control model has been extensively studied; it seems to provide some empirical support for the hypothesis that especially high workload demands interact with control perceptions to explain physical and medical health outcomes[498-500]. However there is an argument that their impact is not solely due to their interaction. This position is supported by studies such as Whitehall II, which reported that the effects of demand and control affected health more than their interactions[496].

Selye suggested that having to live with other people is one of the most stressful aspects of life[501]. Other research data supports the common sense reasoning that relationships can be a major source of both stress and support[502]. Since being employed typically means significant interaction with other people, whether these be colleagues, bosses or subordinates, being at work can constitute one of the most stressful environments for the individual. However, when supervisors provide social support (defined here as having good quality relationship with supervisors, co-workers, family and friends and the amount of positive consideration and task assistance received from them[503, 504]), this has a beneficial effect on worker performance and well-being[505].

Role ambiguity originally referred to the unpredictability of the consequences of one's own role performance while later models extended the definition to include the lack of information needed to perform a role. The typical measure of this construct assesses both the unpredictability and information deficiency regarding role behaviours. Numerous studies have demonstrated a persistent link between substantiated role ambiguity in the job and high levels of psychological strain[506].

While cross sectional surveys and even more sophisticated epidemiological designs can at best demonstrate association between factors and outcomes, they cannot demonstrate causal associations[507].

Biological research data elucidating the mechanisms by which stress can impact on the physical body is considerably less than the epidemiological data; however the insights it provides are relatively more robust. The main candidate mechanisms for a causal link between psychosocial factors and health include (from Mackay et al[508]):

- Neuroendocrine[509] and autonomic changes[510].
- Metabolic syndrome and insulin resistance[511].
- Disturbances in blood coagulation[512].
- Inflammatory/immunological changes that modulate susceptibility to infection[455, 503, 513].
- Homeostatic and allostatic changes in response to stress[514].
- Psychological mechanisms such as anxiety, hyper-vigilance and risk-taking[515, 516].

Therefore it has been suggested that simple health promotional strategies such as stress management interventions (SMIs) make a significant contribution not only to organizational function and individual wellbeing, but also to national health expenditure[32].

### 9.3.2 Potential benefits of managing work stress

The workplace is an ideal setting for the implementation of SMIs since much of the adult population spends at least half of its waking hours at work and most workplaces have large numbers of individuals in single locations. In 1989, approximately 25% of private organisations with more than 50 employees offered stress management strategies in the workplace[472]. Despite this, very few strategies have been rigorously evaluated.

The HSE recognizes the need to reduce stress and in its key statements emphasizes the need for improved workplace organization and management as the most effective way of reducing workplace stress[478]. While it seems logical to deal with the causes of stress at the level at which they are generated (i.e. management and organization), such organization-based strategies have paradoxically, shown disappointing results. For instance, in his review of controlled work stress interventions, Van der Klink concluded that organization-based stress reduction strategies alone yielded minimal measurable benefits, whereas interventions aimed at the individuals within organizations generated much greater and more consistent effects[517]. Thus despite the support of experts, the onus continues to be shifted toward individual orientated SMIs rather than organizational change-orientated SMI strategies. This may not be because the idea of improving workplace management is flawed, but because those workplaces studied in controlled trials have, like many modern workplaces, already explored and initiated organizational reform and dealt with most of the major management problems that were generating stress. Hence residual stress-causing factors in these workplaces are a reflection of demands and environmental factors not amenable to organizational change. Furthermore, while organizational reform and job redesign are theoretically attractive, the necessary initiatives associated with them can provoke significant intra-organisational political opposition and discord.

### 9.3.3 Stress management interventions

Stress management training entails instruction in the use of SMIs aimed at equipping the individual with skills to reduce the negative effects of stress. A quantitative review of controlled trials by Van der Klink[517] identified four broad categories of SMI:

1. *Cognitive-behavioural* – aimed at changing cognitions and reinforcing active coping skills

2. *Relaxation* – as a way of coping with the consequences of stress

3. *Multimodal* – emphasizing acquisition of both passive and active coping skills;

4. *Organization* – focusing on organizational development and job redesign.

In this review's meta-analysis of 43 studies, 17 yielded an overall significant effect size. Looking at these studies, the mean effect size for cognitive behavioural SMIs was 1.37, for multimodal it was 0.89 and for relaxation, 0.77. Within the relaxation category, 3 of the 5 studies were conventional approaches to meditation. One used TM (effect size = 0.54), one used CSM (0.47) and one used a combination of relaxation techniques, including a generic form of meditation (0.43). It is interesting to note that the 3 meditation techniques have almost identical effect sizes, which is an observation consistent with the systematic review in Chapter 2 and in line with the ideas posited in the introduction of this study.

It is also interesting that the effect size of relaxation-orientated SMIs is considerably smaller than that of the other two individual-focused SMI categories. On the other hand, the effect size of individual-focused SMIs was considerably larger than those associated with strategies aimed at organizational change. After further analysis and taking into account occupational and other factors, van der Klink[517] concluded:

> In jobs that already involve a high degree of decision latitude, cognitive behavioural interventions seem to be most effective…in jobs with a low degree of decision latitude, organization-focused interventions aimed at increasing control potentials should prevail, accompanied by cognitive-behavioural interventions. If this strategy is not possible, interventions that focus on passive coping (relaxation techniques) have a moderate but proven effect[517](p275).

### 9.3.4 How meditation may alleviate stress

There are two main strands of thought concerning how SMIs reduce stress. First, the *cognitive behavioural model* posits that stress arises as a result of cognitive appraisal of stressors and resulting reactions. Second, the *somatic-arousal reduction model* suggests that by reducing sympathetic activity and promoting parasympathetic activity (i.e. reducing physiological arousal), meditation produces a general sense of relaxation and enhanced positive affect. In reality most SMIs probably influence both pathways, although each will favour one pathway more than the other in accordance with their individual characteristics[518].

With regard to *mental silence* orientated meditation however, it is quite possible that its effect might occur as a result of a combined effect or possibly other pathways not encompassed in either or the somatic or cognitive behavioural models.

## 9.4 Literature review

In order to develop an understanding of the potential efficacy of meditation as an SMI directed at stress and especially work stress, the evidence in the peer-reviewed literature was reviewed. Computer databases, including MEDLINE, PsycINFO, CINAHL, EMBASE, Current Contents and Biological Reports were consulted. I also searched the Internet, hardcopy reports and other sources of "grey literature". Search terms included "stress", "work", "occupational", "job", "strain", "meditation", "stress management", "psychotherapy", "behaviour therapy", "relaxation" and combinations of these terms. Of the 12 controlled studies found, 8 were described as RCTs and 4 as NRTs. The NRTs all compared meditation to either a waiting list or non-intervention control group, so it is not surprising that they all reported substantial positive effects of meditation[519-522]. Such a design cannot however exclude the impact of non-specific effects such as placebo and spontaneous improvement and so were excluded from this review.

Of the 8 studies describing themselves as RCTs[26, 37, 85, 150, 162, 168, 523, 524], those of Winzelberg and Peters clearly reported using a strategy that cannot be described as acceptable random allocation. Moreover, Peters used self-report questionnaires that had not been validated. They were re-classified as NRTs and excluded from this review.

The remaining 6 RCTs involved comparison with a number of different controls. Two used more than one control, simultaneously giving rise to 8 comparisons. The authors universally concluded that meditation was effective as an SMI. The design and methodological characteristics of these studies are summarised in Figure 9.1 and Figure 9.2 respectively.

Overall, consistent with the pattern that was demonstrated in the systematic review in Chapter 2, the strength of the reported outcome was related to the nature of the comparison strategy. Comparisons using low plausibility control methods tended to report much more favourable findings than comparisons using highly plausible controls. This is brought into focus in Carrington's RCT, where, when CSM is compared to a waiting list control and the outcomes appear strongly to favour meditation, whereas when CSM is compared to RR, there are no differences. This can be interpreted in two ways: 1) if it is accepted that *Relaxation Response* is simply a method of relaxation (as its developer Benson states), then CSM has no specific effects beyond that of generic relaxation methods; 2) or if we accept that *Relaxation Response* is a method of meditation, then CSM and *Relaxation Response* are equivalent despite differences in their overt methods and rationales suggesting that all meditation methods are equivalent.

Table 9.1 Design characteristics of work stress RCTs.

| Author | Year | Technique | Control | n | Drop-outs | Duration (wks) | Follow-up (wks) | Self-report | Objective |
|---|---|---|---|---|---|---|---|---|---|
| Bruning[85] | 1986 | CSM<br>CSM | 1. Exercise<br>2. Education | 86 | 20 | 10 | Nil | Anxiety, stress | |
| Carrington[36] | 1980 | CSM<br>RR | 1. WL<br>2. WL | 154 | 6 | 6 | 22 | SCL90R, stress | |
| Fiedler[524] | 1989 | Multi-modal | WL | 66 | 9 | 7 | Nil | SCL90R, stress | Stressor BP, HR, EMG |
| Sheppard[150] | 1997 | TM | Stress-management | 44 | 12 | 12 | 156 | STAI, depression | Phys BP |
| Tsai[162] | 1993 | Multi-modal | Education | 137 | - | 2 | 5 | QOL, stress | |
| Williams[168] | 2001 | ?MBSR | Reading | 103 | 28 | 8 | 12 | SCL90RQOL, stress | |

Table 9.2 Methodological features of work stress RCTs.

| Author | Year | Sample size calculation | ITT | Partcipants | Rater blind? | Comp. | Exp. | Analysis | Plausibility of control |
|---|---|---|---|---|---|---|---|---|---|
| Bruning | 1986 | N | N | N | N | N | N | unclear | 1. Mod<br>2. Low |
| Carrington | 1980 | N | N | N | N | Y | Y | UniANCOVA | 1. Low<br>2. Low |
| Fiedler | 1989 | N | N | N | Y | Y | Y | UniANCOVA | Low |
| Sheppard | 1997 | N | N | Y | Y | Y | N | UniANCOVA | High |
| Tsai | 1996 | Y | N | N | N | Y | N | RMANOVA | Low |
| Williams | 2001 | Y | Y | N | N | Y | N | RMANCOVA | Low |

A number of other methodological issues were also noted. First, 5 of the trials had authors who either acted as meditation instructors (making it impossible to blind the lead investigators to group comparison) or they had developed the techniques or were employed at institutions dependent on income or profile relating to the scientific credibility of the technique that they were studying. Only 2 studies described steps to blind the raters and one to blind the participants themselves to their allocation or the full hypothesis of the study. Only one trial described the method of randomization used to allocate participants. Four of the trials indicated drop-out rates which ranged from 6% to 32% (mean drop-out rate of 15%) but only one described whether or not the drop-out cohort was comparable to the compliant cohort and only one trial used intention-to-treat analysis. Despite the fact that most trials used multiple outcome measures, none used Bonferroni or equivalent methods to adjust for multiple *t* tests. Two trials clearly described the use of repeated measures style analysis, whereas most of the others appeared to have used univariate ANCOVA, a strategy that while it approximates, is not a truly appropriate, repeated measures approach.

Taking these factors into consideration, the quality of the extant data is low and the current evidence for the specific effectiveness of meditation in the management of work stress is very weak. A number of conclusions can be made from these observations:

1. There is insufficient evidence to support the idea that meditation is any more effective than simple relaxation or rest.

2. The use of plausible control groups is critical to help determine if meditation has a unique role to play in the management of stress and work stress research because of the need to exclude the important confounding effects of non-specific factors that relate to plausibility of the intervention (such as placebo,

expectancy, therapeutic contact). Expectancy alone, for example, has been shown in a number of studies positively to influence the apparent effect of meditation[4].

3. There is at the moment no systematic comparison of different conceptualizations of meditation within the context of work stress. While Carrington has compared two kinds of meditation in the context of work stress and found that there were no major differences between the two, the different meditations in her trial both belong in the same “relaxation-meditation” category. In fact none of the meditation techniques in this review were derived from the traditional *mental silence* genre.

## 9.5 Methods and materials

### 9.5.1 Design

With these considerations in mind, a 3 group, parallel RCT was designed which compared SYM meditation, to a relaxation oriented “non-MS” meditation and a waiting list (no-treatment) control. The study design is summarized in Figure 9.1.

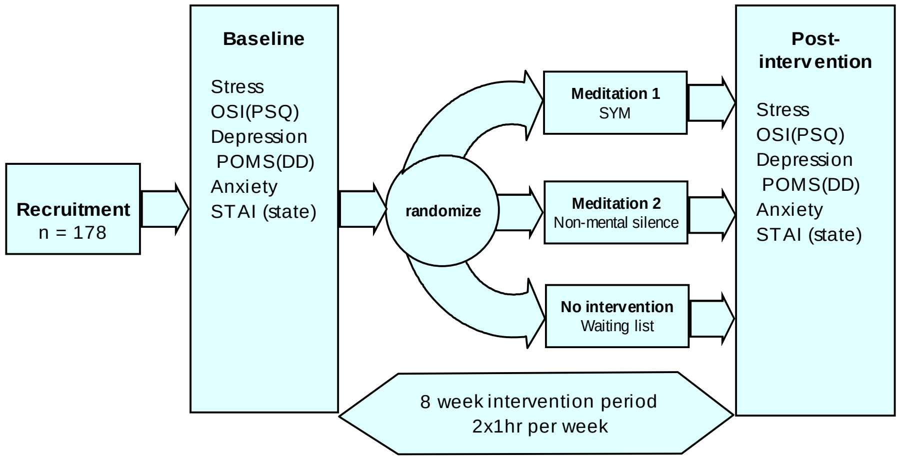


Figure 9.1 Study design.

### 9.5.2 Participants

Eligibility criteria were; being in full time employment (more than 30 hours per week), being willing to commit to the instructional program and to practice twice daily at home, being a non-smoker, imbibing less than two units of alcohol daily, being free of serious psychological/psychiatric/medical morbidity, not having used other stress management strategies (including other meditation techniques) over the previous 12 weeks, having experienced no recent major life events (such as bereavement/major illness in immediate family, moving house, recent divorce or relationship breakdown), not using recreational drugs, and finally, being willing to fill out a questionnaire battery before and after the program.

Participants were recruited by advertising in local newspapers and other popular media. The trial was conducted in the education centre of a local hospital in the CBD of Sydney, Australia.

### 9.5.3 Randomization, blinding and controlling for non-specific effects

#### 9.5.3.1 Randomization

A research assistant, located separately from the main investigators, randomly allocated each subject from each round of recruitment to one of the three groups using a blindfolded lottery allocation system. The subject was notified of their allocation by the assistant and this was not disclosed to the investigators.

#### 9.5.3.2 Blinding

Participants and instructors were blinded to the complete hypothesis of the trial; were not informed about what methods were being used in the comparison groups; and were instructed not to disclose information about the methods used in their classes to other trial participants or the investigators. The investigators, data entry personnel, scorers and statistician were also blinded to group allocation.

#### 9.5.3.3 Non-specific effects

The two meditation interventions were structured identically so that non-specific factors such as credibility, expectation and demand characteristics were matched as closely as possible. Classes for both intervention groups were conducted at the same institutional location, in similar rooms, at the same time of day, with similar support materials; instructional sessions were of equal duration with equivalent periods between interventions.

### 9.5.4 Interventions

The intervention period was 8 weeks, and involved one hour-long evening sessions twice weekly. Participants were asked to practice twice daily at home for 10-20 minutes each time. Instructors for both active groups were health professionals who were also experienced and qualified meditation instructors.

#### 9.5.4.1 *Mental silence* meditation – SYM

This group was taught to elicit a state of *mental silence*, by using a simple series of silent affirmations based on a traditional understanding of yogic psychophysiology[239]. Participants were encouraged to meditate while sitting quietly in a chair or in a comfortable position that facilitated their meditation experience. They were encouraged to develop a sustainable state of "thoughtless awareness" (*nirvichara samadhi* in Sanskrit). The instructional sessions were specifically focused on helping participants achieve the experience of MS and each week informal feedback was sought by instructors regarding each participant's progress. Participants were given CDs with a guided meditation based on SYM for twice daily use at home[276].

#### 9.5.4.2 Non-*mental silence* meditation (RM)

RM was a generic meditation technique based on the "*Relaxation Response*"[245] concept. It was developed by a professional meditation instructor specifically for the study. Participants were instructed to sit comfortably, to breathe regularly and to commence their meditation by reflecting on the day's events. The aim of this method was to induce a meditative experience that was consistent with the "relaxation" meditation concept. The instructor sought feedback each week from participants in order to ensure that the meditative style was adhered to. Participants were given a CD with a guided meditation based on the classes for twice daily use at home. This intervention was designed to control for non-specific effects associated with non-*mental silence* styles of meditation i.e. rest, therapeutic contact, credibility and expectancy associated with any behavioural intervention, in line with the general hypothesis of this thesis.

#### 9.5.4.3 No treatment (NT)

The no treatment group was comprised of participants who were told that they were on a list of people to be admitted into one of the meditation groups at a later date. They were not told that they were a control group. The waiting NT group was included to control for practice effect associated with the psychometric questionnaires, regression to the mean and other non-specific effects[278].

### 9.5.5 Measures

Baseline assessments were done prior to randomization. All potential participants were invited to an evening information session where the basic principles of the study were outlined, including inclusion and exclusion criteria. Those participants who decided that they were able to satisfy these criteria were invited to remain and fill out the baseline questionnaire battery. Any questions or difficulties with the questionnaire were directly addressed by researchers who were also on-site at the time of the briefing/baseline questionnaire session. Participants were allocated to their treatment group within one week, after which the instructional program commenced. Recruitment was done in batches in such a way that the information/baseline questionnaire sessions were not conducted until a minimum number of volunteers had accumulated, usually at least 30 per batch. Post intervention assessments were similarly conducted between 5 and 7 days after the final instructional session, specifically to avoid biasing that may have arisen from acute effects of the intervention.

#### 9.5.5.1 Primary outcome measures

To maximize comparability of the outcomes with other studies, it was decided to use self-report measures. These measures are the preferred measure of stress both in research and the workplace and have therefore been extensively assessed and validated for reliability and clinical salience. While biological measures may be theoretically preferable for the measurement of stress there are no widely accepted measures that are practically applicable in the workplace.

**Occupational stress**

The Psychological Strain Questionnaire (PSQ) is one of the most widely known and accepted measures of work stress and is part of the larger Occupational Stress Inventory (OSI)[279]. The PSQ focuses specifically on the subjective "work stress" experience whereas the larger parent questionnaire assesses environmental stimuli and coping mechanisms as well. (See Table 9.3 for summary of baseline scores).

**General stress/anxiety**

The State-Trait Anxiety Inventory (STAI)[280] is a self-report scale which has been widely used for the assessment of general anxiety but which however, is not restricted to anxiety at work. The state subscale assesses the anxiety of the subject at the time of the response, whereas trait anxiety assesses general predisposition to anxiety states. It is commonly used in mental health trials and this review of meditation RCTs found that the STAI was the commonest of all measures employed. The state subscale was used in this trial (See Table 9.3 for summary of baseline scores).

**Depressive symptoms**

The depression-dejection (DD) subscale of the Profile of Mood States (POMS) was used to assess depressive symptoms[273]. The POMS is not restricted to work stress but addresses general emotional states. While there are a wide variety of validated measures available for the assessment of depressive symptoms, my review of meditation RCTs found that the POMS was the second commonest measure used (See Table 9.3 for a summary of baseline scores).

9.5.5.2 Secondary measures

I used the GHQ28 to assess the mental health profile of the samples before treatment. The SERCIS study used the same instrument to assess the mental health profile of an Australian sample representative of the general population[260]. The GHQ was developed to assist primary care physicians in screening for psychopathological states such as depression, anxiety, somatic complaints and social dysfunction[281]. The GHQ, in its various forms, has been demonstrated to be a reliable estimator of non-specific psychological distress and demoralization[525].

### 9.5.6 Analysis strategy

Intention-to-treat analysis will be reported here. Data for participants lost to follow-up was estimated using the last observation carried forward (LOCF) method. SPSS Version 14.0 was used for analyses. Differences in pre- and post-scores were calculated for the primary outcome measures. If the differences were normally distributed, a one-way ANOVA was used to compare the mean differences. For skewed data, a median test of significance was used to compare frequencies of values above and below the median in the 3 groups. A meaningful change in any of the chosen measures was classified as a more than 30% improvement (a relatively high threshold) as a positive ("improved") clinical response. Those whose score declined by 15% or more were classified as "declined". Multiple logistic regression was used for improved/declined in the outcome measures. Demographic data were included in the logistic regression model if they were associated with an improvement with $p < 0.25$. Work related variables, including classification of occupation, were included in a covariate analysis of work stress variables.

## 9.6 Results

A description of baseline the demographic data and also the pre-treatment status of participants is given in Table 9.3.

### 9.6.1 Recruitment and drop-outs

Drop-outs occurred in both groups, with no significant difference between them. Baseline data on drop-outs were compared to those who finished the trial and no significant differences were observed. In total, 250 people fulfilled phone screening criteria and attended an information session about the trial. Of these, 180 decided to participate and were randomized to one of three groups. A summary of the consort data is presented in Figure 9.2. Two people withdrew shortly after randomization, prior to the first class. Recruitment was conducted in the 2002 and 2003 calendar years. The drop-out rate was 32% with no significant differences between the groups ($\chi^2 = 1.65$, df = 2, $p$ = 0.44). The groups had similar characteristics at baseline. A comparison of drop-outs and completers is set out in Table 9.6 and Table 9.7.

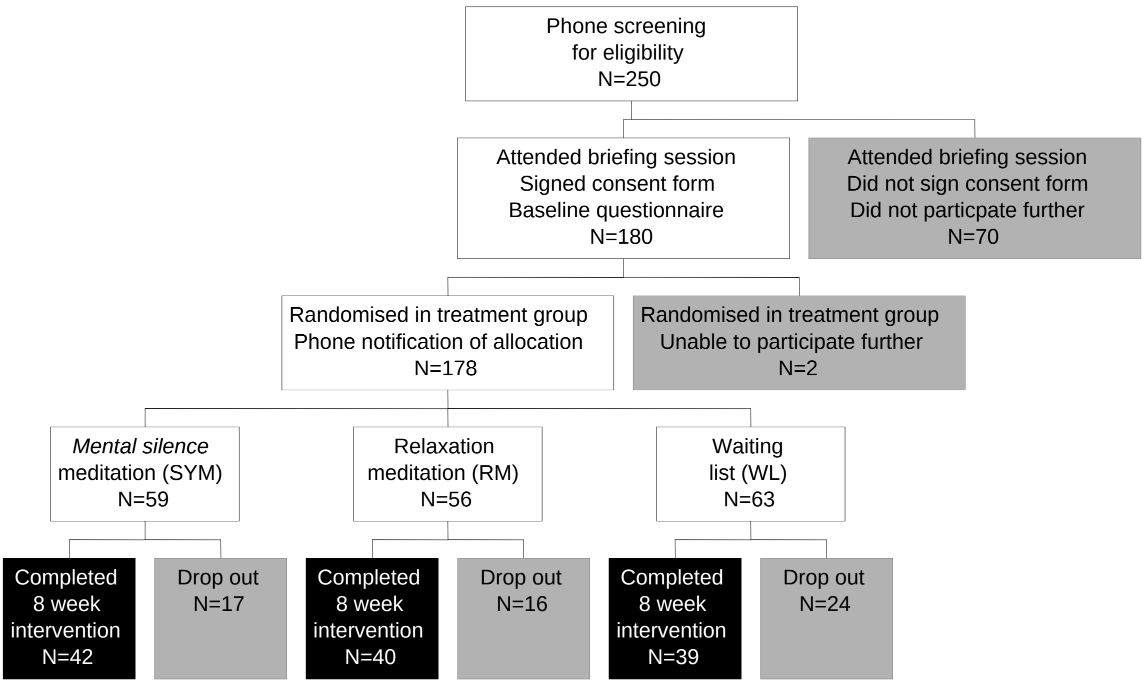


Figure 9.2 Consort diagram for work stress study.

### 9.6.2 Compliance and Drop outs

Average compliance rate was the same in both intervention groups (81% of maximum possible classes). Drop-outs tended to occur earlier in the SYM group (after 37% of classes were attended) compared to the RM group (after 50% of classes attended:) strongly suggesting that credibility and expectancy was very similar in both groups (see Table 9.6 and Table 9.7 for a summary of drop outs versus completers characteristics)

### 9.6.3 Baseline

The GHQ28, the baseline assessment, indicated that the participants as a whole were experiencing considerably more mental distress than the general population. Using the scoring system recommended by its developers, it is generally agreed that a GHQ score of 5 or more indicates high risk of mental health morbidity. The mean score of the reference population from the SERCIS survey was 2.45 (95% CI 2.3–2.6)[260]. The mean baseline score of our sample was 7.5. While the SERCIS survey found that 19.5% of the general population had a score indicating mental health morbidity, our sample had 47% of participants in the same category.

Table 9.3 Comparison of demographic data and primary outcome measures at baseline.

| | **MS** | **RM** | **WL** | ***p*** |
|---|---|---|---|---|
| White collar worker | 76% | 80% | 64% | 0.123† |
| Secondary education | 46% | 57% | 45% | 0.501† |
| Mean age (95% CI) | 42.5 (39.8–45.2) | 41.4 (38.9–44.0) | 42.3 (39.4–45.2) | 0.835†† |
| PSQ (95% CI) | 100.5 (94.6–106.3) | 100.4 (94.6–106.3) | 99.9 (92.8–106.9) | 0.988†† |
| STATE(95% CI) | 41.0 (38.0–44.0) | 41.3 (38.5–44.1) | 40.3 (37.8–42.9) | 0.869†† |
| DD (95% CI) | 14.4 (11.2–17.6) | 14. (12.0–17.7) | 12.3 (9.8–14.8) | 0.384†† |

† $\chi^2$ test †† one-way ANOVA

After adjusting the data for the primary outcomes on the basis of intention-to-treat (LOCF), there was a statistically significant improvement for the SYM group compared to both the non-MS and NT group in the median differences for occupational stress symptoms ($p$ = 0.026) and depressive symptoms ($p$ = 0.019). While an improvement in median difference for state anxiety for the SYM meditation group was noted, it was not statistically significant ($p$ = 0.209) within the intention-to-treat analysis.

Table 9.4 Median difference in pre- and post-primary outcome measures.

| **Median difference for:** | **MS** | **RM** | **WL** | ***p*** |
|---|---|---|---|---|
| PSQ | 37.0 | 22.3 | 17.5 | 0.026† |
| STATE | -15.0 | -8.5 | -9.0 | 0.209† |
| DD | -3.0 | 0.0 | 0.0 | 0.019† |

† $\chi^2$ test

The percentage changes in scores for the 3 primary outcomes were categorized into '1' for improvements of 30% or more and '0' for other changes. There was a statistically significant improvement in occupational stress symptoms ($p < 0.05$) and depressive symptoms ($p < 0.001$). The responder rate outcomes are found in Table 9.5.

Table 9.5 Responder rates post-primary outcome measures compared to pre-measures. A percentage improvement of ≥ 30% was classified as a positive response.

| **% improving 30%+ in:** | **MS** | **RM** | **WL** | ***p*** |
|---|---|---|---|---|
| PSQ | 42.4% | 27.1% | 30.6% | 0.045† |
| STATE | 52.5% | 46.4% | 44.4% | 0.651† |
| DD | 59.3% | 41.1% | 22.2% | < 0.001† |

† $\chi^2$ test

Table 9.6 Comparison of baseline data and test results for those who completed/dropped-out of study by intervention group.

| | Meditation (% drop-out) | | | | Active control | | | | Wait list | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Completed | | Drop-out | | Completed | | Drop-out | | Completed | | Drop-out | |
| Test | Mean | 95%CI | Mean | 95%CI | Mean | 95%CI | Mean | 95%CI | Mean | 95%CI | Mean | 95%CI |
| n | 42 | | 17 | | 40 | | 16 | | 39 | | 24 | |
| Age | 44.0 | 41.1–46.9 | 38.8 | 32.6–45.0 | 42.8 | 39.9–45.7 | 38.0 | 32.9–43.1 | 42.2 | 38.8–45.6 | 42.4 | 37.0–47.8 |
| Primary measures | | | | | | | | | | | | |
| PSQ | 102.1 | 95.0–109.2 | 96.5 | 85.2–107.9 | 99.5 | 91.9–107.2 | 102.6 | 94.1–111.1 | 97.7 | 89.2–106.2 | 103.4 | 90.5–116.2 |
| STATE | 41.5 | 37.9–45.0 | 39.8 | 33.6–46.1 | 40.0 | 36.4–43.7 | 44.6 | 40.8–48.4 | 40.3 | 37.2–43.5 | 40.3 | 35.6–45.0 |
| DD | 15.0 | 11.0–18.9 | 12.9 | 7.1–18.8 | 14.8 | 11.5–18.2 | 15.0 | 9.0–21.1 | 12.4 | 8.8–16.1 | 12.0 | 8.7–15.3 |
| Secondary measures | | | | | | | | | | | | |
| GHQ | 29.0 | 24.8–33.3 | 25.7 | 17.0–34.4 | 27.5 | 23.2–31.7 | 27.5 | 23.0–32.0 | 24.5 | 19.7–29.3 | 28.4 | 21.4–35.4 |
| ORQ | 152.4 | 144.9–160.0 | 142.7 | 130.8–154.6 | 156.3 | 148.3–164.3 | 147.5 | 139.1–155.9 | 143.7 | 137.0–150.4 | 141.1 | 128.0–154.3 |
| POMS | 52.9 | 41.6–64.2 | 41.4 | 21.9–60.9 | 52.6 | 41.9–63.3 | 48.9 | 32.5–65.2 | 41.5 | 32.1–50.9 | 46.4 | 31.3–61.6 |

Table 9.7 Comparison of baseline data and test results for those who completed/dropped-out of study by intervention group.

| | Meditation (% drop-out) | | | | Active control | | | | Wait list | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Completed | | Drop-out | | Completed | | Drop-out | | Completed | | Drop-out | |
| **Test** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** | **n** | **%** |
| Total n | 42 | | 17 | | 40 | | 16 | | 39 | | 24 | |
| Male | 8 | 19.0 | 1 | 5.9 | 9 | 22.5 | 4 | 25.0 | 10 | 25.6 | 4 | 16.7 |
| Business | 9 | 22.5 | 4 | 26.7 | 11 | 28.2 | 5 | 31.3 | 7 | 18.4 | 4 | 20.0 |
| Admin | 4 | 10.0 | 3 | 20.0 | 5 | 12.8 | 2 | 12.5 | 7 | 18.4 | 5 | 25.0 |
| Education | 7 | 17.5 | 1 | 6.7 | 6 | 15.4 | 0 | 0.0 | 4 | 10.5 | 0 | 0.0 |
| Other WC | 15 | 37.5 | 6 | 40.0 | 14 | 35.9 | 8 | 50.0 | 14 | 36.8 | 8 | 40.0 |
| BC | 5 | 12.5 | 1 | 6.7 | 3 | 7.7 | 1 | 6.3 | 6 | 15.8 | 3 | 15.0 |

In the multiple logistic regression analysis for occupational stress symptoms, the occupation variable was included as a covariate. Comparing the NT group with the SYM group showed a significant improvement in the SYM group ($p = 0.034$, OR = 2.64, 95% CI 1.22–5.68). There was no significant improvement in the non-MS group compared to the NT group ($p = 0.546$, OR = 11.266, 95% CI 0.589–2.724). There was no association between improvement in PSQ and occupation ($p = 0.999$, OR = 1.00, 95% CI 0.491–2.033).

In the multiple logistic regression analysis for depressive symptoms, sex was included as a covariate. The SYM group showed a significant improvement compared to the NT group ($p < 0.001$, OR = 5.27, 95% CI 2.38–11.69). There was also a significant improvement in the non-MS meditation group compared to the NT group ($p = 0.029$, OR = 2.441, 95% CI 1.10–5.43). There was no association between improvement in depressive symptoms and sex ($p = 0.373$, OR = 0.701, 95% CI 0.320–1.534) (see Table 9.4).

Table 9.8 Improved and declined responses of intervention groups.

| **Test** | **Meditation** | **Active Control** | **Wait List** | **$\chi^2$ statistic (*p*)** |
|---|---|---|---|---|
| *Primary measures (n)* | 42 | 40 | 39 | |
| **PSQ** | | | | 21.466 (0.00001) |
| Did not improve | 7.1 | 22.5 | 35.9 | |
| Improved 30 or more | 45.2 | 17.5 | 5.1 | |
| **State** | | | | 21.466 (0.00001) |
| Did not improve | 7.1 | 22.5 | 35.9 | |
| Improved 30 or more | 45.2 | 17.5 | 5.1 | |
| **DD** | | | | 16.202 (0.00001) |
| Did not improve | 11.9 | 30.0 | 48.6 | |
| Improved 30 or more | 85.7 | 60.0 | 40.5 | |
| *Secondary measure (n)* | 42 | 40 | 39 | |
| **GHQ** | | | | - |
| Declined more than 15 | 9.5 | 20.0 | 33.3 | |
| Improved 30 or more | 66.7 | 47.5 | 33.3 | |

Statistic used: Mantel–Haenszel $\chi^2$ test (df=1)

## 9.7 Discussion

### 9.7.1 Major findings

From the point of view of this study, the most important finding was that there is a definite differential effect between the two types of meditation that were trialled in this study and that the *mental silence* approach is specifically effective in reducing work related stress and anxiety. This is the first RCT of meditation for occupational stress which clearly demonstrates a specific effect in comparison to a credible control (in this case an alternative definition of meditation) and suggests that SYM, and possibly other forms of meditation that are directed at the experience of *mental silence*, has real potential as a health promotional strategy for managing the widespread problem of occupational stress.

A fundamental challenge for those who design RCTs of meditation is how to develop the behavioural equivalent of a "sugar pill" (to test for the placebo effect). It is argued that one potential solution to this problem was successfully addressed in this study. Since the literature suggests that the non-*mental silence* models of meditation generate predominantly non-specific effects, rather than using it as an intervention, in this trial we attempted to use it as a control. In the context of this study, by comparing the Westernized model of meditation to the traditional *mental silence* model, it becomes possible to control for the important non-specific effects (placebo, credibility, activity and simple rest) in a head-to-head comparison of the two definitions. In this scenario, despite both approaches being "meditative", the *mental silence* approach was shown to have more effect. Moreover, while the non-MS meditation generated some changes that were greater than the no treatment control (which was to be expected), that effect was still significantly less than that of the SYM meditation.

Attempting to explain the differential effects of the two approaches is difficult within the framework of current thinking about meditation. First, current theories of stress management conceptualize SMIs as acting via either a "somatic arousal" mechanism or a "cognitive behavioural" mechanism. Second, predominant opinion in the West seems to have concluded that meditation as acting primarily via the somatic arousal pathway to achieve stress reduction (although this is changing with the increasingly popularity of *Mindfulness* meditation and similar techniques with more cognitive behavioural orientations). Third, the *mental silence* basis of SYM has been clearly described as the experiential construct that characterizes this technique and possibly distinguishes it from the other understandings of meditation, even those used in the West.

The *post hoc* analysis of the data suggests that the *mental silence* intervention does more than simply reduce arousal: PRQ scores diminished more in the SYM group than in other groups. The PRQ is a measure of a subject's perception of resources available to help them cope with demands. This suggests that SYM practitioners may well have altered the way in which they interpreted the various demands placed on them in the workplace. Furthermore, it was found that along with the significant improvements in PSQ and State Anxiety, significant changes occurred in the ORQ in the SYM group compared to the no treatment group. This would seem to suggest that perception of environmental stressors changed in concert with the improvement in the subjective experience of work stress. That in turn suggests that despite the meditation instructional program having had no specific focus on altering cognitive-behavioural patterns, a greater alteration of perceptions occurred in the SYM group compared to the other groups. Moreover, although there are subtle but important physiological differences between relaxation and SYM (explored further in Chapter 10), meditators using the latter technique reported feeling calm and peaceful during meditation and manifested a number of physiological changes consistent with somatic de-arousal. This suggests that *mental silence* to achieve both reduction of somatic arousal and beneficial changes in cognitive behavioural style. This seems to occur despite the fact that its practice does not focus specifically on reducing arousal or changing cognitive behavioural patterns but rather on cultivation of the experience of *mental silence*.

A distinction has been drawn between *Mindfulness*-style meditation techniques and relaxation orientated techniques , because *Mindfulness*:

> is not aimed at achieving a state of clinical relaxation, but more at the cultivation of insight and understanding of self and self in-relationship via the cultivation of a moment-to-moment, non-judgmental but highly discerning awareness[66].

A study by Jain compared *Mindfulness* to relaxation and the waiting list control in an RCT design to assess their effects on distress and mood. At the end of the intervention, the two techniques were shown to be equivalently effective in reducing distress and improving positive states of mind. *Mindfulness* however, was associated with significantly less ruminative and distractive thought compared to relaxation[66]. Although only a single study, it indicates that *Mindfulness* is as effective as relaxation but that it may achieve at least part of its effect by altering cognitions. However it also suggests that the clinical effect of MM, although different, is still no greater than the non-specific effects generated by relaxation-like methods. This is interesting in the context of the proposed mechanism that has been examined with regard to SYM, because I also propose a dual cognitive/somatic effect. However this study appears to demonstrate substantial effects above and beyond non-specific effects, whereas *Mindfulness* in Jain's study demonstrated relatively minor differences. One might speculate that the "skill" of *mental silence* more effectively facilitates greater awareness by reducing distracting and unnecessary mental activity, thereby facilitating greater veridical perception, reduced negative affect and improved vitality, as compared to methods of meditation that emphasize relaxation or mindful awareness. Given these considerations, a head-to-head experimental comparison of *mental silence* and *Mindfulness* orientated meditations could be very fruitful.

Possibly the most interesting implication that arises from this reasoning relates to the way meditation has been categorized as an SMI. Meditation, like relaxation and many other similar interventions, has been described as a passive intervention, directed at mitigating the symptoms of stress rather than its causes. The data and reasoning here however, suggest that *mental silence* has a more significant role than this because it can not only reduce symptoms but may also change cognitive and perceptual patterns. Therefore there may be a role for meditation as a resilience-enhancing, preventative measure as well.

Aftanas' neuro-physiological trials of the same *mental silence*-orientated meditation technique, looked at EEG changes in advanced meditators. They showed that the practice was associated with reproducible electrical changes in the brain and that these patterns correlated with the specifically-defined subjective experience[358 526]. Future research should reveal whether these specific patterns of brain activity have a causal relationship with positive alterations in cognitive style.

### 9.7.2 Strengths and limitations

This study has a number of strengths that indicate significant progress in the field of meditation research. First, this was the largest RCT of work stress undertaken to date and was one of the few studies that made serious attempts to control for non-specific effects. Second, it was one of the few RCTs which has compared two different understandings of meditation. There was no evidence of adverse effects associated with either intervention since both groups generated significantly fewer negative responders than the untreated group (see Table 9.8). As was argued in the introduction, this is an important though often neglected consideration. Instructors established personal contact with each participant and were instructed briefly to enquire about progress and the occurrence of any notable adverse experiences. No participants reported adverse events despite these direct and regular queries. In addition an assessment was made of those participants who experienced deterioration as measured by worsening of scores in the self-report scales, especially the GHQ28. Third, this study provided evidence to suggest that a *mental silence* definition of meditation is associated with specific effect that positively alters both arousal and cognition.

This trial was conducted with full-time workers and despite its arduous nature, the majority of the participants fulfilled the demands of the trial. That, together with the results of the trial, suggests that the intervention is feasible in the "real world" and that the outcomes will be helpful in informing the development of future health promotional strategies aimed at reducing work stress.

This trial has a number of other methodological strengths not specifically described in many other meditation RCTs:

- the investigators, statisticians and data-entry personnel were all blinded to the allocation of the participants
- the participants themselves were also blinded to the hypothesis of the study as well as to the nature of the comparison group
- intention-to-treat analysis was used—this has been used in only one other RCT of meditation for work stress to date

- the outcomes were specifically modelled around work stress issues identified by key labour-force agencies
- unlike the majority of identified trials, this author did not develop, deliver or have any direct/indirect financial interests in the intervention.

In fact the intervention is remarkable in that it is publicly available on a free-of-charge, open-access basis.

A basic limitation of this study which needs mention, results from the fact that the primary research question was whether or not SYM meditation had a specific effect on work stress. This however, is best assessed at the post-intervention point and therefore this trial did not incorporate a follow-up assessment. In the systematic review of RCTs of meditation reported in the introductory chapter, approximately 25% of RCTs featured follow-up assessments. However an even smaller proportion of the work-stress RCTs do the same. Those that do have follow-up data indicate that benefits are maintained mostly by those who continue to utilize the practice regularly. In view of the results from this study, future studies should include a follow-up assessment in conjunction with a measure of self-directed compliance that can be used as a covariate in assessment of long term benefit.

Another limitation is that recruitment through newspapers and other media, evoked responses mainly from participants working in the CBD of Sydney. This means that inferences from the study can only be made on the basis of this particular population.

It has also been suggested that SMI studies tend to attract people with lower levels of stress thereby further increasing measurement error[278]. This can impact on the likelihood of the trial demonstrating the true benefits of the tested intervention since the "subclinical" population effectively dilutes the measurable effects of the SMI. In fact this reasoning has been used to explain why many studies of meditation, behaviour therapies and SMIs, when comparing two or more different approaches to stress management, often demonstrate equivalence of outcome. To determine if this was a real issue we compared the baseline GHQ scores of the cohort with population norms. Analysis indicated that the participants as a whole were experiencing significantly more mental distress than the general population thereby confirming that the sample was clinically appropriate for the study. Further, give that the trial outcomes indicate that *mental silence* orientated meditation is an efficacious option for work stress it seems logical that it may manifest even more profound effects in more highly selected (stressed) populations.

The use of self-report instruments such as the PSQ, DD and STAI in this study may be considered by some as not adequately objective, but it should be noted that the use of such measures is currently considered to be both a reliable and standard approach to studying the effects of interventions for work stress[527]. There is good evidence that these measures are clinically useful and reliable and in fact, although more objective measures might be more desirable in studies like this, there is currently no agreement among work-stress researchers about which objective measures are both reliable and feasible for use in field studies[527]. Ideally, future trials seeking to develop these findings should employ more objective measures. Such measures might include biological parameters, although there is currently little agreement about which biological measures might be reliable indicators of stress. Other objective measures such as workplace performance, absenteeism, cognitive function or other task-based assessments, may prove useful as objective although indirect indicators.

### 9.7.3 Drop-out rates

While all clinical trials suffer from drop-outs, those seen in meditation trials seem particularly high. The systematic review in Chapter 2 reported that average drop-out rate across meditation RCTs was 17%. The drop-out rate in the asthma RCT reported in Chapter 8 was 30%. These were somewhat higher than other similar trials and meditation trials in general. The high drop-out rate in this trial (approximately 30%) could potentially introduce a selection bias in the outcome data. To assess for this possibility, analysis indicated first, that drop-out rates in the two groups were not significantly different although they did occur earlier from the SYM group (mostly in week 4) than they did from the RM group (mostly in week 6). Secondly, there were no significant differences between the drop-outs and finishers in either total scores of the questionnaires nor in the demographic data, suggesting that the rate of drop-outs did not introduce any major selection bias. It may be that the demands of the trial, in combination with the overall constraints relating to the morbidity of the subject, were too arduous for some participants. This trial required participants to attend sessions held after normal working hours at a site separate from their workplace; future trials that are well integrated into working hours and physically located within an organization would probably generate substantially lower drop-out rates.

In Van der Klink's quantitative review of SMI controlled trials, the mean drop-out rate for individual focused SMIs (more or less comparable in nature to the SMI) was 11%. However, it is likely that the majority of these SMIs were conducted in-house during work hours whereas, as pointed out above, this study was conducted in an external location after working hours[517].

## 9.8 Conclusion

This study has a number of features that make it unique and groundbreaking in the field of meditation research. These include:

- choice of methodology
- randomized design (only one other trial specifically describes the method of randomization)
- use of plausible controls to exclude the effects of non-specific factors (only one other trial has compared different approaches to meditation and the outcome of that trial was negative)
- use of widely accepted and validated assessments of work stress and anxiety
- relatively large sample size — even excluding drop-outs, this was the largest RCT of its kind exploring the effect of meditation on work stress ever undertaken in Australia.

In addition, the special consideration of safety and adverse effects issues is a unique aspect of this study and suggests that *mental silence* approaches to meditation may be associated with a lower risk of adverse effects. Finally, perhaps the most significant aspect of this study is that it clarified a popular misconception that has plagued meditation research. From the comparison of two different conceptual definitions of meditation, it became clear that one definition was associated with considerably weaker effects while the other generated a definite effect that was consistently distinct and indeed possibly unique to meditation *per se*.

The outcomes of this trial support the hypothesis of this thesis and suggest that the heterogeneous performance of meditation in RCTs might be explained by the fact that some definitions are more likely to generate specific effects than others. That means that in practical terms, health professionals would be well advised to distinguish between the two approaches to meditation in their clinical recommendations. On the basis of the RCT-based research reported above, there can be no doubt that *Sahaja Yoga* Meditation, centred as it is on *mental silence*, is highly effective as a general strategy for dealing with anxiety and work stress. However, as this is the first trial to identify the differences between two contrasting conceptualizations of meditation, it would be wise to interpret the results cautiously and await future research and replication to verify these findings.

The distinction between *mental silence*-based and relaxation-based meditative practices appears to be useful in identifying potentially efficacious forms.

# Chapter 10. Skin Temperature Change Under *Mental silence* Meditation

## 10.1 Overview

The literature review, of qualitative and quantitative research, gave a strong indication that conventional conceptualisations of meditation were not providing convincing evidence that meditation has a specific effect. The cultural review argued that this was likely to be due to the non-inclusion of *mental silence* in the types of meditation investigated. The series of clinical trials reported on here has provided reasonably convincing data to support this contention. This raises the questions about the mechanism by which *mental silence* asserts its apparent effects on the body and mind. This final empirical study describes a small but important controlled physiological trial which aimed to explore this issue.

There is widespread agreement in the literature that meditation reduces sympathetic activation and increases parasympathetic activation of the ANS, that is, it reduces physiological arousal thereby triggering a characteristic spectrum of simultaneous physiological changes: reduced respiratory rate (RR), reduced heart rate (HR), reduced blood pressure (BP), reduced electrodermal activity (EDA) and increased skin temperature (ST)[249]. Many studies of non-meditative practices such as relaxation, listening to music and sitting quietly have demonstrated the same pattern, leading to the assumption that meditation can be defined merely as a method of rest or relaxation — no different to other methods.

The significance of this study is that it has challenged current thinking by demonstrating that SYM meditators manifest changes that in some part are opposite to that which one would expect to see in participants who simply undergo rest/relaxation. Specifically, while the “relaxation” explanatory paradigm for meditation predicts that meditators’ ST should increase, this study found that it decreases and that this decrease correlates with the degree of *mental silence* reported by the meditator. A review of the literature indicates that this pattern of changes is difficult to mimic consciously. The observations in this study correspond closely with other studies on SYM reported in the “grey literature”[51, 52]. Taken together these findings suggest that the *mental silence* experience may be associated with a relatively unique pattern of physiological activity.

## 10.2 Introduction

### 10.2.1 History of the *Relaxation Response*

In the 1970s physiological studies of meditative practices in Western laboratories clearly demonstrated that meditation involved a characteristic set of physiological changes associated with reduction of autonomic arousal[74]. This led to the widespread assumption that meditation could be characterised as a “relaxation response”[245]. Importantly, many studies of non-meditative practices such as relaxation, prayer, listening to music, sitting quietly and indeed virtually any technique resembling meditation, was likely to demonstrate the same pattern of changes. This led to a second assumption, that all activities resembling meditation such as prayer and even just sitting quietly, are psycho-physiologically equivalent. Benson proposed this as way of demystifying spiritual and religious practices[249, 245]. The characteristic constellation of changes involved in the reduction of physiological arousal has been given various labels such as the “relaxation response”[245], “trophotropic response”[528] “rest and digest”, (the opposite to “fight or flight”).

Until now, no evidence contradicting these assumptions has emerged in the peer-reviewed literature and thus the notion that meditation is equivalent to simple rest has become pervasive. In direct opposition to this line of thought however are two small, psycho-physiological studies from the “grey literature” conducted by Chugh and Rai in India, whose hypotheses were structured around a definition of meditation as a state of *mental silence*. These will be described in greater detail later (see Section 10.2.4).

### 10.2.2 The physiology of stress

Mammals, including humans, have over millions of years evolved the ability to deal rapidly and reflexively with perceived threats to survival using the “fight or flight” mechanism. This ability can be defined as an effective “stress response” and has conferred a considerable survival advantage to this group of animals.

Potential stressors are assessed by higher brain centres (e.g. sensation and memory) to determine whether or not they are threatening. The limbic system of the brain generates an emotional response which is then communicated to other parts of the brain and body. The hypothalamus, under influence of both the limbic system and higher centres, then orchestrates appropriate physical responses dictated by the emotional context of the moment[529]. In humans however, the same stress response can be triggered in situations which, while they do not necessarily threaten survival, occur fairly frequently. Such a typical situation is in the workplace. Repeated activation of the stress response is thought to result in dysregulation of physiology which leads to the body’s own survival mechanisms and this in turn damages health[529]. This phenomenon will be discussed more fully shortly.

Two stress response systems are controlled by the hypothalamus; the sympatho-adrenal response system (SAM, involving the SNS component of the ANS) and the hypothalamic pituitary adrenal axis. These two systems regulate the cardiovascular system, metabolic energy supply and immunological activity which in turn influence both short term survival as well as the long term health status of the body. The fact that the hypothalamus receives a huge variety of complex inputs from different parts of the brain, makes a link between perception, cognitive style, emotion and physical wellbeing theoretically possible[529]. In fact, this reasoning provides the foundation for ideas such as psycho-neuro-immunology and mind-body medicine.

#### 10.2.2.1 The role of the autonomic nervous system

The ANS is part of the peripheral nervous system and its role is to regulate organ function. In order to do this it has two parts that basically act in dynamic opposition, the sympathetic nervous system (SNS) and parasympathetic nervous (PNS) system. Different emotional states cause differential activation of the two parts, which means that "stress" is associated with SNS dominance, while relaxation involves PNS dominance.

The SNS works via the SAM system rapidly to prime the cardiovascular system for "fight or flight" (i.e. to cope with the perceived stressor). Activation of the SAM leads to release of norepinephrine from nerve endings (which exist at almost every organ in the body) as well as stimulation of the adrenal medulla which then releases norepinephrine into the bloodstream. This increases HR, BP (there are SNS nerve endings in the blood vessel muscularis), diversion of blood flow from viscera and skin toward skeletal muscle and CNS. Vasopressin is released to further reduce urine production (in order to maintain blood volume and hence target organ perfusion)[530].

Thus the conventional understanding of the physiology of stress characterises it as a state of autonomic arousal associated with a spectrum of characteristic changes including increased HR, BP, RR, release of catecholamines into the bloodstream and reduced ST. Relaxation methods and other approaches that reduce stress cause these parameters to change in the opposite direction[531].

In an attempt to explain epidemiological associations between stress and health outcomes various pathophysiological mechanisms involving the stress response have been proposed. For example, to explain the association between stress and heart disease, it has been proposed that prolonged or repeated activation of the SNS/SAM system may increase wear-and-tear on blood vessels, thereby promoting development of atherosclerotic plaques and hence cardiovascular disease[507].

#### 10.2.2.2 The physiology of skin temperature

Unlike the understanding of the ANS and the physiology of the fight or flight response the physiology of human cutaneous circulation is less well understood. Charkoudian explains that the human cutaneous circulation is controlled by both sympathetic (adrenergic) vasoconstrictor nerves and sympathetic vasodilator nerves. The sympathetic vasodilator nerves are not active in normothermia but are active during exercise, environmental heat exposure and other causes of increased internal temperature. The vasoconstrictor system however, is tonically active even in thermoneutral environments. The vasoconstrictor nerves innervate arteriovenous anastomoses (AVAs) whose highly variable diameter can effectively regulate blood flow to the skin and hence change ST. Small changes in skin blood flow (say, less than 10% of resting neutral levels) mediated by the vasoconstrictor system can lead to substantial increases in rate of heat transfer to the environment. Subtle changes in skin blood flow rates can thereby provide moment-to-moment maintenance of body temperature[532].

The mechanism by which skin blood flow is regulated is as follows. The sympathetic vasoconstrictor nerves release 2 neurotransmitters: 1) norepinephrine, which binds to postsynaptic alpha1 and alpha2 receptors on cutaneous arterioles and AVAs, and 2) (in the case of noradrenergic vasoconstrictor nerves) a co-transmitter which is yet to be identified. This results in relaxation of AVAs and therefore a shunting of blood towards superficial capillary beds (glomus bodies) leading to a concomitant rise in ST. In this way the vasoconstrictor system is responsible for decreases in peripheral blood flow seen with cold exposure. Similarly, withdrawal of vasoconstrictor activity (i.e. reduced sympathetic tone) leads to substantially increased blood flow to the surface of the skin[532].

Interestingly, glabrous skin is exclusively innervated by sympathetic vasoconstrictor nerves. It is also rich in AVAs whereas non-glabrous skin is not. Thus at normal temperatures glabrous skin can more rapidly alter its perfusion, and hence temperature, than non-glabrous skin[532]. This explains why glabrous ST is potentially sensitive to the effects of psychobehavioural techniques aimed at modifying ANS activity and hence sympathetic tone.

#### 10.2.2.3 The effect of stress reduction strategies on physiology

In a series of key experiments on felines, Hess found that stimulation of parts of their limbic systems led to a decrease in RR, muscle tension, anxiety and frequency of EEG as well as an increase in ST. This he called the "trophotropic response"[528]. These changes have been found reliably to occur in humans in association with a wide variety of self control interventions such as listening to music[533], hypnosis[534], progressive relaxation, meditation as well as simple rest. Obversely, stressors cause increased arousal[76].

In this context a number of studies have used ST as a reliable index of general ANS arousal (i.e. stress response). For example, Ohsuga assessed the effects of a stressful workplace task on physiological markers including heart rate and ST. During the stressful task, heart rate increased and ST decreased significantly[535]. Similarly, Kistler reported that laboratory stressors (such as watching a horror movie) reduced finger tip temperature significantly, concluding that palmar fingertip temperature was a useful indicator of sympathetic arousal[536].

### 10.2.3 The psycho-physiology of meditation

Early uncontrolled or own-control studies of meditation suggested that psycho-physiological parameters such as HR could change quite dramatically in a single meditation session[537 538]and this led to initial enthusiasm for meditation as a potentially unique self control strategy.

Later however, properly controlled studies reported considerably less positive outcomes[246]. For instance, a controlled study comparing TM, general relaxation training and muscle relaxation via EMG biofeedback, demonstrated that while TM significantly reduced parameters associated with arousal (i.e. a significant within-group difference), it was not any more effective than the comparator interventions. In other words, there were no significant between-group differences[247]. Similarly, a study comparing TM to listening to music, found that oxygen consumption and carbon dioxide production dropped in the meditating group (consistent with reports in uncontrolled studies) but that the same change occurred in a non-meditating control group (who simply listened to music) and that there were no significant differences between the two practices[248]. In other words, when meditation was compared to rest, and relaxation or other appropriate controls, it demonstrated minimal differences in both the magnitude and direction of any major parameters. Thus emerged the notion that meditation, contemplation, prayer and rest and relaxation, were psycho-physiologically equivalent.

This type of thinking is typified in the work of Herbert Benson. He argued that Eastern meditative traditions, Western religious practices and even secular activities such as hypnosis or simple rest were essentially the same despite their philosophical or metaphysical differences[245]. He coined the term "*Relaxation Response*" and proposed it as a universal physiological process underlying apparently divergent tasks such as listening to music while sitting in a chair, light sleep, Christian prayer and yogic meditation. His bestselling book, *The Relaxation Response*[245]*,* sets out methods of eliciting reduction of autonomic arousal. Since its publication in 1975 it has sold in excess of two million copies and is now considered a classic of the self help genre[249]. Benson describes the *Relaxation Response* as a secular form of meditation which captures the essentials of the Eastern meditative tradition while discarding the unnecessary religious, spiritual and sometimes cultic paraphernalia that can accompany them.

#### 10.2.3.1 Holmes' seminal review

In parallel with the rising popularity of Benson's publications and ideas, consistent scientific evidence has continued to accrue appearing to confirm the idea of "psycho-physiological equivalence". For instance, in 1984 Holmes published a definitive review of published physiological investigations into meditation and found that the widely held perception of meditation as a superior method for reducing arousal was (spuriously) based on studies that did not use experimental methods[246]. Vigorous debate ensued between enthusiasts and critics of meditation with Holmes strongly and effectively defending his position[74].

A brief critique of the findings of the Holmes review follows:

**Heart rate**: of the 18 experiments he reviewed, none evidenced reliable reductions in HR between meditating and resting participants. In fact 5 trials showed that meditation was associated with increased HR in meditators compared to rest.

**Electrodermal activity**: of 14 trials, only one demonstrated a reliable difference between meditation and rest. However the description of the study raises the possibility that this difference was artefactual.

**Respiration rate**: of 9 trials, 2 demonstrated that meditation lowered *Relaxation Response* more than rest and one experiment showed meditation increased *Relaxation Response* more than rest.

**Blood pressure**: of 5 trials in which BP changes were assessed, only one small trial found that meditation reduced BP more effectively than rest.

**Electromyography**: of 6 trials, 3 indicated that meditation was superior to rest.

**Skin temperature***:* of 4 trials, none showed any difference in STs.

Predictably, Holme's findings generated consternation among the meditation community. Thus in 1987 he revised and updated his review, but found that his conclusions if anything, were strengthened, namely that there is no consistent evidence to suggest any major physiological difference between meditation and rest and relaxation despite the claims of meditation enthusiasts[76]. The cogency of Holmes' observations and arguments appear to have withstood the test of time.

Holmes himself suggested that the available data led to a limited number of possible conclusions:

- meditation is no different to rest and relaxation; or
- meditation may have a specific effect but the measures used to assess it in scientific trials are not sufficiently sensitive to its specific effects; or
- the assumption that “what is being tested as meditation is real meditation” may be wrong.

The findings of reviews such as those of Holmes more or less closed the case on the question about meditation for supporters of Benson’s paradigm of psycho-physiological equivalence. The idea of meditation as a technique which can reduce physiological arousal has not only gained substantial currency in the mainstream scientific community but has also extended well beyond scientific circles and, as demonstrated in Chapter 3, became somewhat entrenched in popular perception.

It is argued in this study however, that the third point is more relevant to the question about whether or not meditation has a specific effect. Furthermore, in Chapter 9 I did in fact execute an experiment to test the differences between conventional notions of (non-*mental silence*) meditation and *mental silence* meditation and demonstrated differences between the two paradigms. Holmes himself points out in his review that in much of the extant research it has been assumed that whatever techniques labelled as “meditation” were sufficiently homogenous to allow inter-trial comparability. However, quite apart from the issue of homogeneity, the cultural naivety of Western researchers raises a question as to whether the independent variable labelled “meditation” bears any resemblance to the notion of meditation as it was originally intended. As was argued in the introductory chapters, the issue of definition is a crucial weakness in Western thought, both scientific and non-scientific, and it is asserted here that Western researchers have in fact failed to provide the necessary definitions.

Holmes and other reviewers justifiably argue that, since much of the therapeutic effects of meditation and meditative practices appear to rely on reducing arousal as a key component of the process, the absence of evidence for meditation having a unique effect on physiology has implications that also extend to the claims for the therapeutic value of meditation. This is borne out by the systematic review in Chapter 2, which clearly demonstrates that the extant RCT database does not contain any convincing evidence for a specific effect.

Thus the search for a unique physiological dimension to meditation and the search for a definition that may facilitate the observation of any such uniqueness are interlinked and are of broad significance.

### 10.2.4 SYM – contradictory evidence from India

Having established the scientific and historical background, it is appropriate at this point to consider paradoxical studies reported by Rai and Chugh. In Rai's laboratory at the Lady Hardinge Medical College, New Delhi, meditating participants manifested the expected reductions in RR, HR, BP and catecholamine production that might be expected. However they also demonstrated paradoxical reductions in palmar ST[51 52]. A comparison of 10 novices with 10 experienced SYM practitioners involved measurements of EEG, HR, BP, GSR, ST (measured in the palm of the hand), RR, serum lactic acid and urinary vanylmandelic acid (UVMA, a catecholamine breakdown product). In this experiment novices were compared with experienced meditators at various stages of novice training (i.e. in week 0, week 4, week 8 and week 12). Substantial within-group differences were observed. HR, RR, Systolic BP and ST all reduced with each 20 minute meditation session and basal (trait) levels also appeared to reduce at each stage. Mean ST in the experienced group dropped by 0.8 °C during a single meditation session whereas it dropped by 0.5 °C after 8 weeks of training in the novice group. Unfortunately, between-group comparisons were not described[52, 53].

Rai's findings were replicated and expanded in a study conducted in the same laboratory by Chugh and reported in his doctoral dissertation[51]. This involved an RCT with 18 female sufferers of severe asthma allocated to either to a SYM group or a waiting list/standard treatment control group. In 9 patients randomised to the SYM group, substantial improvements in lung function and asthma symptoms were observed. In addition to asthma-specific outcomes, Chugh also assessed psycho-physiological measures of stress. He observed differences in serum lactic acid, UVMA, percentage alpha activity in occipital EEG leads, GSR, HR, RR, and ST. Again, the majority of parameters shifted in the direction predicted by the RR[51]. Although direct statistical comparisons were not made between intervention groups and no measures of clinical progress correlated with physiological measures of stress, both Chugh and Rai proposed that there was a causal relationship between the two phenomena.

ST reduction is not only the opposite of what has been reported in other studies of meditation and rest, but it also contradicts the physiological understanding that underlies generally accepted ideas of arousal, relaxation and their theoretical linkage with health.

## 10.3 Strategies to assess physiological effects of meditation

With regard to the physiology of meditation, research designs can be divided into 3 categories:

1) Case studies of meditation featuring small numbers of participants in which there is no attempt to control for confounding variables. While these are useful for generating

hypotheses, they do not provide scientifically valid insights into meditation's purportedly unique effects.

2) Own-control studies use participants in time sequential series (ie ab, aba or similar designs) in which the "a" condition is pre-meditation or non-meditation and the "b" condition is meditation. The "a" and "b" conditions are then compared. These studies have generally demonstrated significant differences (interpreted to be in favour of meditation) but they suffer from substantial limitations because they compare meditation to non-meditation and then assume that any differences are due to meditation, whereas they may in fact be due to methodological factors not specific to meditation at all (such as rest, expectancy, researcher demand and environmental issues). Further, this design is vulnerable to the possibility that one condition might be contaminated by carry-over effects from the preceding condition. A further important consideration applies especially to the case of novices — if the meditator is not sufficiently skilled then they may have difficulty in generating physiological changes and the effects (although potentially real) may not become detectable.

3) Experimental control studies are much more reliable as they involve two independent groups in which one meditates and the other engages in a control activity such as rest. There are however, methodological difficulties associated with this approach as well. First, use of novices (who are introduced to meditation during the trial) may mean that the effects of meditation are not large enough to generate a detectable change. Second, while use of advanced meditators (those who have practiced meditation over many years) may ensure that the necessary magnitude of effect is achieved, the question of selection bias becomes a significant consideration.

An ideal strategy would involve an experiment in which participants are randomly assigned from the same sample to either a meditation or a control group. This approach is rarely feasible however, since it would conventionally require many months or even years of practice before the participants achieved competence. With such lengthy timelines the accumulation of drop-outs may in any case lead to selection bias. Therefore, a reasonable compromise strategy might involve using experienced meditators and comparing them to non-meditators who have either been matched for parameters including interest in meditation, or have been randomly selected from the population. This latter design was selected for the study described in this chapter.

## 10.4 Literature review

A search of the scientific literature was conducted using computer databases (MEDLINE, PsycINFO, Current Contents, Biological Reports and Ovid), the Internet and also paper searches. Key words used were "meditation" and "skin temperature".

A search of the English-speaking scientific literature found 8 controlled trials which had been used to assess the physiology of meditation and its effect on ST. Although none of these had reported reductions in that variable:

- a group of novice TM practitioners showed increases in ST, paradoxically more experienced TM practitioners showed no such change when compared to a group trained in relaxation[247];
- "biofeedback-supported respiratory meditation" led to an increase in digital ST[539];
- a significantly larger increase in digital ST occurred during "mantra meditation" than it did in a resting control[96];

- when progressive relaxation was compared to a Christian-based "devotional meditation," within-group increases were reported but no significant difference between the two groups was described[86].

- 4 other studies reported no significant changes in ST resulting from the use of different meditation techniques, including Ananda Marg[540], a modified TM technique[101], RR[79] and clinically standardised meditation and biofeedback[541].

Importantly, there is nothing in the Western literature which reports reductions in ST as a result of meditation. It should also be noted that no controlled studies were found that assessed the effects of either *Mindfulness* or *mental silence* styles of meditation on ST. A more detailed description and discussion of each of the trials follows.

### 10.4.1 Randomised trials

Fee conducted an RCT in which 54 participants were allocated to one of 5 groups; EMG biofeedback (BF), PMR, meditation (based on TM), a pseudo method (using a set of mood control tapes) and a waiting list control. All groups except for the control group, attended ten 30-minute instructional sessions for 5 days prior to post-assessment testing. In an attempt to control for expectancy, all groups were told that their intervention was effective in eliciting relaxation. Measures included subjective tests (the STAI) and measures of arousal including EMG, HR, GSR, RR and ST (palmar aspect, digit i.e. glabrous skin). Analysis found that the BF and meditation groups were similarly able to reduce EMG more than the other groups. PMR and meditation were similarly able to reduce RR more than the other groups. No other differences were reported, implying that neither HR nor ST were differentially affected by any of the interventions. The authors therefore reported that while BF reduced muscle tension, meditation and relaxation training reduced autonomic arousal. They suggested that the lack of more extensive changes might be due to the fact that the participants' skills were not sufficiently developed within the short training period[101].

Bahrke conducted an RCT involving 75 participants allocated to either *Relaxation Response* meditation (after Benson), vigorous exercise or a control method which involved sitting quietly in a recliner chair. Subjective measures (the STAI) were combined with objective measures of arousal and metabolism, these being $O_2$ consumption, HR, ST (measured just proximal to the wrist, i.e. nonglabrous skin) and BP. Participants were assessed during a single session and it appears that no prior training was involved. While all 3 groups improved in state-anxiety scores, no difference between the groups was observed despite there being considerable differences between tasks. Similarly, while an increase in ST was expected in the exercise group, it was also observed in the meditation and control groups. However, again no significant between-group differences were reported. Heart rate in the meditation and control groups did not decrease during the meditation period, nor was there a significant difference between the two "meditative" groups as a result of either of the interventions. The fact that divergent physiological effects of exercise and meditation, and also the divergent conceptualisations of meditation and simply sitting in a comfortable chair, all produced similar anxiety-reducing effects, highlights the degree to which non-specific effects may bias the outcomes of meditation research[79]. Moreover, as discussed previously, measurement of ST from nonglabrous skin is probably sensitive to changes that may occur during exercise, but is likely to be insensitive to changes associated with psycho-behavioural tasks in thermo-neutral conditions.

Carlson conducted an RCT in which 36 participants were allocated to groups devoted to progressive relaxation, devotional meditation — defined as "a period of prayer and quiet reading and pondering of biblical material (Psalm 23)”, or a waiting list control. Subjective measures comprised self-report questionnaires (TM, STAI, SCL90R and the EAS) while objective measures were EMG, HR and ST (although it is unclear which part of the finger was used). The majority of measures did not evidence any significant between-group differences (including HR and ST). The author did not report on whether HR or ST changed within the groups. Some other significant differences did occur; the devotional meditation group manifested greater decreases in 2 of the 4 EMG measurement sites (frontal and brachioradialis), the anger subscale of the EAS and the anxiety subscale of the SCL90R. While participants “trained” for 6 sessions and practiced daily at home, measures from the second session were compared to measures from the last. The fact that participants were recruited from a Christian college may have introduced a selection bias for participants with more practice at (and allegiance to) devotional meditation than progressive relaxation[86]. Regardless, the results of the study suggest *prima facie* that those attracted to devotional meditation did manifest some physiological changes when compared to those in the *Relaxation Response* group.

Credidio conducted an RCT in which he compared biofeedback, CSM and a sitting quietly condition in 30 female participants. Each subject in both the interventions had an initial training session and then practiced at home twice per day for 7 weeks with the aid of tape recorded instructions. In addition, the biofeedback group received weekly biofeedback training. The control group was asked to sit quietly for 20 minutes twice a day. EMG and ST (from the finger, although it is not clear whether glabrous or non-glabrous skin was used) were outcomes. While EMG activity tended to reduce in all groups, the drop in the CSM group was significantly greater than in the control condition, but not more than the biofeedback condition. There were no significant differences between or within the groups with regards to ST. In fact it can be argued that all groups learned some form of relaxation method, although that the control group learned a rather simple one, may explain the similar performance of the 3 groups. Interestingly, the literature indicates that while biofeedback is often effective in teaching, the ability to modulate a single biological variable, eliciting a specific patterned response in 2 or more variables, has been reported to be difficult if at all possible to achieve. The phenomenon of biofeedback and ST regulation is discussed at greater length later in this chapter.

Delmonte used a complex design to compare the effects of expectancy on novice meditators compared to rest in a sequential, permuted design. He measured SBP, HR, GSR, ST and found that meditation did reduce most paramaters consistent with reduced arousal, including reduced ST as compared to rest. Interestingly he found that the introduction of a positive expectation added an increased effect on most parameters of reduced arousal but not ST[96].

**10.4.2 Non-randomised trials**

It seems logical that experienced meditators would be more likely to be able to generate the experiential and physiological changes associated with meditation at a magnitude sufficient for detection; however selecting them from the wider population necessarily precludes the use of randomisation. This weakens the likelihood that the intervention and comparison groups are truly homogenous. In order to compensate for this comparison participants can be selected to match key parameters. In the case of meditation research, these parameters should include an interest in and motivation to practice meditation.

Cauthen compared 5 different groups; Advanced TM practitioners (with an average of 5 years experience), moderately experienced TM practitioners (with approximately one year of experience), novice TM practitioners (with approximately 7 days experience), novice relaxation practitioners (with approximately 5 days experience) and novice pseudo-meditation practitioners who were given an arbitrary word to meditate on at the beginning of the study. It is unclear whether the novices were matched for any specific parameters. Measures of arousal included RR, ST, GSR and HR during a 20-minute meditation period (no information about specific apparatus or data collection and treatment methods was given). No significant changes in RR occurred in any of the groups during the study. While the experienced meditators had lower GSR at the beginning of the meditation period, no significant changes during the meditation period were reported. ST increased in the novice relaxation practitioners and the novice TM practitioners but no between-group differences were reported. HR decreased in the experienced and median TM practitioners. The authors concluded that the expected "greater arousal reduction with increasing amounts of practice with TM, was not supported". [page ref needed] Indeed this study failed even to report a significant difference between advanced TM practitioners with several years of experience and those with minimal experience practicing pseudo-meditation, let alone simple relaxation[247].

Elson compared 11 experienced Ananda Marg meditators to 11 non-meditators matched for age, height and weight. EEG, GSR, HR, forehead and finger ST (palmar surface of digit) were measured during a 40 minute meditation period. While there were significant changes in EEG and GSR in favour of the meditation group, significant differences did not appear to occur during the meditation period on the other parameters. The difference between forehead (which has few AVAs and is hence thought not to change regardless of arousal[542]) and finger ST (which has been shown to be very sensitive to arousa[536]) tended to become progressively smaller for meditators and larger for the control group, suggesting that while there was greater reduction in the meditation group, this difference did not reach statistical significance[540].

Zeier found that biofeedback-supported respiratory meditation led to an increase in finger temperature. He assessed 10 participants over 2 sessions, one with and one without feedback. Both procedures elicited a trophotropic response — finger temperature increased while skin conductance level, number of skin conductance responses and muscle tension decreased. However, with respiratory feedback and meditation, there was an additional effect, a decrease in respiration and heart rate to an extent not found in the control procedure. It is suggested that exhalation feedback helps to concentrate on the exhalation process and by this means slows respiration rate and as a consequence, heart rate[539].

Delmonte compared 12 TM practitioners to 40 novice meditators using a generic form of mantra meditation. He measured BP, HR, GSR, digital Bl Vol, ST and EMG. Using a complex sequential design he demonstrated that the novice meditators manifested a reduction of ST but that the relatively more experienced TM practitioners did not[543].

Barmark studied a group of 42 participants Of these, 23 were experienced TM meditators (recommended by the local TM centre and who had an average experience of 3 years), while 19 novices who were high in hypnotic sensitivity and were therefore exposed to hypnosis. Matching parameters were not described. Both groups also undertook "sitting quietly" conditions. Participants gave subjective ratings of their experience and also had physiological measures comprised of HR, RR and ST. No significant differences between-group physiological measures were observed, although changes did occur within each of the groups (including sitting quietly) during the measurement session. This suggests several things; first, that experienced TM meditators generate no greater change than that which results from sitting quietly; second, that a short session of hypnosis, even in those susceptible to it, does little more to promote arousal than sitting quietly and third, that prolonged practice of TM (by those with proclivity to meditation) is no more effective in reducing arousal than the short term practice of hypnosis (by those that are susceptible to hypnotic effects)[544].

Finally, although theirs was not a study of ST, Wallace *et al*. reported no significant changes in rectal temperature during TM[538].

These data, along with Rai's and Chugh's, are summarised in Table 10.1.

Table 10.1 Summary of literature review.

| Author | Year | n | Technique | Comparators | Sessions | Physical measures | Skin temperature: Between group differences | Skin temperature: Within group differences |
|---|---|---|---|---|---|---|---|---|
| Fee | 1978 | 54 | TM | EMG, BF, PMR, Pseudo, WL | 10x over 5 d | EMG, HR, GSR, RR, ST | NR | NR |
| Bahrke | 1975 | 75 | RR | Sitting quietly, Vigorous exercise | 1 | $O_2$ consumption, HR, BP, ST (non glabrous)† | NR | Increase |
| Carlson | 1988 | 36 | Devotional meditation | WL | 6x over 2 wks | EMG, HR, ST, | NR | NR |
| Credidio | 1982 | 30 | CSM | BF, WL | 2x/day 7 wks | EMG, ST | No difference | No change |
| Cauthen | 1977 | 35 | TM advanced | TM (intermediate & novice) Pseudo-meditation | 1 | RR, GSR, ST, HR | NR | Increase in novices |
| Elson | 1977 | 22 | Ananda Marg | Non-meditators | 1 | EEG, GSR, HR, ST | NR | No change |
| Zeier | 1984 | 10 | BF supported respiratory meditation | Respiratory meditation without BF | 1 | EDA, EMG, ST, RR, HR | Increase in BF supported group | Increase |
| Delmonte | 1985 | 40 | Mantra meditation +/- positive expectation | Rest | 1x 1 hour session | SBP, HR, GSR, ST | Increase in mantra meditation, | Increase |
| Delmonte | 1984 | 52 | Advanced TM | Novice generic mantra meditation +/- positive expectation | 1x session | BP, HR, GSR, digital Bl Vol, ST, EMG | Increase in novice, generic mantra group | Increase in novices |
| Barmark | 1979 | 42 | TM advanced | Hypnosis novices | 1x session | HR, RR, ST | NR | No change |
| Rai | 1993 | 20 | SYM advanced | SYM novices | 4x over 12 wks | HR, RR, ST, UVMA, alpha EEG, BP | NR | Decrease |
| Chugh | 1987 | 18 | SYM | Pseudo- meditation | NR over 12 wks | HR, RR, ST, UVMA, alpha EEG, BP | NR | Decrease |

† measurement of ST from non-glabrous skin is probably insensitive to changes associated with psycho-behavioural tasks. NR=not reported

The extant Western scientific evidence thus suggests little physiological distinction between the effects of meditation and other methods of reducing physiological arousal. Where there was a ST change, whether in a control or an experimental group, it tended to be an increase in ST, as would be expected from the "psycho-physiological equivalence" paradigm.

With this in mind a preliminary investigation was designed to determine whether the reported reduction in ST in Rai's SYM trials was replicable and to explore its relationship with the extant data on the physiological effects of meditation.

## 10.5 Method

Advanced meditators were compared with a convenience sample of non-meditators of similar age and gender with a strong interest in meditation who were willing to participate in a study about the effects of relaxation and meditation. The study was approved by the South Eastern Area Health Service Ethics committee.

Sixteen SYM practitioners with between one and 25 years of experience of daily meditation and 10 novices with no experience of meditation, were recruited by advertisement in university newsletters. Exclusion criteria included regular alcohol, tobacco or recreational drug consumption, history of mental illness, current physical illness of any kind, history of major physical illness and consumption of any regular prescription medication. In order to control for the most important factor — motivation — the novices were specifically selected for a high interest in learning meditation. Potential participants were promised that after the study they would be given a series of free instructional lessons in meditation.

Participants sat in a moderately sized, quiet, climate-controlled room in a comfortable chair. The participants were connected to the various sensors and then allowed to become accustomed to the environment for 30 minutes, after which a research assistant asked them if they were ready to commence the data collection session. When the participants indicated such, the lights were dimmed and the volunteers commenced either meditation or relaxation by closing their eyes.

They were asked either to meditate or relax as best they could for the next 10 to 15 minutes. This time frame was selected because in preliminary trials it was found that meditators had difficulty sustaining the *mental silence* state for much longer in the laboratory environment. At the end of the session, participants opened their eyes to indicate that they had finished. The use of brief meditation sessions in psycho-physiological research is relatively common in the literature. Takashati demonstrated impressive EEG changes in Zen meditators limited to 15 minutes or less of meditation[545]. Similarly, Arch studied the effects of a 15 minute "focused breathing" meditation modelled on *Mindfulness* methods in participants new to meditation, and found that the meditators manifested a number of significant effects in comparison to controls. Finally, although participants in studies such as the asthma RCT in this thesis were instructed to meditate for only 10–20 minutes twice per day, this seemed sufficient to generate significant outcomes. Using a brief meditation period has a number of practical and scientific advantages in psycho-physiological studies of the acute effects of meditation, as it minimizes the confounding effects of factors that can act over longer periods of time. In this study, both participants and researchers agreed that a longer meditation session might not be much more successful than a brief one.

ST was measured with a thermistor sensor affixed to the palm of the non-dominant hand. The thermistor was calibrated and accurate to $0.1^{\circ}$C. HR was measured by a standard WR413 pulse oximeter. The change in ST from baseline at each 60 second interval was calculated. A pulse oximeter with a sensor was placed on the middle finger of participants' dominant hands. HR was recorded every 7 seconds and ST every 60 seconds.

Participants were asked to give a general rating with regard to how relaxed they felt at the beginning and at the end of the relaxation/meditation session using a linear analogue scale. For the meditators the minimum value on the scale equated with normal thinking activity and the maximum value equated with profound *mental silence*.

There were no statistically significant differences in age, the relative proportions of males/females or baseline ST and HR (see Table 10.2) between the two groups.

Table 10.2 Baseline values.
Age in years, HR in beats per minute, ST in degrees Celsius.

| | **Controls** | **Meditators** | ***p*** |
|---|---|---|---|
| Sex (% male) | 63.6% | 62.5% | 0.952 ($\chi 2$ = 0.004, df = 1) |
| Mean Age (sd) | 28.5 (7.8) | 29.0 (8.2) | 0.887 (t = 0.144, df = 25) |
| HR (sd) | 69.9 (15.2) | 72.3 (9.5) | 0.635 (t = 0.481, df = 23) |
| ST (sd) | 31.8 (1.4) | 30.9 (2.4) | 0.290 (t = 1.08, df = 24) |

## 10.6 Analysis and results

As the meditation session progressed, the mean ST of the two groups changed; that of the rest-group increased compared to the baseline, whereas the SYM group's mean ST decreased (see Figure 10.1).

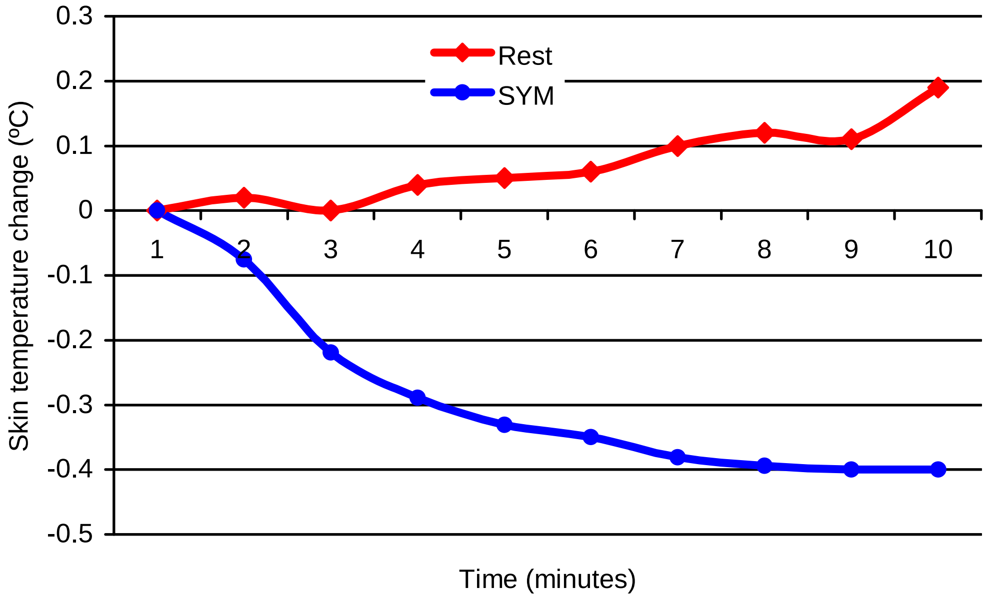


Figure 10.1 Skin temperature change (mean for each group) during meditation compared to baseline.

As this was an exploratory study, the primary aim of analysis was to determine the direction of ST change that each subject manifested and in terms of this, whether there was any difference between the 2 groups. Therefore the number of participants whose ST increased or decreased in relation to the baseline in each group at the end of the meditation session, were compared.

At the 10 minute time point 13 of the 16 meditators manifested a reduction in ST compared to their baseline value and 3 manifested an increase. In contrast, in the rest group only 2 manifested a reduction, 7 manifested an increase in ST and one manifested no change.

In line with the hypothesis and to facilitate statistical comparison, participants whose ST decreased during the meditation session as one category (i.e. comprising those whose ST changed in the opposite direction to that predicted by the reduced arousal model of meditation) were compared with participants whose ST either increased or did not change. These comprised those whose ST changed in the same direction predicted by the reduced arousal model of meditation and the extant literature. When the relative proportions of participants in each of these categories was compared, 81.3% of meditators manifested a decrease in ST whereas only 20% of the rest participants manifested a decrease in ST. As is evident in Table 10.3 below, statistical comparison using Chi-Square tests between these two categories and between the two groups showed significant differences between the two groups ($p = 0.003$). HR did not change consistently in any direction in either of the groups.

Table 10.3 Cross tabulation of groups by difference in ST response.

| Group | Number of participants (% of group) | |
|---|---|---|
| | **ST decrease** | **ST increase** |
| SYM | 13 (81.3%) | 3 (18.8%) |
| Rest | 2 (20.0%) | 8 (80.0%) |

All participants in both groups indicated that they felt more relaxed/meditative at the end of the session than they did at the beginning. The degree of *mental silence* on the linear analog scale correlated significantly with degree of ST reduction in the meditator group ($r = 0.65$, $p < 0.05$). In contrast, the degree of relaxation experience did not correlate significantly with the degree of ST increase in the rest group.

## 10.7 Discussion

In this study, both groups of participants performed tasks that ostensibly resembled relaxation and that would be conventionally explained as conducive to reducing arousal. Moreover, both groups reported subjective experiences which are consistent with reduced arousal. The reduced arousal paradigm of meditation and indeed the empirical evidence, predicted that both groups would manifest similar physiological changes, with

ST increasing. This study found that ST moved in opposite directions despite the fact that the HR changes in the two groups did not differ across the duration of the task — the rest-group's ST changes were consistent with reduced arousal, but those of the *mental silence* group were not. Thus, the changes produced by the meditation seem to reflect a pattern of selective arousal/de-arousal that is distinct from simple rest. Importantly, the findings of this study are in agreement with the reports of Rai and Chugh. Taken together, these 3 studies provide reasonable evidence to suggest that a *mental silence* orientated meditation may be physiologically distinguishable from rest.

EEG studies suggest that different approaches to meditation have different neurophysiological bases. For example, a study of advanced Tibetan Buddhist meditators reported large increases in 40Hz gamma power in the meditative state[546] and it was also advanced Tibetan meditators who Benson described as manifesting considerable increases in ST. In contrast, Aftanas et al. conducted a well designed study of EEG on novice and advanced SYM practitioners. During meditation substantial changes in midline alpha-theta power, rather than gamma power, distributed more or less symmetrically in the fronto-parietal parts of the brain, occurred in a pattern that was significantly repeatable from subject to subject. Most significantly these changes correlated significantly with the participants' self-reported experience of *mental silence* and were more pronounced in the advanced meditators. Thus the MS state of SYM was associated with changes in central nervous system activity that are both reproducible and correlate with subjective experience of meditation[318, 358]. This adds further support to the idea that MS may be as much a biological phenomenon as it is a conceptual one. In other words, MS may even have a neurophysiology unique to that state of consciousness.

Goleman proposed that meditative styles might be classified into two types, *Mindfulness* and concentrative, depending on how attention is directed during meditation[547]. While Andresen suggested that these two categories might be better understood as two poles on a continuum upon which most other meditative techniques can be positioned[548]. On the other hand, Cahn acknowledged the limitations of this taxonomy and suggests that a different way of categorizing techniques may be according to the underlying experience that the various techniques aim to elicit[549]. In the context of Cahn's proposition, *Mindfulness* and SYM may belong to similar places on the physiological and clinical spectrum since both compel the subject to attend to mental content, regardless of their state of physiological arousal, whereas relaxation-orientated methods might belong to an entirely different part of that spectrum. On the other hand, the possibility that *mental silence* orientated forms of meditation, such as SYM, might be associated with relatively unique physiological changes suggests that a taxonomy based on the physiology of different states of consciousness may be possible.

In general, the mechanism of action provoked by meditation is thought primarily to involve its ability to reduce stress. There are two main theories about how this happens. First, that it reduces somatic-arousal[245] thereby reducing the reactivity of the individual to environmental stressors and, second, that it alters the individual's cognitive appraisal of and perceived self-efficacy with regard to stressors[518, 550]. By eliminating background mental noise, the meditator probably increases internal and external awareness and therefore somehow achieves more veridical perception, reduced negative affect and improved vitality and coping capacity, as is hypothesized with MM[252]. The findings of this study, in conjunction with those of Aftanas et al., suggest that the *mental silence* experience may be associated with a specific pattern of activity in both the CNS and

ANS which is more complex than simple reduction of arousal and yet different from the cognitive changes seen in association with MM.

Thus, although Eastern and Western ideas of meditation may seem externally similar (as might meditation and relaxation) and may initially share a number of physiological similarities, the point of both physiological and philosophical divergence between the two paradigms may be with the onset of the *mental silence* experience.

Practitioners of this technique described a subjective sense of cooling of the hands during meditation. The objective ST measures appear to support this. While the ST changes appear real, it is not clear to what degree this is the result of suggestion/self regulation as opposed to meditation specifically. A review by King[551] reported that biofeedback has been shown to induce both increases and decreases of ST. Although the changes induced by biofeedback are generally small and more commonly involve increases in ST, reductions in ST are also consistently achievable. In addition, the empirical evidence for reducing ST by self regulation (unassisted by biofeedback), although less consistent, also suggests that such changes might be achievable. The fact that the meditators in this trial were long-term practitioners, raises the possibility that they may be a subgroup highly selected for their ability to voluntarily induce such changes. In fact, a sociological analysis of the SYM movement[552] suggests that the subjective reports of cool sensations on the hands may be the result of an extensive socialisation process, which might bring about a set of expectations and demands that more or less act in the same way as formal instruction in biofeedback. Credidio[541] attempted to produce a patterned biofeedback response that mimicked the multiple changes associated with reduced physiological arousal. The study failed to produce a combined EMG reduction and ST increase, suggesting the difficulty in achievement of the full constellation of changes in multiple parameters reported in the trials of Rai, Chugh, Aftanas and also in this study.

A potential physiological distinction between modern and traditional understandings of meditation also explains some other discrepancies between popular, stereotypical ideas about meditation and traditional understandings. For instance, the common contemporary perception of meditation is that the stereotypical meditator sits quietly, reduces their physiological arousal as a result of practice of meditation and experiences whatever may result from the prescribed practice. Alternatively, in the classical view of meditation, the meditator is experiencing *mental silence*, the *sine qua non* of meditation, and although sitting quietly is a common association, the same state may arise in ecstatic dance (e.g. the whirling dervishes of Turkey's *mevlana Sufi* sect), song (devotional music is commonly associated with meditative ecstasy) or other activities characterised by a distinct level of physiological activation.

Interestingly, an association between meditation and the subjective sensation of coolness can be found in some traditional Eastern texts. For example, in the Sikh text *Guru Granth Sahib* the importance and effects of meditation are described frequently and there are a number of instances in which mental tranquillity, even transcendent experience is associated with a sense of coolness:

> The mind and body are colled and soothed, by the touchstone of truth.
> p152, Line 12 Guru Nanak Dev[553]

> The Name of the Lord, Har, Har, is soothing and cool; remembering it in meditation, the inner fire is quenched. p399, Line 1 Guru Arjan Dev[553]

> Remembering, remembering God, the Lord Master in meditation, my body, mind and heart are cooled and soothed. p681, Line 9 Guru Arjan Dev[553]

> My mind and body have been cooled and soothed, meditating on God, most worthy of meditation. p814, Line 6 Guru Arjan Dev[553]

> Remembering the Lord in meditation, you shall find bliss and peace forever deep

> within, and your mind will become tranquil and cool.
> p860, Line14 Guru Ram Das[553]

A phenomenological, experiential definition, such as the idea of *mental silence* may be more successful in capturing a wider spectrum of meditative styles and uniting them with a consistent underlying feature.

## 10.8 Conclusion and implications

This study is unique in that it compares the physiological differences between two sharply contrasting taxonomies of meditation. It provides preliminary support for a distinction between *mental silence* orientated meditation and rest with promising implications for the field of meditation research. Although it does not offer a direct explanation as to why the clinical outcomes in comparative trials of SYM are different to those of conventional meditation, it is logical to suggest that the clinical differences may be related to differences in physiological effects.

Larger studies with both multiple control groups and multiple measures are needed to further assess, first, whether or not the changes in ST are a specific effect relating to the experience of *mental silence* and second, the precise relationship between these physiological changes and the apparent therapeutic effects reported in other studies of *mental silence* orientated meditation.

Without overstating the significance of the findings of Rai, Chugh, Aftanas and this study, together they provoke some broader considerations, since the specific effect that they appear to report will require a radical rethink about the various preconceptions that have developed about meditation in the Western scientific community. Furthermore, the idea that the state of *mental silence* is associated with a specific set of physiological features has unique implications for the nascent field of consciousness research.

# Chapter 11. Adverse Effects Associated with Meditation and Contemplative Practices

The National Centre for Complementary Medicine made the following statement about the safety of meditation:

> Meditation is generally safe. There have been a small number of reports that intensive meditation could cause or worsen symptoms in people who have certain psychiatric problems, but this question has not been fully researched. Individuals who are aware of an underlying psychiatric disorder and want to start meditation should speak with a mental health professional before doing so. [554]

However it is important to recall Ospina's concluding statement from her review[10]:

> Many uncertainties surround the practice of meditation. Scientific research on meditation practices does not appear to have a common theoretical perspective and is characterized by poor methodological quality. *Firm conclusions on the effects of meditation in healthcare cannot be drawn based on the available evidence*.

That is, despite the very positive perception enjoyed by meditation, there is little evidence for a specific effect. While this is in itself not necessarily problematic for consumers, the risk versus benefit perception might change considerably if consumers became aware that there is a growing body of literature describing both serious and non-serious adverse reactions[555] which some might perceive as contradictinig the reassuring tone of the National Centre for Complementary Medicine's statement. These experiences range from mild increases in anxiety (the opposite of the desired effect)[488] to more severe symptoms such as epileptiform EEG changes[556], antisocial behaviour[557], depersonalization[558] and occasionally even psychosis[559, 560].

> A good deal of the time, the practice of *Mindfulness* may mean being with and observing states of mind and body that are extremely painful or dysphoric, including fear, loneliness, anger, bodily discomfort, impatience, boredom, and the like. These are to be experienced as best as one can with the same non-judgmental attitude as pleasant or neutral experiences.[297]

Given that anthropologists describe the phenomena of transient psychosis, such as mystical trances[561], in many non-Western cultures, Stanslav Grof proposed a modern explanatory framework for psychosis as a transpersonal crisis when he stated that "…traditional psychiatry does not recognize the difference between mystical and psychotic experiences and suggests that spiritual emergencies (transpersonal crises) can actually be therapeutic and transformative"[562]. Indeed, it has been reported that TM teachers generally felt that meditation-provoked seizures (should such a phenomenon actually exist) might be interpreted as a positive indicator of progress and would typically recommend more meditation in such circumstances[563 564]. Although most clinicians would find it difficult to agree with the implications of these perspectives, it is an acknowledgement that such phenomena may well be occurring in modern Western society in association with meditation and other new age practices.

In contrast to this are the conclusions from extensive reviews of the scientific literature on the question about whether or not meditation is effective. For example, from the review presented in Chapter 2 it was clearly evident that there is no convincing evidence to suggest that meditation has a specific effect. At least one other review agrees with this conclusion[10]. In light of this, and the distinct possibility that meditation, or at least some techniques of meditation, are associated with adverse effects, a close examination of the literature is imperative for us to develop a clear understanding of the "risk benefit ratio" associated with this phenomenon.

An extensive search of the scientific literature was undertaken. Computerized databases (MEDLINE, PsycINFO, Current Contents, EMBASE, Biological Reports, CINAHL) as well as Internet and paper searches were used to identify adverse effects. Keywords "adverse effect", "side effect" and "meditation" were used. Both idiosyncratic and dose-related adverse effects associated with the practice of meditation were described in approximately 25 reports. Although the systematic review in Chapter 2 specifically excluded *Qigong* a number of reports relating to this practice emerged during the search. Moreover, given that that some reviews, including Ospina's, did actually include *Qigong* as a meditation technique, the search was expanded to include this term. These descriptions and data are summarized below.

## 11.1 Historical

Traditional meditation texts often warn of the potential negative effects of meditation. These can arise as a result of incorrect preparation, instruction, practice or supervision. Traditionally speaking, misconceptions about the ultimate goals of meditation have often led to unfortunate consequences. Popular myth and legend describe how the use of meditation in attempts to invoke supernatural powers and extraordinary capabilities have typically lead to Faustian consequences.

Some meditation traditions describe common patterns of adverse effect. For example, the Zen tradition describes unpleasant experiences associated with meditation, that can be terrifying and are not unlike visual hallucinations with delusional content[565]. Similarly, St. John of the Cross described the false enchantments that may tempt the aspirant in prayer, warning that "devils may come in the guise of angels"[566]. This would seem to be in the same genre as the saying: "If you see the Buddha on the road then kill him". That is, that harmful events during meditation can occasionally take the form of what the novice might mistake for spiritual progress.

## 11.2 Case reports

French[567] reported on altered reality-testing and behaviour in a 38 year old woman after she had experienced several weeks of TM. Psychological assessment revealed mild thought disorder, dysphoria and other psychosis-like features.

Lazarus[559, 568] described several cases in which psychiatric problems such as depression, agitation and schizophrenic de-compensation were observed. These included a 34 year old woman who became suicidal and a 24 year old woman who experienced severe de-personalization, apparently as a result of TM. He also suggested that participants who failed to experience the benefits of meditation might experience a sense of failure and anxiety rather than the enhanced self-understanding that they perhaps were looking for.

Kennedy[558] described 2 cases in which de-personalization appeared to be triggered by meditation. The first case developed after the subject used breathing and meditation exercises described in a book on self-development[569]. The experience continued for at least 16 months. The second case involved the use of meditation techniques recommended by the Arica Institute. While at first pleased with the experiences, the subject soon found he was unable to maintain a job and needed professional help.

Vanderkooi[570] recounted 3 cases of Westerners who, because they were experiencing the negative side effects of Buddhist meditation, had to be counselled and taught how to integrate their negative experience into seeing them as positive progress.

Xu[571] described and discussed the adverse effects of *Qigong,* which has been described as both a therapeutic practice as well as the "Chinese equivalent of Indian meditation"[571]**.** The clinical consequences of inappropriate use of this technique has been described as the "Quigong deviation syndrome", which has become a diagnostic term "now used widely in China" and is associated with a range of somatic and psychological disturbances[571]. The commonest somatic symptoms include headaches, insomnia and discomfort caused by abdominal distension, while common psychological symptoms include anxiety, agitation and depression. Extreme psychological symptoms can include uncontrollable behaviours, psychosis and suicide. Importantly, normal administration of *Qigong* can also be associated with effects such as muscle jerks and tremors, an abnormal sense of warmth, of cold, itching, numbness and *formication* More extreme symptoms can include, disorientation, de-personalisation-like experiences and pseudo-hallucinations[571]. Xu implied that "clinically acceptable" adverse effects cease when the treatment ends, whereas clinically unacceptable effects continue after treatment is finished and are often uncontrollable.

Two cases are described in Xu's report. The first involved a 22 year-old man who sought treatment for lumbago and experienced the onset of adverse effects while undertaking self-teaching of the Wu Qin Xi form of *Qigong*. He experienced anxiety, physical pain, psychosis and suicidal thoughts. Some relief was experienced as a result of treatment by a *Qigong* master, but symptoms recurred. These included hearing the "voices of evil spirits", uncontrollable behaviour and attempted suicide. Some months later he developed similar symptoms when his family would not allow him to do his *Qigong* exercises. He attempted suicide and was admitted to a psychiatric institution. After ECT treatment he was discharged and was subsequently stable. The second case involved a 44 year old male who developed delusional psychosis after practicing *He Xiang Zhuang* (a form of *Qigong*) for a cervical disorder.

Hwang described an important part of the management strategy in a patient who experienced a psychotic reaction to *Qigong* treatment: "Reformulating her illness as a culturally normative response to practicing *Qigong* during a weakened state helped her feel less stigmatized and created a cultural bridge that increased treatment adherence and understanding"[572]. Shan described a similar scenario[573]. While Lim observed in the management of a "57 yr-old married Chinese-American male who presented with a 3-wk history of auditory hallucinations and delusions following practicing *Qigong*". The hallucinations "consisted of voices of supernatural beings communicating with him regarding how he should practice *Qigong* and delusions that he was contacting beings from another dimension...A diagnosis of schizophreniform disorder versus schizophrenia, paranoid type, and was treated with low doses of haloperidol". Importantly, it was unclear to the management team "whether haloperidol or the cessation of the practice of *Qigong* was responsible for these improvements"[574]. Chan described 3 cases of psychosis. In 2 of these cases, sleep deprivation arising from a misinterpretation of meditation instruction was proposed as an explanation while in the third case, the subject appears to have been undergoing withdrawal from addiction to a drug[561].

Yorston described 2 separate episodes of mania after meditation (yoga and Zen) in a 25 year old woman[575]. Kujpers describes a single case study of a male who developed an acute, transient psychosis with polymorphic symptomatology[560].

Sethi also described the relationship between meditation and psychosis where psychotic exacerbation in 2 male patients with underlying schizophrenia appears to have been triggered by meditation[576]. A similar report was provided by Trujillo[577] and also by Walsh[578].

Naveen proposed that although yoga and meditation might be associated with the precipitation of psychosis in certain circumstances, a highly selective and cautious application of meditative techniques can also be helpful to those suffering from psychosis[579].

## 11.3 Surveys

In his random survey of 23 students of yoga and meditation, Kennedy[558] found that all but one of them had experienced some form of mild to moderate de-personalization and/or de-realisation. Most of the experiences involved feelings of unreality or a sense of altered reality for a few seconds. Experiences mostly occurred in the presence of a meditation teacher and none of the respondents considered their experiences as abnormal.

West[580] conducted a survey of 83 TM practitioners to ascertain the nature of their experience. He used an open-ended questionnaire and a structured analysis strategy to break the responses down into broad categories. While many meditators described positive and pleasant experiences, some of the experience categories suggested less beneficial sensations, including visual and auditory perceptions (3.1%) and abnormal physical perceptions (5.4%).

Debate has recently refocused on the parallels between certain forms of meditation, particularly TM, and epileptiform activity and hence the potential risks that meditation might pose to epileptics seeking help from meditation or possibly even to those who may have no prior history of epilepsy[563, 581]. These are considerations primarily provoked by the publications of Persinger, discussed below.

Persinger examined a sample of 221 university students who had learned to meditate and compared it to 860 non-meditators. He found that the meditators were significantly more likely to experience a "sensed presence" or "ego-alien intrusion", a transient intrusion of the right hemispheric equivalent of the left hemispheric sense of self. Persinger concluded that this placed people with fragile self concepts (such as those with borderline, schizotypal or dissociative personalities) at risk of psychiatric adverse effects[582]. In the same survey, Persinger found that meditators reported a significantly wider range of “complex partial epileptic-like signs”. Moreover, meditators were more likely to experience “vibrations”, “hearing one’s name” and “paranormal phenomena”. Number of years of meditation practice were correlated with a number of these features[556]. In another remarkable case study, Persinger described close EEG similarities between TM meditation and glossolalia[583]. More recently, in another comparative survey between Dharma meditation practitioners and carefully selected non-meditating controls, Persinger found no differences in the incidence rates of complex partial epileptic-like experiences[584].

In 1971, Otis conducted a study at Stanford Research Institute to assess the possible negative effects of TM. He sent a mail survey to more than 1,000 people who had participated in a TM instructional program for local students and approximately 47% responded. Dropouts from the program reported significantly fewer complaints than did experienced meditators. Effects were positively correlated with the length of time that participants had been practicing meditation. Long-term meditators reported a range of effects. These included antisocial behaviour (13.5%); anxiety (9.0%); confusion (7.2%); depression (8.1%); emotional instability (4.5%); frustration (9.0%); physical and mental tension (8.1%); tendencies to procrastination (7.2%); restlessness (9.0%); feelings of suspicion about others (6.3%); intolerance of others (4.5%); and desire for withdrawal from daily life (7.2%). He concluded that the longer an individual practiced TM, the greater the likelihood that he or she would experience adverse effects[296].

## 11.4 Observational studies

Shapiro observed the effects of *vipassana* meditation on a small group of meditators and found that while most participants experienced positive results, a small number of meditators experienced distinctly negative states[488].

A study commissioned by the German government to assess the effects of TM on youth created controversy when it reported that the majority of participants observed during the trial experienced psychological problems, worsening concentration and variety of physical complaints[557]. Publication of the study was unsuccessfully contested by the TM organization in the German courts.

Glueck studied 110 participants and reported that the practice of TM appeared to release repressed subconscious impressions. A small proportion of participants reacted adversely to this experience[585]. Heide found that 54% of anxiety prone participants demonstrated increased anxiety during mantra meditation modelled on TM[586, 587]. Otis observed a cohort of 62 novices who tried TM and concluded that it was not suitable for those with serious emotional problems[588].

## 11.5 Conclusion

Although many of these findings are anecdotal cases studies, incidental findings or unexpected outcomes it is clear that meditation is not a universally benign intervention and that it can be associated with both serious and non-serious adverse reactions. Some studies, such as those of Otis[296] and Persinger[556, 582], suggest a dose response relationship whereas others, such as that of Xu[571], suggest an unpredictable idiosyncratic effect.

What does this mean for the average health professional who has a duty of care to minimize risk to individuals who may be candidates for meditation? The answer is not clear. TM and *Qigong* seem to be particularly associated with adverse effects in the literature. This may be due to its immense popularity of TM in the West and of in China and other countries and hence over-representation in the literature. TM is taught on a commercial basis, with a basic introductory course costing in the region of AU$2,000 and further advanced courses costing proportionately more. *Qigong* is not a commercialized technique but is often used by natural therapy practitioners who do charge for such services. The prospect of financial reward certainly creates a conflict of interest that may reduce the likelihood that those at potential risk of adverse effects might be advised not to learn or to desist by instructors/practitioners.

Clinical trials of meditation should systematically monitor for adverse effects and report both mild and severe occurrences.

When decisions about a new intervention are being made, the net clinical benefit needs to be carefully assessed by balancing reported benefits and side effects. The CONSORT checklist includes reporting of such adverse events as item 19 of the CONSORT statement[589]. Only proper and systematic reporting of side effects will allow adequate assessment of the potential net benefit of any intervention.

The International Conference on Harmonisation adopted a definition of adverse events (AEs) designed to facilitate systematic recording of all untoward events occurring in clinical trials. An AE does not necessarily require a plausible association; rather its definition requires only that it may be reasonably associated with the treatment. AEs can be non-serious or serious (SAE). SAEs are defined as any adverse event that results, in requirement for hospitalization, results in persistent or significant incapacity, causes a congenital anomaly, is life threatening or results in death[590]. Since many research trials are blinded, data and safety monitoring boards have been proposed as mechanisms to monitor safety of trial participants[591].

Many trials report AEs with insufficient detail to allow meaningful analysis and consideration[592, 593]. While guidelines for the reporting of AEs in general and for particular classes of drugs are now emerging, there are none for CAMs, let alone meditation. Therefore, in order to determine whether guidelines for meditation AEs are necessary and for what pattern of AE the guidelines should be prepared, a review of adverse events associated with meditation is necessary.

In view of the seriousness of some of the reactions described above it is questionable whether all forms of meditation can be viewed as "generally safe for general consumption". Moreover, given that recent reviews of meditation have clearly demonstrated a lack of convincing evidence for a specific effect, the importance of developing a comprehensive understanding of meditation's adverse effects, and the risk to both healthy and unwell populations is of considerable importance. I propose that a more cautious set of clinical recommendation guidelines be considered until more thorough, independent studies are done.

A simple guideline may be that candidates should be recommended to experienced instructors with health professional backgrounds and that referring clinicians should screen for history/susceptibility to serious mental illness. It may be also appropriate to avoid recommending methods in which commercialization or similar considerations may lead to a conflict of interest. There are many meditation techniques that can be accessed on a low fee/non-commercial or free of charge basis and these ought to be recommended over expensive, commercialized methods. Should negative experiences occur, novices should be advised to cease practising the techniques immediately. It seem reasonably clear that TM ought not to be a first-line option. This is not the first scholarly work to recommend caution with regard to TM.

Having said this, it should also be noted that there are also conventional therapies that may seem benign but are in fact associated with recognised adverse effects. Psychotherapy is one example for which documentation of adverse and iatrogenic effects are being accumulated. These effects may include dependence, false memories, worsening of symptoms, indoctrination, superficial insight, malingering and further dysfunction[691, 692].

Another example is hypnosis. For example, a survey of 202 Australian practitioners regarding adverse effects of hypnosis in therapy found that 24% of practitioners reported adverse effects with one or more patients over the preceding year[693]. A review by Gruzellier[694] states that "Adverse effects are common, may be physiological or psychological, and are mostly short lived". More serious adverse effects may include psychopathology, seizure, stupor and dissociation.

Reports such as those described in this review call for a deeper examination of meditation's potential adverse effects. Thorough, systematic surveys post marketing surveillance-style studies need to be conducted. For this to be done properly, meditation instructors and organizations may be required to cooperate by providing comprehensive lists of those who have learnt or who currently practice meditation. In practice this may be difficult to achieve given the commercial interests of some organizations, the somewhat anti-establishmentarian views of those who practice in or participate in these organizations as well restrictions arising from privacy laws.

Nevertheless, broad based surveys need to be conducted and given that studies such as Kaldor's[2] suggest that up to 10% of the population may have tried meditation at some time, a direct-to-public cross sectional survey may be sufficiently effective in quantifying adverse effect rates. Also important are controlled observational studies with a specific focus on detecting, characterising and quantifying adverse reactions. Moreover, meditation should not be the only modality assessed but instead, the opportunity should be taken to assess the effects of all related quasi therapeutic practices including hypnosis, faith healing, *Qigong*, *Reiki* and other new age practices. Comparisons must be made with conventional interventions such as psychotherapy and hypnotherapy, for example. Combining the outcomes from these different data gathering strategies on a wide variety of contemplative and new age practices will not only help us understand adverse effects associated with meditation but also provide a perspective with regard to related mainstream and non-mainstream practices.

Although this review raises more questions than it answers, its intention is to direct attention at the often neglected area of adverse effects that may be associated with meditation and related practices. Important work remains to be done to answer questions about how prevalent negative and iatrogenic disorders may be, what factors may influence the risk of them occurring and how any such risk may be mitigated. Such information will help to explain why a practice traditionally described as beneficial seems to be associated with a low but consistent reporting rate of adverse events.

# Chapter 12. Conclusion

## 12.1 Summary comments

To briefly summarize the current state of knowledge, prior to the completion of the research described in this thesis it was clear in both the systematic review of RCTs described in Chapter 2 as well as other thorough reviews conducted by Holmes, Canter, Ospina and others that there was no consistent evidence to suggest that meditation had either specific physiological or specific clinical effects. As Holme's suggested, this may be explained in several ways, one of which is the possibility that what is being tested as meditation by modern researchers may not actually be meditation as was intended by its ancient originators. The need for a new and workable definition of meditation, and hence a completely fresh approach, seemed obvious.

In Chapter 3 I re-examined the cultural background of meditation and pointed out an important feature of meditation that had been virtually ignored by the Western scientific establishment — the experience of *mental silence*.

As result of the systematic review in Chapter 2 important insights into the methodological challenges unique to meditation research became clear. The main issues impacting on the quality of extant empirical data on meditation were 1) poorly developed strategies to control for non-specific effects, 2) poor control of common sources of bias and 3) use of inappropriate statistical methods of analysis. Taking these and other considerations into account a series of increasingly rigorous studies, mostly clinical in nature, was undertaken to determine whether or not the practice of a meditation technique that focused primarily on eliciting the *mental silence* experience might demonstrate any evidence of a specific effect. *Sahaja Yoga* meditation was selected as the independent variable for this series of studies because of its emphasis on *mental silence*, its ease of use, promising preliminary studies published in both the peer-reviewed and grey literature, and its low cost/zero cost philosophy which made it accessible for research (and accessible to the community, should the clinical trial outcomes warrant it).

## 12.2 Population survey

A national survey of SYM practitioners using standardised measures revealed that meditators experienced significantly better levels of quality of life and mental health as compared to population data drawn from national health surveys using the same instruments. Similar surveys of populations practicing Western forms of religiosity also reported better health than the general population but the meditators appeared to experience substantially greater advantages. Remarkably, analysis revealed a robust and consistent relationship between reported frequency of *mental silence* experience and health scores, especially mental health, thereby providing support for the central hypothesis that emerged from the cultural review in Chapter 3. That is that the experiential, *mental silence* aspect of meditation is associated with health benefits. An association however does not prove causality and so it became necessary to conduct observational experiments to determine if meditation, and more specifically, *mental silence*, was specifically responsible for the health benefits observed in the health survey.

## 12.3 Exploratory clinics

A series of exploratory clinics were set up to develop qualitative and quantitative impressions of meditation and to refine delivery strategies for larger more rigorous trials. These clinics included patients with a wide variety of problems including menopausal symptoms and attention hyperactivity disorder. The results from the latter two clinics were documented for this thesis.

In Chapter 6 a small uncontrolled trial of SYM for menopausal hot flushes resulted in notable reductions in symptom severity and improvements in quality of life over an 8 week period of twice weekly instructional sessions. The degree of benefit was impressive with all women experiencing major, clinically significant improvements. However an obvious and substantial weakness of this study was its small sample size, potential for selection bias and absence of controls.

In Chapter 7 a controlled study of children with ADHD who were taught SYM as an adjunct to their normal management for 6 weeks generated an average of 35% improvement compared to a waiting list control. Several children were able to reduce or even eliminate their need for stimulant medication. The results were again promising but the lack of randomization and other issues limited the generality of the findings.

## 12.4 Randomised controlled trials

**I**n order to effectively tease out the effects of *mental silence* as opposed to the effects of other aspects of SYM it was obviously necessary to use RCT methodology. Having refined the practical approach in previous clinics it became possible to develop a standardized, instructional strategy whose structure could also be mirrored in control strategies in order to optimize the exclusion of non-specific effects.

The first attempt at this was described in Chapter 8. A well-designed RCT was implemented, involving 59 participants in which SYM was compared to a standard stress management programme for sufferers of moderate to severe asthma (on pre-stabilised, optimised treatment but who remained symptomatic). This trial was designed to compare two similarly active and credible interventions in which the main critical difference was the use of *mental silence* in the SYM group. While both groups experienced similar improvements in a number of outcome measures, the SYM group demonstrated significantly greater improvements in clinically important subjective measures such as aspects of asthma specific quality of life, mood state and, notably, an objective measure of disease severity known as airway hyper-responsiveness[594]. The outcomes suggest: first, that *mental silence* does appear to have a specific effect on mood as well as some aspects of quality of life; second, that *mental silence* also has some effect on pathophysiology itself. Although well designed the sample size was small and drop out rates were somewhat higher than expected thereby raising the possibility that important effects were not detectable because of type 2 errors in the statistical analysis. A larger sample size was needed to overcome this possibility. Moreover, although *mental silence* had been compared to stress management, it would be more informative to determine its effect in comparison to an intervention that more closely resembled a non-*mental silence* approach to meditation.

Taking these considerations into account in Chapter 9, a second, larger RCT of *mental silence* orientated meditation is reported. SYM, as an example of the *mental silence* approach, was compared to a "non-*mental silence*" approach to meditation. SYM was, on average, twice as effective as the comparator in reducing work related stress, general depressive symptoms and anxiety.

Thus in two well-designed RCTs in which the *mental silence* approach to meditation was compared to highly credible and active controls, substantial differences in therapeutic effects were observed, clearly suggesting that a specific effect is associated with *mental silence* orientated meditation techniques.

## 12.5 Physiology of *mental silence*

Finally, in attempt to begin exploring the physiological features of the *mental silence* state, an exploratory physiological trial of SYM's effect on skin temperature was conducted. Physiological studies in India suggested quite potent effects on conventional measures of physiological arousal but importantly while many of the parameters changed in the expected direction skin temperature paradoxically decreased, yet according to the relaxation model of meditation it should increase. We replicated these findings in an Australian psychophysiology laboratory using a physiological trial of experienced meditators compared to novices matched for age, sex and interest in meditation. This unprecedented observation clearly suggests that the *mental silence* orientated definition of meditation is not just conceptual, philosophical or experiential but quite possibly biological as well.

## 12.6 Limitations of the findings

The findings of this thesis are limited by a number of factors. First, the RCTs both experienced significant drop-out rates that may have influenced the outcomes. Drop-out rates in both trials however were similar to that reported in other meditation trials. In addition, both the asthma and the occupation stress RCTs reported outcomes based on intention to treat analysis which represents a conservative indication of effect. The asthma RCT featured a follow-up phase over which time it appeared that a considerable part of the intervention's impact appeared to wane. Informal feedback seemed to indicate that this is probably related to participants no longer practicing or attending classes. The occupation stress trial did not feature a follow-up phase due to lack of resources. Neither trial used completely objective outcome measures (even AHR can be influenced by participant motivation) thereby raising the possibility that subjective factors may have influenced the trial outcomes. The physiological trial in Chapter 10 is limited by the relatively small number of participants and the possibility that the sample may suffer from selection bias. The skin temperature changes were however fundamentally different in the two comparison groups suggesting that larger samples would probably strengthen the statistical confidence of the findings. The national health survey is limited by the possibility that the whole meditating population is probably highly selected for certain parameters specific to those who are enthusiastic about meditation. The fact that two consecutive prior surveys yielded virtually identical response patterns, and the correlation between the key defining factor of *mental silence* nevertheless strengthens my confidence in the findings.

## 12.7 Implications of the findings

### 12.7.1 The search for a specific effect

Despite the fact that scientific assessment of the *mental silence* approach is much less common than non-*mental silence* approaches in the Western scientific literature the data in this thesis provide some compelling evidence to suggest that this approach to meditation, unlike approaches that do not involve *mental silence*, has a specific and detectable effect. The *mental silence* versus non-*mental silence* dichotomy therefore offers an effective explanation for the discrepancy between popular perceptions of meditation and the current scientific facts.

The fact that the *mental silence* construct has demonstrated a wide range of effects raises interesting implications in several areas of study.

### 12.7.2 Clinically useful taxonomy of meditation

*Mental silence*, and its associated yogic philosophy, may provide a basis for a taxonomy of meditation that is practically useful in the delivery of healthcare. See Figure 12.1 for a proposed relationship between wellbeing and mental activity. An intervention with a specific effect, such as SYM, has a wide range of applications in medicine, psychology and neuroscience. It is particularly relevant to the growing field of complementary medicine since meditation represents an important genre of CAM modalities and the apparent therapeutic effects of *mental silence* that are apparent in this thesis now position this genre of CAMs in a higher category of practical importance to healthcare.

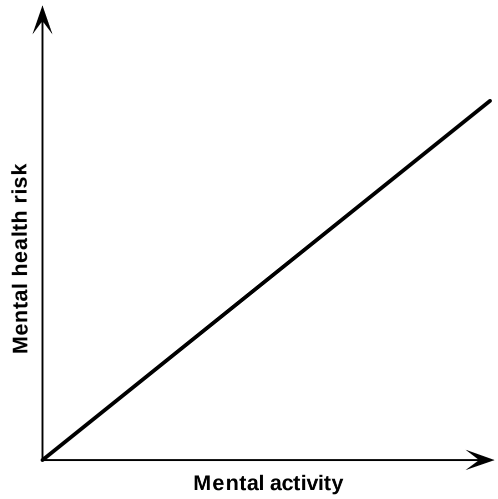


Figure 12.1 Proposed relationship between mental wellbeing and thinking activity.

Explaining the idea of *mental silence* and how it compares to other forms and understandings of meditation is important. Based on the ideas and evidence put forward throughout this thesis, I propose the following schema: As a starting point, reiterating from Chapter 3, *Mindfulness* aims to "develop enhanced awareness of moment-to-moment experience of perceptible mental processes"[252]. Kabat-Zinn, the best known scientific exponent of the technique, stated that it involves "training practitioners to attend to a wide range of changing objects of attention while maintaining moment-to-moment awareness (*Mindfulness*), rather than restricting one's focus to a single object such as a mantra"[251]. By attending to the moment-to-moment experience, attentional processes are more or less prevented from becoming engaged in these events[251, 253].

Now, while *Mindfulness* may be defined as a state in which one passively observes the ebb and flow of thoughts while not getting involved with them, the ancient Eastern meditator sought to unite their awareness with the "space between the thoughts" in order to achieve *mental silence*, such as in the practice of SYM. Thus, while *mental silence* is a specific experience that can be preceded if not facilitated by present-moment observation and other *Mindfulness* methods, it is distinguished from *Mindfulness* by its *sine qua non,* the elimination of thought activity, elimination of the effort of thought in addition to the disengagement of attentional processes from thinking. All of this of course occurring without the meditator losing any sense of self control.

It is possible to broaden this notion by also positioning other meditation techniques in relation to *Mindfulness* and SYM according to the way in which they require the meditator to deal with mental activity. For instance, Benson proposed that the *Relaxation Response* can be elicited in a number of ways but a common one is to use a mental device such as a phrase, or one or two words which can be repeated in synchronisation with breathing[249](p173) — whereas TM is directed at using constant repetition of a single word or syllable (a mantra). Visualisation techniques, on the other hand, actively encourage cultivation of mental activity in the form of repeated mental images. Therefore a kind of spectrum can be proposed upon which techniques can be positioned according to the way in which they seek to modulate mental activity and possibly also the way in which attentional processes engage with it (see Figure 12.2). At the high end of the mental activity spectrum visualisation techniques might be positioned, followed by the *Relaxation Response* which by encouraging meditators to use a repeated mental device might reduce mental activity vis a vis visualisation, but not as much as TM or other kinds of mantra based meditations that focus on a single syllable or word. *Mindfulness,* which encourages witnessing and hence disengagement from the effort of thought, might follow mantra based meditation. Finally, *mental silence* orientated techniques such as SYM and Zen might follow. These not only disengage attention from thinking and aim to neutralise the effort of thinking but in fact also aim to stop thinking activity altogether, albeit possibly for brief periods at a time.

Taking this hypothetical schema another step forward, for the sake of perspective, one might then position normal daily "rumination" when we are not meditating somewhere on either side of visualisation. Whereas a person who is experiencing considerable psychological distress, usually characterised by higher levels of (albeit negative) thoughts, might position their state of mind (or consciousness) somewhere at a higher mental activity level than daily rumination. Following this might be states associated with progressively higher psychological distress such as anxiety, depression (which are commonly characterised by excessive, negative thoughts) and then at the extreme end mania and psychosis. Figure 12.2 illustrates the relationship between thinking activity and mental health diagrammatically where mental health/wellness forms the vertical axis and mental activity forms the horizontal. The maximal height of the mental wellness is at the zero mental activity level, which is in line with the *Sahaja* tradition of Yoga, discussed in Chapter 3, wherein the sustained state of meditation (trans-thought awareness) represents the Eastern ideal of complete psychospiritual integration[213].

Logically, the state of non-thought must necessarily relate to heightened self control and not loss of mental control, in line with the Eastern ideas of *Sahaja*. It is important to point out that notions of mind control raised by scholars such as Hassan[595 596], whose main concern is exploitation of individuals involved in "cults"[597] are antithetic to the principle of *mental silence*, yoga and *Sahaja*. Although a fascinating topic, discussion unfortunately it is outside of the scope of this thesis.

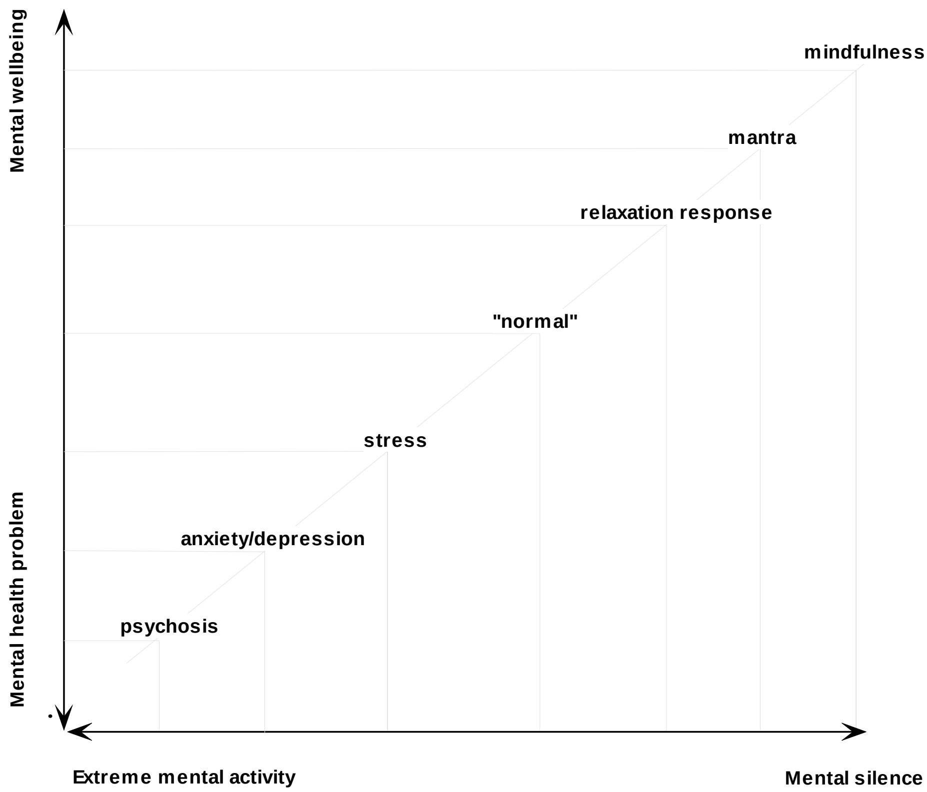


Figure 12.2 Mental activity spectrum and mental wellbeing.

### 12.7.3 Healthcare

Mental health is an increasingly important issue in population health. The World Health Organization estimated that the burden of mental illnesses constitutes 10% of the global burden of disease. Depression, for example, is anticipated to be one of the largest health problems worldwide by the year 2020[598]. The National Survey of Mental Health and Wellbeing in Australia indicated that almost 1 in 5 (18%) people in the community has a diagnosable form of mental illness at some time — young adults having the highest prevalence. In young men the commonest issue is substance abuse, while in young women it is anxiety and depression[303]. It is well recognized that stressful life events can influence the onset and outcome of illnesses of various types[599]. Notably, the clinical studies in this thesis demonstrate substantial anxiolytic effects.

The WHO defined *health promotion* as action and advocacy to address the full range of potentially modifiable determinants of health, "the process of enabling people to increase control over, and to improve their health"[600]. It implies that strategies for mental health promotion are related to improving quality of life and potential for health rather than just the treatment of disease. There is strong evidence that a number of factors play an important role in promoting mental health and protecting against ill health. Herrman[601] proposed that these factors may be clustered around 3 themes. First, the development of healthy communities that can provide safe, secure and supportive environments to allow not only food, warmth and shelter but also self determination and control of one's life; Second, the ability to deal with the social world through skills involving tolerance, responsibility and communication-skills which themselves are associated with positive experiences of relationships with others; Third, the ability to deal with thoughts and feelings, management of life and emotional resilience which are themselves associated with factors such as self esteem, conflict management skills and general health. Many of these factors, particularly general health, emotional resilience and the ability to deal with thoughts and feelings, are positively related to meditation skills and the meditative experience. This study suggests that regular meditation practice may empower its practitioners to pursue and maintain higher levels of wellbeing and therefore represents a potentially valuable mental health promotion strategy.

Mental health *prevention*, on the other hand, can be seen as involving strategies directed at intervening in the assumed causal chain that ultimately leads to mental illness[600]. Prevention can occur at several levels; primary, to prevent onset of illness; secondary, to reduce duration and associated disability by early treatment; tertiary, to reduce the sequelae of the illness.

With these ideas in mind, my studies clearly indicate that *mental silence* orientated forms of meditation have considerable potential as a primary prevention strategy as well as a health promotional tool. Meditation not only alleviated a diverse range of conditions including asthma, menopause, attention disorders and occupational stress but the national meditators survey demonstrated that it also appears to be associated with higher levels of quality of life and functional health thereby implying a role in health promotion.

### 12.7.4 The study of religion and the religion-health connection

As stated previously, the association between religiosity and mental health is not always positive. Larson's review of studies exploring the relationship between religious commitment and mental health[283] reported that while 72% described a positive relationship, 16% reported a negative relationship. This proportion is somewhat higher than would be expected by chance alone. Some scholars propose that this wide variation in benefit/detriment may be explained by underlying "essential factors" which although common to all forms of religiosity, vary in their presence, magnitude and the interactions between various other factors.

The persistent association between *mental silence* experience and health outcomes inevitably leads to the idea that the valence of internal experience might provide some explanation for the association between religiosity and health, across different forms of religiosity. Some evidence-based argument for these notions is explored below.

Ryan conducted a study on Christians of several different denominations and concluded that the way in which religiousness was internalised, rather than religiousness itself, influenced both the magnitude and direction of health benefit[602]. He examined two forms of internalisation: first, "introjection" which involved maintenance of belief and practices through self-approval, guilt and esteem-related anxieties (therefore associated with conflict and pressure) and, second, "identification" in which the individual experienced personal value in the beliefs and practices and considered them to be emanating from him/herself. "Identification" was associated with positive mental health benefits whereas "introjection" was associated with negative effects.

Similarly, Hackney[603] conducted a meta-analysis of 34 studies of religion and health. He proposed 3 general types of religiousness, not unlike Ryan's; "institutionalised" (attendance of services, participation in ritual, participation in church activities and extrinsic religious observance i.e. the social and behavioural aspects of religion), "ideological" (ideology, attitudes, belief salience, fundamentalism i.e. the beliefs involved in religious activity) and "personal" (intrinsic religious orientation, emotional attachment to God, devotional intensity, colloquial prayer i.e. personal and internalised devotion). He also categorized the various mental health measures into; "psychological distress", "life satisfaction" and "self actualization". The strongest positive association was between "personal devotional" style of religiousness and "self actualization". Personal devotion had the strongest, positive relationship with all 3 measures of mental health while "institutionalised" religiousness had the weakest. Importantly both institutional and ideological religiousness had weak but significantly negative associations with the "psychological distress" category of mental health.

These findings imply that internalised, experiential, less institutionalised forms of religiousness may more effectively tap the beneficial effects of religiosity as compared to external, ritualistic observances. Interestingly the Eastern meditative tradition is also characterized by ideas of non-institutionalised, internal experience and this study demonstrates that a measurable relationship between such experiential factors and health outcomes does in fact exist. These ideas are further corroborated by the fact that in the same study of "formal meditation", the outward actions associated with meditating and health outcomes have much weaker relationships with health outcomes as compared to *mental silence*.

It is therefore possible to propose that meditative practices, particularly those that focus on *mental silence*, may be a particularly efficient way of tapping the beneficial dimensions of religiosity.

Following this line of argument, one might also propose that the principle of "internal experience" might be one of the essential explanatory factors for the relationship between religiosity and health. *Mental silence* might be an internal experience whose valence is particularly associated with benefit, whereas the valence of negative emotions such as guilt are more associated with detriment. Later in this chapter the relationship between negative emotions, immunological function and health will be described in further detail. It may be relevant to position religious practices according to their emotional and cognitive content on an "internal experience spectrum" in accordance with the emotional cognitive content that they elicit and its resulting effects on health and wellbeing.

The findings of this thesis provide a new perspective for scholars interested in the study of religion and spirituality by highlighting the importance of subjective experience in religious practices both as a phenomenon in itself as well as providing an explanatory factor for the various outcomes associated with religious expression. This is one of the few studies that relates an experience, possibly unique to meditation, that is traditionally associated with religious practices to measurable and practically useful outcomes.

Therefore the findings of this thesis strongly suggest that meditative practices, particularly those that focus on *mental silence*, may be a relatively efficient way of tapping the beneficial dimensions of religiosity.

### 12.7.5 The religion versus spirituality debate

The persistent association between *mental silence* experience and health outcomes brings another area of discussion into focus. There is currently debate about how to define the term *spirituality* and how it might differ from terms such as *religion* or *religiousness*[604].

Zinnbauer stated that spirituality is commonly regarded as an individual phenomenon and identified with experiential phenomena such as personal transcendence, supra-conscious sensitivity and meaningfulness[605]. Religiousness is frequently identified with formal structure, religious institutions, prescribed theology and ritual[604]. Modern scholars of religion and sociology observe that in many ways spirituality is taking on specific connotations relating to its association with transcendent experiences[605], whereas religiousness is taking on a negative connotations relating to the notion that it somehow obstructs these experiences[606]. The findings from studies such as those of Ryan[602], Hackney[603] and the present one may provide some valuable empirical data to facilitate discussion around these questions.

This and other studies provide empirical data to support the notion that less dogmatic, less institutional, internalised experiences of religiousness has positive associations with health whereas the features of religious orthodoxy, externally applied authority and ritual, tend to have less positive or even negative associations with health. In many ways these empirically determined relationships reflect the popular perceptions associated with the term *spirituality* as compared to those associated with *religion/religiousness*.

The popular cultural distinction between spirituality and religion may be an intuitive recognition of this practical difference. Indeed Roof described a segment of the baby-boomer generation who are specifically focused on developing a highly individualized spirituality that rejects religious orthodoxy. He called this segment "highly active seekers". They characterized themselves as spiritual but not religious. They are more educated, more individualistic, more interested in mystical religion and New Age ideas[189]. Roof's "high intensity seekers" demographic seems to describe a stratum of the population that is specifically preoccupied with the notions discussed above. Does the field of religiosity-health have something to learn from them?

As Zinnbauer stated, "[T]he religious landscape has undergone changes in recent history and it appears as if researcher's conceptualizations of religiousness and spirituality have not all caught up…[V]ery little attention …has been paid to the ways the general public defines the terms"(p551)[604]. It seems clear that popular perceptions about these two potent terms may end up being vindicated by evidence from studies such as this.

### 12.7.6 The study of consciousness and the consciousness-health connection

The introductory chapters to this thesis describe how mystics have often asserted that the presence or absence of altered states of consciousness (such as *mental silence*) comprise the crucial difference between religious ritual and religious experience.

Western scholars such as William James mirror the Eastern ideas:

> In just the degree that we come into a conscious realization of our oneness with the Infinite Life, and open ourselves to this divine inflow, do we actualize in ourselves the qualities and powers of the Infinite Life, do we make ourselves channels through which the Infinite Intelligence and Power can work. In just the degree in which you realize your oneness with the Infinite Spirit, you will exchange dis-ease for ease, in harmony for harmony, suffering and pain for abounding health and strength…[607]

James particularly pointed to the Indian tradition of yoga and meditation as a source of such systematic knowledge about the interconnectedness of health, personal development, consciousness and spirituality.

In this study *mental silence* has a much stronger association with better health. This constitutes important empirical support for the notion that *mental silence*, and possibly other "noetic" states, belongs to a separate category of religious "practice" with very different implications for health and behaviour.

Practitioners consistently report that the state of *mental silence* is characteristically associated with other subjective phenomena such as a natural focusing of attention and a sense of wellbeing which somehow leads to improved physical health. A number of SYM practitioners do describe occasional transcendent experiences, with concomitant benefits to physical and mental health, that in many ways reflect traditional descriptions of mystical experiences and states such as *Sahaja* yogic tradition. Modern SYM practitioners ascribe these experiences to a unique, spontaneous and more or less involuntary psycho-physiological process that occurs during meditation. The process is said to involve a system of yogic energy centres (*chakras*), interconnecting channels (*nadis*) and activating energy (*kundalini*). Modern proponents of the yogic tradition put this "psychic anatomy" forward as a kind of psychosomatic theory of health[239].

The emphasis on personal development of consciousness and experience in Eastern religiosity creates a paradigm in which the achievement of health (in all its dimensions), is one stage on a more fundamental continuum of "consciousness development". The starting point of this continuum is mundane, everyday life and the endpoint is variously described as enlightenment, *sahaja samadhi* or the Bhudda-state. Meditation and related psycho-spiritual practices are seen as essential for progress along this continuum.

*Mental silence* represents an important progression on a spectrum of consciousness that begins with the mundane state of mind and ends in the state of complete unity with the cosmic principle.

This raises the final idea revealed by the findings of this study, that the connection between religiosity and health, rather than being understood as part of the field of religious studies, may be better accommodated as part of the wider systematic study of consciousness.

### 12.7.7 Consciousness and Health

Shakespeare describes an understanding of the unity between mind, mood, the organs of the body and general health:

> when the rich golden shaft
> Hath kill'd the flock of all affections else
> That live in her; when liver, brain and heart,
> These sovereign thrones, are all supplied, and fill'd
> Her sweet perfections with one Self king!
> William Shakespeare
> (Twelfth Night—Act 1, Scene)

In traditional cultures around the world, Spirituality has been associated with better health. Both Eastern and Western historical traditions closely linked physicians with the religious establishment. In the East, Traditional Chinese and Indian medical systems clearly describe, even today, the idea that the mind/soul is an important influencing factor in health is integral to their healing approaches. In the Western tradition, the ancient symbols of medicine, Aesclepius and Caduceus, were in fact scepters carried by the Gods whose touch would heal the sick suggesting that health and the greater cosmic order are fundamentally interconnected. Hippocrates' theory of humoralism[608] paralleled the yogic ideas of subtle psychosomatic energies whose fluxes determined both personality and health. Later, Galen linked physical illness with imbalance in the soul[609].

Only for the last 300 years has the idea, established by Descartes that the mind (or psyche or soul — Descarte did not distinguish between the two) has no significant influence on the body's health, predominated in Western understandings of health. There is now emerging a broad evidence base; clinical, physiological, laboratory, human and animal; indicating that there are potential pathways by which certain behaviours, cognitive styles and lifestyle practices might impact on wellbeing. The evidence converges on some basic principles, particularly the cultivation of positive personality traits and coping styles, the discouragement of negative personality traits and coping styles, and reduction of negative mood and stress, as well as the circumstances that may lead to them.

The notion that religious and spiritual traditions have somehow evolved knowledge and methods to exploit the most potent of these mind body pathways is fascinating and provocative. Importantly these biological explanations might help to understand the mechanisms by which religiosity, and especially psychospiritual practices such as meditation, can influence health in the ways that have been observed in the studies documented in previous chapters.

**A brief look at the evidence for the mind-body connection**

Probably the two most cited clinical experiments illustrating the connection between the mind and body are those done by Fawzy and Spiegel. Fawzy assessed melanoma sufferers who participated in a multimodal support programme. Subjects in the intervention group demonstrated better mood, immune function and survival than those who did not [610, 611]. Spiegel found that women with a diagnosis of metastatic breast cancer had significantly better survival rates (36.6 months) if they were involved in a regular support group compared to those who did not (18.9 months)[612]. Although several attempts to replicate Spiegel's findings have failed, his study has been cited over 260 times in the medical literature alone. Nevertheless the outcomes of these and other studies suggest that psychobehavioural strategies might be useful for the maintenance and achievement of health.

The word "placebo" has been in use for at least the last 2 centuries, if not longer[613]. While detailed discussion of the placebo effect is not possible here, suffice to say that at least part of the phenomenon appears to relate to an interaction between the subjective mind and the physical body leading to a biologically measurable outcome. Generally speaking, a clinician researcher's rule of thumb is that one third of a control group taking placebo might manifest improvements. However the placebo response in clinical trials can be much higher (for instance Maclennan demonstrates that the placebo effect in HRT trials can be as high as 50%[351]). Indeed it has been suggested that "harnessing the power of the placebo" ought to be a major priority for researchers looking for new strategies to alleviate illness[614]. Recall also the effects of suggestion described in Chapter 8 where Luparello and other researchers not only demonstrated that suggestion could either mitigate or exacerbate lung function in asthma sufferers but also that acetylcholine inhibiting agents seemed to block this effect[39, 41]. This suggests that at least part of the placebo effect may be vagally mediated i.e. involving the parasympathetic component of the ANS. The fact that meditation appears to reduce sympathetic activity and drive parasympathetic activation is an interesting corollorary. That mental-silence orientated meditation appears to also drive a similar autonomic response[51] but is, first, somehow fractionated as compared to the Relaxation Response since it elicits reductions (rather than increases) of skin temperature but, second, at the same time it seems to be associated with a pronounced specific effect above that of the placebo response provides some interesting clues as to how the mind-body effect of *mental silence* may be elicited.

A number of epidemiological studies indicate a robust relationship between emotions, especially negative emotions such as depression, hostility, agression and cardiovascular disease. Some of the evidence includes:

*Depression:* Major depressive disorder, current depressive symptoms, and a history of depression all have been associated with increased risk of CVD morbidity and mortality. In psychiatric patients with depression it has been noted that CHD-related death is more common than in non-psychiatric controls[615]. Similarly there are high rates of CVD in patients with unipolar and bipolar depression[616]. Rates of depression are higher in patients after suffering a myocardial infarction and the presence of depression adversely effects CVD prognosis[617]. Anda and colleagues reported that depressed affect, measured by 4 items from the General Health Questionnaire, was significantly associated with a 50%–60% excess risk of fatal and nonfatal ischemic heart disease (IHD) after adjusting for traditional coronary risk factors over 12 years of follow-up of more than 2800 initially healthy men and women from the National Health Examination Follow-up Survey (NHEFS)[618]. Most recently, data from the Women's Health Initiative Observational Study, which followed a multi-ethnic sample of nearly 94,000 women aged 50–79 years for approximately 4 years, found that current depressive symptoms, measured by a short form of the CES-D, were associated with a significant 1.5-fold higher risk of death, after controlling for education, income, and traditional coronary risk factors[619].

Hopelessness is one symptom of depression that appears to have particularly adverse effects on health. In their report from the NHEFS, Anda et al. reported that the single item on hopelessness from their measure of depressed affect predicted a more than two-fold risk of fatal and nonfatal IHD and was a stronger predictor than the complete measure. Everson found that hopelessness predicted a two-fold increase in CVD mortality, MI, and all-cause mortality over 6 years of follow-up in a population sample of middle-aged Finnish men from the Kuopio Ischemic Heart Disease (KIHD) study, after controlling for demographic characteristics, cardiovascular risk factors, and overall depressive symptoms. Hopelessness also was related to accelerated progression of intimal-medial thickening (IMT) in the carotid arteries and three-fold greater risk of incident hypertension over 4 years in the KIHD study[620, 621].

*Hositility*: This understanding arose from Friedmann's identification of the Type A personality, characterized as a competitive, impatient, hurrying behavioural and emotional style and its apparent association with CVD risk[622]. However, a meta-analytic review of 45 studies published in 1996 concluded that hostility is an independent risk factor for CHD and all-cause mortality[623].

The mechanism by which personality trait influences health has not been elucidated, but a number of pathways are suggested by the evidence. Scherwitz found that those with high hostility scores were more likely to have conventional CVD risk factors such as smoking, overeating, alcohol consumption and dyslipidemia[624]. Several studies have found that chronic hostility was associated with reduced vagal antagonism (parasympathetic activity) of SNS effects on the heart[625]. Markovitz found that men with high hostility scores had increased platelet adhesiveness[626], while Rabin observed that high levels of hostility showed differential changes in expression of cytokines[487]. Some research suggests that hostility is associated with low brain serotonergic function. For instance, fluoxetine, an SSRI, reduces aggressive behaviour in both humans and animals and increases extracellular serotonin in certain areas of the brain[627]. Ravindran gave a group of men who had no history of depression a tryptophan (a precursor of serotonin) deficient diet and found that negative affect, especially anger and depression, increased in direct relationship to the reduction in plasma tryptophan and serotonin levels[628].

Interestingly, in the studies described in this thesis, the practice of SYM was consistently associated with improvements in mood and emotional factors thereby indicating that *mental silence* has potent mood altering effects. Again, the beneficial role that such an intervention might play in mitigating the health impact of negative emotion is worthy of further exploration. Studies focusing specifically at the behavioural factors associated with disease risk would be of particular importance.

**Psychoneuroimmunology**

Pathways by which mental states, emotions, perceptions, experiences and behaviours can influence physical function and health include the well recognised neuroendocrine pathways such as the limbic hypothalamic pituitary adrenal system and the autonomic nervous system described in the Chapter 10[529]. In addition, newly discovered humoral factors involved in mood regulation, pain perception and other diverse biological functions may play a part. A large array of peptides, such as endogenous opioids, substance P, neuropeptide Y, somatostatin, vasoactive intestinal polypeptide, growth hormone and insulin-like growth factor, prolactin and melatonin have been proposed as potentially important transmitter substances[629]. The mechanisms and pathways are complexly interconnected and feedback on each other at multiple levels to allow subtle modulation of organ function, energy production, immune status and possibly even mood and behaviour on a moment to moment basis.

In addition to the effects of SAM and HPA activation on the cardiovascular system, both of these mechanisms may well exert further effects via the immune system. This is part of a broader field of research that has identified a myriad of potential pathways by which the mind body connection might work to modulate activity of various aspects of the immunological system, thereby influencing susceptibility to illness. The term used to describe this notion is *psychoneuroimmunology* (PNI). Although ignored for many years, evidence to support it is now rapidly accumulating, especially in the past decade[630]. Some of the key evidence is summarised below.

Felten found that sympathetic, noradrenergic nerve fibres innervated specific zones of lymphoid tissue, bone marrow and thymus[631] while Smith found that lymphocytes synthesized both ACTH and beta-endorphin[632]. Clearly suggesting that the physiological response to stress might directly influence cells and tissues of the immune system.

Szentivayni et al. found that anaphylactic reaction in guinea pigs could be inhibited by certain brain lesions. He and other researchers found that: (1) hypothalamus lesions in preimmunised animals inhibited anaphylactic reaction otherwise elicited by specific antigens, (2) the same lesions prevented antibody production if made prior to antigen first exposure, (3) antibodies taken from non-lesioned animals (that did experience anaphylaxis upon antigen exposure) did not elicit anaphylaxis in lesioned animals when exposed to the same antigen, and (4) despite the absence of anaphylactic reaction the antibodies from lesioned animals maintained activity when exposed to antigens[633, 634].

Ader gave both saccharin and cyclophosphamide to rats to bring about an immunosuppressive reaction that the rats associated with the taste of saccharin. When these conditioned rats were then given saccharin only an immunosuppressive response still occurred. More sophisticated studies include that of Renoux who demonstrated that the immune system communicated to the brain in mice via corticosterones (the mouse equivalent of human cortisol)[513, 635].

Studies of personal relationships and their influence on immune function provide important evidential support for the notion of PNI. For instance, studies of married couples show that close personal relationships that are chronically abrasive or stressful may actually cause immune dysregulation[636, 637].

Specific personality characteristics such as academic achievement, motivation and aggression have been associated with immunological alterations[638, 639]. Similarly, coping styles such as repression[640, 641], denial, escape-avoidance[642] and concealment have also been associated with immune alterations.

Possibly the most significant psychobehavioural factors associated with immunological consequences is negative emotion. Negative affect has frequently been associated with immunological dysregulation in a wide variety of scenarios ranging from stress, depression to laboratory manipulations. In fact negative affect has been proposed as a final common pathway by which these various psychosocial factors, personality traits, coping styles and dispositions impact on CNS and then immunological activity ultimately manifesting as effects on health[643].

The process of emotional disclosure seems immunologically beneficial. RCT studies in which subjects in the active group wrote about traumatic events whereas subjects in the control group wrote about trivial events over several days. Subjects in the disclosure group manifested significant immunological differences[644, 645].

Bovbjerg describes data suggesting classical conditioning of the immune system associated with chemotherapy. Women receiving chemotherapy for ovarian cancer manifested immune suppression just prior to chemo-infusion, compared with samples drawn a few days earlier[646]. The authors propose that, like Ader's study, subjects associated attendance to the clinic with the effects of chemotherapy and became classically conditioned into manifesting immunological changes even without administration of the drug.

Studies have also shown some effects of humour on immunological factors. A comprehensive review by Rod[647] examined 9 studies that have assessed the effects of humour on salivary immunoglobulin A. While the majority of these studies have shown evidence of effects associated with humour, few thoroughly controlled for confounding factors such as diurnal variation, distraction, positive emotion and general emotional arousal. A number or other methodological issues were identified that prevented firm conclusions from being made.

Uchino conducted two extensive reviews and found that social support was inversely related to blood pressure and positively related to NK cell activity again suggesting a biological pathway by which a major aspect of religiousness might influence health.

Correlational studies of religious expression have reported some interesting associations. Schaal assessed the association between religious involvement and immune function in 112 women with metastatic breast cancer. Small but significant correlations between immune cell counts and importance of religious/spiritual expression and inverse correlations between evening cortisol and religious expression were reported[648]. Katz found that in a group of 30 women waiting for breast lump biopsy those that used prayer and faith to cope tended to have lower cortisol levels[649].

This raises interesting questions about how to position current ideas about meditation, religion, spirituality and consciousness in relation to our knowledge of the mind body connection and psychoneuroimmunology.

The direct impact of negative thoughts and emotions on immunological function seems to be reasonably well documented and, since many PNI phenomena seem to be mediated by negative affect, rather than situational "stress" — strategies that directly modify this factor may manifest greater benefits. While relaxation orientated meditation most likely acts to reduce the impact of stress that are mediated by neuroendocrine mechanisms such as the sympathoadrenal and hypothalamicpituitary axes, so too do other strategies that reduce physiological arousal. It might be argued that since *mental silence* approaches to meditation aim to not only reduce physiological arousal but also mitigate negative rumination and affect this may be one reason why it seems to be associated with a specific effect.

## 12.8 Recommendations for further research

Given the outcomes described in this thesis, and the evidence for a specific effect, the *mental silence* experience clearly warrants further investigation within this context. Some research ideas are discussed below. Needless to say, it would be ideal if this research was carried out by those without a financial, emotional or reputational stake in any such research. Experience however suggests that for the foreseeable future it will be meditation enthusiasts who will drive this field of exploration. In view of the promising findings future RCTs should include even more rigorous adhesion to CONSORT guidelines for clinical trials. Further, self report outcomes should be complemented by objective biological outcomes.

The various potential mechanisms put forward to support the idea of, and explanatory mechanisms for, a connection between mind and body are a rich source of hypotheses for future research projects. Importantly, brain imaging and neuro-, endo- and psycho-immunological studies of meditators promise to elucidate the neural and physiological mechanisms by which this relatively unique form of consciousness affects health. Generally speaking, biological research data elucidating the mechanisms by which constructs such as stress can impact on the physical body are an ideal starting point for the development of hypotheses. The main candidate mechanisms for a causal link between psychosocial factors and health include (from Mackay et al. [508]):

- Neuroendocrine[509] and autonomic changes[510]
- Metabolic syndrome and insulin resistance[511]
- Disturbances in blood coagulation[512]
- Inflammatory/immunological changes that modulate susceptibility to infection[455, 503, 513]
- Homeostatic and allostatic changes in response to stress[514]
- Psychological mechanisms such as anxiety, hypervigilance and risk taking[515, 516].

Given the discussions above, I feel that the most promising dimensions worth examining include immunogenetic studies, brain imaging and field evaluations. These will help us move past the question about specific effect and onto the question of how might this effect occur as well as what practical benefit can the community derive from meditation.

**Immunogenetic Studies**

Acute laboratory stressors have been shown to provoke transient immune changes, often increased numbers in the peripheral circulation of some lymphocyte populations. These changes tend to return to resting levels after withdrawal of the acute stressor[637]. In fact epinephrine injections have been shown to induce very similar changes in lymphocyte numbers as acute stressors[650], probably mediated by the sympathoadrenal medullary innervation of spleen and lymphoid organs as well as receptors on lymphocytes[651].

Glaser studied the effect of medium-term stress in medical students on seroconversion after hepatitis B vaccination. Students who seroconverted earlier (after the first vaccination) were significantly less stressed and anxious than those who seroconverted only after the second. Implying that even relatively mild stress can impact on even young healthy adults' ability to respond to pathogens[652].

Stress can significantly slow wound healing. For instance Marucha assessed the impact of stress on standardized wounds and found that stress lead to 24–40% delay in healing time[653]. This and other research may explain why other studies have shown that pre-operation fear and distress is associated with poorer post-operation outcomes[654].

Recently the role of chronic inflammation factors, particularly pro-inflammatory cytokines (PICs), especially IL6, have received attention as potentially central factors in a range of diseases in older adults[655]. For instance, depression and distress have been shown to enhance production of PICs, especially IL6 (as well as dysregulation of other aspects of immunity)[656, 657] which may explain why wound healing and recovery are slower in people with these characteristics. Consequently, just as repeated, chronic or slow-resolving infections and wounds enhance PIC production, which can then contribute to further dysregulation of immunity, so too might negative emotional states.

Depression and anxiety may act directly on immune cells via mood-related peptides or indirectly by up/down regulation of PICs. Thus negative emotions might contribute to prolonged, chronic wound healing and infection that themselves can indirectly fuel PIC production. This may explain phenomena such as the immunodepression characteristically associated with ageing and suggests why the elderly, who already have age-related increases in IL6 production, may be particularly at risk of contagion and prolonged illness[658].

Indeed, inflammation has now been implicated in a wide spectrum of age-related illnesses ranging from cardiovascular disease, osteoporisis, arthritis, type 2 diabetes, alzheimer's and periodontal illness[659]. In fact chronic inflammation has been suggested as a key biological mechanism contributing to declines in physical function, frailty and disability[660]. IL6 levels in blood for example have been shown to predict future disability on older adults, leading some researchers to propose it as a "global marker of impending deterioration in health status of older adults" with predictive value approaching that of traditional markers such as cholesterol, hypertension and obesity[661].

The ashma study described in Chapter 8 demonstrated substantial improvements not only in mood and quality of life scores but also in airway hyperresponsiveness suggesting that *mental silence* may somehow directly influence the pathophysiological processes that underlies asthma. Asthma is a disease characterised by, among other things, chronic inflammation. A logical progression in design would be to repeat this study using a larger simple size and include a range of biomarkers for inflammation, both specific and non-specific to asthma using an RCT methodology. Study outcomes would be focused not only at clinical outcomes but also correlating inflammatory markers, experience of *mental silence* and clinical status.

Looking at the effects of stress reduction on immunocompetence, Davidson studied a group of workers who had received flu vaccine, and were then allocated to either meditation or a wait list control in an RCT design. After 8 weeks antibody response to the vaccination was significantly higher in the meditation group. While this trial was not designed to exclude non-specific effects it clearly illustrated the potential impact of such interventions[662]. Given the promising outcomes of the occupational stress study in Chapter 9, a logical and fascinating progression of this line of investigation would be to replicate the design of the study and in addition include a series of immunological measures to assess the impact not only of *mental silence* but also of non-specific effects. Moreover, a substantial follow-up period should also be included to determine what conditions are necessary for participants to maintain any benefit, should one be detected at all.

Recently a number of fascinating studies have been published describing the impact of psychosocial factors on gene expression and cellular ageing. Epel[663] studied the association of chronic stress with telomere length, telomerase activity and oxidative activity (regarded as known determinants of cell senescence and longevity) in peripheral blood mononuclear cells in women who either had healthy children or chronically ill children. As expected the women with ill children reported more stress however the chronicity of this stress correlated negatively with both telomere length and telomerase activity. This suggests that stress can impact at fundamental levels of cell biology, reducing the effectiveness of immune cells and, more broadly, possibly accelerating the ageing process and susceptibility to illness. These effects may be mediated by neuroendocrine mechanisms or by other pathways not yet clearly identified.

Following on from the survey described in Chapter 5, larger cross sectional and cohort studies might be implemented to examine the relationship between the meditative experience, stress and gene markers such as those described in Epel's study as well as factors such as IL-6. Data of meditation populations should be extended to include practitioners of non-*mental silence* definitions to ascertain the magnitude of benefit compared to other *mental silence* definitions and even other forms of spiritual expression. More thorough exploration of the interrelationship between *mental silence*, self report measures and biological measures in prospective cohort designs would be ideal.

Physiological trials of skin temperature could be expanded to include larger numbers of participants as well as other basic physiological parameters. Larger sample sizes and perhaps also randomization which would necessitate the use of novices instead of experienced meditators. Such rigour will be necessary to ensure that the exploratory findings from Chapter 10 are adequately assessed. Importantly, while reduced skin temperature cannot be explained by reduction in physiological arousal it may be explained by biofeedback and hence possibly even a socialisation process. Therefore future trials should be designed to exclude this possibility.

**Brain imaging**

In addition to peripheral physiology, there been recent advances in neuroimaging which open up important opportunities to study the physiological corollaries the meditative experience, the brain and therapeutic effects. Given that changes in peripheral physiology are probably related to changes in the central nervous system that reflect the *mental silence* experience it seems logical to expand any such psychophysiological research to combine both peripheral and central neurophysiological methods. Aftanas clearly demonstrated the value of EEG in mapping brain electrical activity and relating it to meditative experience[318, 358, 526] but there are 2 other brain imaging technologies worth examining. These are functional magnetic resonance imaging (FMRI) and magnetoencephalogrophy (MEG).

FMRI is just over a decade old and is the most prolific of all brain imaging techniques. It is relatively easy to implement and is a completely non-invasive procedure. A variety of neurophysiological information can be obtained using FMRI. For example, baseline cerebral blood volume measurements, changes in this blood volume, quantitative changes in the levels of blood oxygenation, as well as the rate of resting state oxygen extraction.

In brief, the signal of most relevance to meditation research is driven by a difference in the blood oxygenation levels in capillaries and veins compared to the arteries during a particular task. Russell, 2003 #11}. Deoxygenated blood is paramagnetic (attracted to a magnetic field) as opposed to when it is oxygenated. On presentation of a specific stimulus, oxygenated blood flow will increase locally within an active region of the brain. This will cause deoxygenated blood levels to decrease and subsequently leads to a signal detected by the FMRI apparratus[664].

FMRI has excellent spatial resolution but relatively poor temporal resolution because it relies on shifts in blood flow which take seconds to occur, despite the fact that mental activity occurs in much more smaller timeframes. Therefore, as a tool, FMRI should generally be used for the identification of brain areas associated with the independent variable but not necessarily the way in which those areas might function in real time .

MEG involves the measurement of extremely weak magnetic fields generated by the electrical activity of neuronal populations. Compared with FMRI, MEG has excellent temporal resolution but relatively poor spatial resolution. Measuring such minute neural activity is challenging, due to the very weak nature of the neuronal clusters and interference with nearby electromagnetic noise. During a MEG scan, the subject's head is raised into a “dewar” which houses an array of superconducting sensors called superconducting quantum interference devices (SQUIDS)[665].

The temporal resolution of MEG is close to real time, but its ability to detect the onset of cortical activity is not its only advantage. The use of MEG also allows study of changes in neuronal oscillatory rhythms, i.e. the specific frequency at which neurons in a particular cluster fire together. A specific oscillatory frequency range, e.g. 28-40 Hz, will either increase or decrease during an experimentally salient period of time, such as when participants view a visual stimulus[665]. Whilst still preliminary, there is an emerging evidence that certain frequency bands can be identified as signatures for specific cognitive tasks, e.g. 28-40 Hz ERS for object recognition or 14-28 Hz ERS for verbal working memory [666]or even 4-8 Hz ERS for episodic recall[667] Might meditation, or perhaps *mental silence*, be associated with certain oscillatory rhythms?

Clearly, the necessary technology to study the neurophysiological features of the *mental silence* experience exists and warrants usage in the field of meditation research. A number of brain imaging and neurophysiological studies of meditation have already been published although they are still relatively few in comparison to studies of more conventional variables. For instance Cahn’s review of electrophysiological data suggested that the anterior cingulated cortex is the most likely structure involved in the practice of meditation[549]. These studies are of course limited by several factors. Notwithstanding the considerable variations in actual methodology, the most important confounding issues are, again, lack of a consistent definition of the meditation variable and, most relevant in this case, few studies other than Aftanas's focusing on the experience of *mental silence*.

Finally, future research emphasis should be placed on the evidence in this thesis and elsewhere that suggests that *mental silence* is not only a therapeutic tool, but a method that changes cognitions and perceptions. In health behaviours, interpersonal relationships, the management of organizations, and society, the "human factor" is both the key weakness and the most precious resource. The limitations of people, organizations, and indeed society, are often a manifestation of the limitations of individuals to overcome their ingrained personal cognitive, emotional and behavioural patterns. A technique that facilitates positive transformation of such patterns would be an invaluable tool for the betterment not only of health but society in general.

### 12.8.1 The commoditisation of meditation

Another important retarding force impacting on meditation research relates to the fact that meditation has become an important commodity and many of its leading lights have made their fortunes by selling books, CDs, courses and qualifications on or about meditation. Virtually none of these highly commercialized, mass market products discusses or describes how to achieve the *mental silence* experience. Might this be because its creators are unable to deliver that experience? A vague definition of meditation has commercial advantages since it allows a wide variety of practices to be marketed under an attractive banner without obligating its proponents to deliver much more than a sense of rest, relaxation or even just a an odd sensation, if anything at all. The New Age industry, culturally handicapped academics and a popular media eager for content appear to have unwittingly cooperated to promote a fundamentally inadequate, but much more marketable, idea of meditation.

## 12.9 Recommendations for implementation

The evidence presented above, particularly in combination with the earlier work of Rai, Aftanas and others, clearly indicates that meditation techniques which involve *mental silence* , such as SYM, have considerable potential to contribute to health and wellbeing. *Mental silence* does appear to have a specific effect and therefore by inference practices such as SYM do as well.

Summarizing the basic features of this approach, it is:

1. Relatively simple to learn and practice.
2. Appears to have a specific, positive effect on health.
3. Can be made available on a low-cost/zero-cost model.
4. Can be taught via mass media vehicles such as radio, television, Internet.
5. Evidence to date suggests a low side effect profile.

These features make *mental silence* orientated techniques such as SYM ideally suited as strategies to promote and preserve health as well as prevent disease, mental disorders.

Quite apart from the important theoretical research that needs to be done to help unravel the why and how of *mental silence*'s specific effect, practical primary health strategies need to be developed around methods that can cultivate the experience of *mental silence*. Continuous evaluation of the impact of such strategies would be an important part of this process.

Some potential initiatives worth exploring include:

1. Stress management programmes for at risk populations. These may be implemented in the workplace where high stress has been identified as a problem.

2. Universal mental health primary prevention strategies aimed at building resilience in those not yet at risk as well as providing a first-line coping strategy for those who may be likely to become at risk.

3. Ongoing community based services established in conjunction with healthcare facilities to enhance health and wellbeing of disease sufferers, especially those with chronic disease.

## 12.10 Conclusion – *cogito ergo sum* or *sum ergo cogito*?

The popularity of meditation in the West has grown in parallel with the mainstreaming of alternative health and the New Age movement and is now fuelled by a potent combination of traditional anecdote, selective misreadings of the scientific database and marketing hyperbole. Popularity with consumers may well be encouraged by apparent acceptance amongst health professionals.

The scientific evidence clearly shows that prevalent definitions of meditation do not have much of an effect beyond that of simple rest. This is primarily because the original understandings of meditation and its relationship to *mental silence* have not been successfully translated into the West.

The current lack of clarity about definition is used by the New Age industry and entrepreneurs to perpetuate a misunderstanding of a form of meditation that is basically no more effective than sitting quietly, listening to music or walking in the park. In contrast the traditional understanding of meditation as *mental silence* does appear to generate scientifically verifiable effects and is therefore likely to be if considerable value to health professional and indeed modern consumers. *Sahaja Yoga* meditation is an example of such an approach to meditation.

Finally, in some ways the fact that specific effects appear to be associated with the *mental silence* experience poses a challenge to the philosophical underpinnings of Western culture by not only describing a state of non-thought, but also demonstrating that this state is accessible and of practical importance to the general population.

The *cogito ergo sum* argument essentially states that "I am thinking therefore I exist". To some extent Western culture's difficulty in apprehending the idea of non-thought is the result of its Cartesian underpinnings — the idea that one cannot exist if one is not thinking. The metaphysical implications of Descartes' phrase, which equate thinking activity with self identity contrast sharply with the Eastern metaphysical idea that existential reality can be perceived only when one is not thinking, which might be stated in Latin as *sum cogito ergo* (I am, therefore I think)!

The ancient Eastern perspective on meditation, the mind, consciousness and health has here been demonstrated to have an important potential role to play in the health and wellbeing of people both in the East and West.

## 12.11 Prologue

Until 2006 the USA's authoritative National Centre for Complementary and Alternative Medicine defined meditation as "a conscious mental process that induces a set of integrated physiological changes termed the *Relaxation Response*"[5]. The NCCAM recently reviewed its definition of meditation, now defining it in this way:

> In meditation, a person learns to focus his attention and suspend the stream of thoughts that normally occupy the mind. This practice is believed to result in a state of greater physical relaxation, mental calmness, and psychological balance. Practicing meditation can change how a person relates to the flow of emotions and thoughts in the mind.[254]

I feel that it is noteworthy that, in this considerably revised position paper, one of its few citations is a publication derived from the work described in this thesis. This previous publication specifically spells out the nature and significance of the West's misunderstanding of meditation and emphasises the idea that meditation is traditionally characterised by a state of *mental silence*[594]. It seems that the ideas encompassed by the hypothesis proposed and examined in this thesis have begun to gain traction within the scientific community.

# Glossary and Abbreviations

| | |
|---|---|
| β | beta coefficient. |
| ACS | Australian Community Survey |
| ADHD | attention deficit hyperactivity disorder |
| AE | adverse events |
| AHR | airway hyper-responsiveness |
| AHR | airway hyper-responsiveness. |
| am PEF | average morning peak flow |
| ANCOVA | analysis of covariance. |
| ANOVA | analysis of variance. |
| ANS | autonomic nervous system. |
| AQLQ | asthma quality of life questionnaire |
| AR | applied relaxation. |
| AVA | arteriovenous anastomose |
| BDI | Beck Depression Anxiety Index |
| BEACH | Bettering Evaluation and Care of Health |
| BP | blood pressure. |
| CAM | complementary and alternative medicine. |

| | |
|---|---|
| CBT | cognitive behaviour therapy. |
| CDC | Centers[sic] for Disease Control and Prevention |
| CES-D | Center for Epidemiological Studies Depression Scale |
| CHD | coronary heart disease |
| CI | confidence interval. |
| Climacteric Scale | validated menopausal symptoms self report instrument (questionnaire). |
| COMP | comparison meditators |
| CONSORT | Consolidated Standards of Reporting Trials Statement. |
| CRUFAD | Clinical Research Unit for Anxiety and Depression |
| CSM | clinically standardised meditation. |
| CVD | cardiovascular disease |
| CVS | cardiovascular system. |
| DD | depression-dejection |
| DP | duration of practice |
| EAS | emotion-anger subscale |
| ECT | electroconvulsive therapy |
| EDA | electrodermal activity. |

| | |
|---|---|
| EEG | electroencephalography |
| ES | effect size. |
| FEV | forced expiratory volume |
| FMRI | functional magnetic resonance imaging |
| FM | formal meditation. |
| FMP | final menstrual period |
| FS | foot soak. |
| GH | general health |
| GHQ | The General Health Questionnaire. |
| GLM | general linear model |
| GLM | generalized linear model for ANCOVA statistical analysis. |
| GSR | galvanic skin response |
| HADS | Hospital Anxiety/Depression Scale |
| Hathayogapradipika | A tract of almost 400 verses on the so-called *Hatha Yoga*. The first chapter of the Hathayogapradipika describes a variety of bodily postures, diet and general topics. The second deals with the control of the life force to be achieved by breathing exercises. The third chapter describes the 10 *mudras* which are said "to destroy ageing and death". The fourth chapter describes the liberating experience of *Samadhi* (a meditative state) which is the culmination of the |

| | |
|---|---|
| | whole training process wherein "...when the "great force", i.e. *kundalini* is awakened, the life force dissolves and mental activity ceases"[215]. |
| HF | hot flushes |
| HP | A hypothalamic pituitary axis |
| HR | heart rate |
| HRT | hormone replacement therapy |
| HSE | Health and Safety Executive |
| HT | hypertension |
| IHD | ischemic heart disease |
| IS | interpersonal strain |
| ITT | intention-to-treat. |
| K10 | Kessler Psychological Distress Scale 10 item |
| KIHD | Kuopio Ischemic Heart Disease |
| Kupperman Index | validated menopausal symptoms self report instrument (questionnaire). |
| LOCF | last observation carried forward |
| *Mahabhrata* | ancient Indian text describing the battle between two royal houses, one committed to morality and the other to immorality. It became |

the stage to illustrate many of the spiritual principles of Indian culture, of which the yoga tradition is fundamental.

| | |
|---|---|
| MANCOVA | multiple analysis of covariance |
| MANOVA | multiple analysis of variance |
| MBSR | mindfulness based stress reduction programme |
| MCS | mental health summary score of the SF-36 |
| MEG | magnetoencephalography |
| MENQOL | menopause specific quality of life questionnaire |
| MH | mental health, subscale of the SF-36 |
| MLS | meditation lifestyle survey |
| MM | mindfulness meditation |
| MOS SF-36 | Medical Outcome Study Short-Form Health Survey 36 (SF-36) |
| MS | mental silence |
| MSCL | Medical Symptom Checklist |
| MTA | Multimodal Treatment |
| NCLS | National Church Life Survey |
| NHEFS | National Health Epidemiologic Followup Study |
| NHIS | National Health Interview Survey |

| | |
|---|---|
| NR | not reported |
| NRT | non-randomized controlled trial |
| NT | no treatment |
| ORQ | organisational resource questionnaire. |
| OSI | Occupational Stress Inventory |
| PANAS | Positive and Negative Affect States |
| *Patanjali* | ancient Indian physician and mystic (c2500 BC) who attempted to synthesise the many disparate texts on yogic discipline (such as the, cited above) into single coherent practical guide for those aspiring to experience higher consciousness and self realisation. |
| PCS | physical health summary score of the SF-36 |
| PEFR | peak expiratory flow rate |
| PF | physical function subscale of the SF-36 |
| PHS | physical strain |
| PIC | proinflammatory cytokine |
| PMR | progressive muscle relaxation. |
| POMS | Profile of Mood States |
| PRQ | personal resources questionnaire. |
| PS | parasympathetic |

| | |
|---|---|
| PS tone | parasympathetic tone. |
| PSQ | Psychological Strain Questionnaire |
| PSY | psychological strain |
| QOL | quality of life |
| RACGP | Royal Australian College of General Practitioners |
| RCT | randomised controlled trial |
| RE | role emotional |
| RM | relaxation-based meditation |
| RP | role physical subscale of the SF-36. |
| RR | relaxation response or respiratory rate |
| S | sympathetic |
| S tone | sympathetic tone. |
| SAE | serious adverse event |
| *Sahajaiya* | Buddhist sect concerned with the esoteric spiritual ideas of *sahaja* |
| SAM | sympathetic adrenal medullary system |
| *Samadhi* | state of meditation |
| SAMS | sympatho-adrenal medullary system |
| SCL90R | Symptom Checklist 90 Revised |

| | |
|---|---|
| SD | standard deviation. |
| SDA | Seventh Day Adventists |
| SEE | standard error of the estimate |
| SESAHS | South-Eastern Sydney Area Health Service |
| SF | social function |
| SF-36 | Short-Form health survey 36 item |
| SM | frequency of attending social gatherings that mostly involve other SYM practitioners but does not involve formal group meditation. |
| SMC | Sydney Menopause Centre |
| SMI | stress management intervention |
| SNS | sympathetic nervous system |
| ST | skin temperature |
| STAI | State-Trait Anxiety Inventory |
| SYM | *Sahaja Yoga* meditation |
| TA | thoughtless awareness, a term used to describe the *mental silence* experience |
| TM | Transcendental Meditation™ |
| Total SF-36 | SF36 total score |

| | |
|---|---|
| *Upanishad* | part of the trilogy of scriptures which Vedanta (a school of Hinduism) is based on. (The other two are *Brahma Sutra* and *Bhagavad Gita*). An *Upanishad* is the last part of a *Veda* (a sacred Hindu scripture) and, unlike the first part of *Vedas* which gives strict injunctions about rituals and ethics as well as the forms of meditation, it is exclusively dedicated to philosophical discussions as to how to obtain the real wisdom, or reach enlightenment. |
| UVMA | urinary vanylmandelic acid |
| V | vitality |
| *vipassana* | a term used as one of two poles for the categorization of types of Buddhist meditation, the other being *samatha*. The term is also used to refer to the Buddhist *vipassana movement* (modeled after *Theravāda Buddhism* meditation practices), which employs *vipassanā* and *ānāpāna* meditation as its primary techniques and places emphasis on the teachings of the *Satipatthāna Sutta*. The primary initial subject of investigation in that style of meditation is sensation and feeling. |
| VS | vocational strain |
| WL | waiting list |

# Appendix 1. Data Extraction Criteria and Rules

Relevant journal articles were collected from electronic databases such as MEDLINE, PsycINFO and Current Contents, and from Internet and paper searches. Data was extracted from these journal articles and encoded and analysed using SPSS. The types of data extracted and the encoding rules used in SPSS are as follows:

**Author.**

**Year of Publication.**

**Author as:**

1. trainer of participants;
2. developer of meditation technique;
3. employee of institution with conflict of interest.

All encoded in SPSS as 1= "yes", "2="no".

**Meditation Technique Studied**. The various techniques were encoded into SPSS as follows (Multiple techniques examined in the one study were collected into separate columns):

1= "TM" for Transcendental meditation;

2= "CSM" for clinical standard meditation;

3= "MBSR" for Mind-Body-Spirit Medicine and similar interventions based on the MBSR;

4= "RR" for the *Relaxation Response* technique;

5= "SYM" for *Sahaja Yoga* meditation;

6= "MuMo" for multimodal techniques not including MBSR;

7= "mind" for *Mindfulness* only techniques;

8= "NS" if the technique was not specified;

9= "O" if the technique did not fit into any other categories;

10= "mantra" for Mantra Meditation techniques;

11= "MMTM" for Mantra Meditation techniques based on TM

12= "zen" for Zen meditation techniques;

13= "Acem" for Acem meditation;

14= "KM" for Kundalini Meditation;

15= "RRB" for RR-based techniques.

**Number of arms of the study**. These ranged from 2 to 5 arms and were encoded as 1= "2 arm study", 2="3 arm study", 3="4 arm study" and 4="5 arm study".

**Type of study:**

1= "Clinical trial, behavioural" Where primary condition being treated and/or outcomes measures are behavioural /psychological (but not psychiatric);

2= "Clinical Trial, Medical": Where primary condition being treated and/or outcome measures are medical /psychiatric;

3= "Psychological trial, effects after prolonged training", prolonged being more than one week;

4= "Psychological trial, effects after brief training", brief being less than one week (usually a single session);

5= "clinical trial, medical and behavioural" for Clinical trials involving both medical and psychological dimensions.

**Comparison method.** The technique the participants were instructed to undertake: to act as a control for the meditation technique were extracted from the journals and inputted into SPSS. The rules for inputting the data and a description of each category follow:

1= "WL" for if comparators were put on a waiting list;

2= "ST" for if the comparators were given the standard treatment in their condition;

3= "NT" for if the comparators were given no treatment;

4= "UR" for if the comparators were given community resources, unstructured reading;

5= "SR" for if the comparators were given educational materials and a structured method to read the materials;

6= "UEM" for if the comparators were given educational materials presented in an unstructured fashion;

7= "EC" if the comparators undertook educational classes;

8= "EX" if the comparators were instructed to exercise;

9= "JW" if the comparators were instructed to write journals;

10= "RM" if comparators were instructed to engage in relaxation methods such as Progressive Muscle Relaxation;

11= "RE" if the comparators were instructed to rest or take a nap;

12= "HY" if the comparators were hypnotised;

13= "PQ" if the comparators engaged in pseudo-, quasi- or anti-meditation;

14= "BT" if the comparators engaged in behaviour therapy;

15= "GT" if the comparators engaged in group therapy;

16= "BFB" if the comparators engaged in biofeedback;

17= "Vis" if the comparators engaged in visualization exercises;

18= "Bre" if the comparators engaged in breathing exercises;

19= "O" if the comparators were instructed to engage in an unlisted activity;

20= “Mus” if the comparators were instructed to listen to specific music;

21= “SM” if the comparators engaged in stress management exercises.

**Comparison methods** were collapsed into the following groups according to face-validity:

1. minimal credibility, non-specific effects:
    a. waiting list, no treatment;
    b. community resources, unstructured reading, unstructured educational materials;
2. moderate credibility, non-specific effects:
    a. structured reading, educational classes, journal writing, standard treatment;
3. high credibility, non-specific effects:
    a. biofeedback, visualization, relaxation, rest, napping, hypnosis, music;
    b. pseudo, quasi, anti-meditation;
    c. behaviour therapy, group therapy, stress management, exercise.

These were encoded into SPSS as follows:

1= “low credibility”

2= “moderate credibility”

3= “high credibility”

In SPSS multiple columns were created for credibility to accommodate for if a study had more then one comparison.

**Condition assessed**. The conditions each study were attempting to assess were inputted into SPSS as follows:

1= “anxiety” for studies assessing the anxiety in the participants;

2= “stress/adjustment” for studies assessing either stress or the adjustment levels of participants;

3= “depression” for the assessment of the depression levels of the participants;

4= “physiological effects” for the assessment of physiological effects of meditation on the participants;

5= “hypertension” for studies assessing hypertension of the participants;

6= ”work stress” for studies assessing the levels of stress as a result of work;

7= “athletic performance” for the assessment of performance ;

8= “oncology” for the assessment of the impact of meditation on cancer in participants;

9= “substance abuse” for the assessment of level of substance abuse participants undertook;

10= “cardiometabolic risk, heart disease not HT” for the assessment of cardiometabolic risk factors in participants, not including hypertension;

11= “ageing” for the assessment of the impact of meditation on aspects of ageing by participants;

12= “pain" for the assessment of the level of pain felt by participants in specific circumstances;

13= “HT” for the assessment of symptoms of hypertension in participants;

14= “wellbeing, QOL, functional health” for the assessment of the levels of wellbeing, the quality of life or functional health, reported by the participants;

15= “academic, school performance” for the assessment of the performance of the participants in an academic settings;

16= “other” for the assessment of a condition not fitting into any other category;

17= "chronic illness (HIV, epi, ibs, asthma etc)" for the assessment of the impact of meditation on aspects of chronic or relapsing and remitting illness such as asthma, epilepsy or irritable bowel syndrome;

18= "self actualisation" for the assessment of the subject's levels of self actualisation or spirituality.

In SPSS multiple columns were created to accommodate when a study assessed more then one condition. The primary conditions assessed were listed first.

**Sources of participants**. The place where by the participants were recruited from were inputted into SPSS as follows:

1= "university";

2= "community";

3= "inpatient referrals" if participants were recruited as sufferers of a condition;

4= "outpatient referrals" if participants were recruited from hospital outpatient departments or via primary care facilities a disease;

5= "workplace";

6= "organization";

7= "school";

8= "athletic group";

9= "other".

In SPSS multiple columns were created to accommodate for if a study recruited from more then one source.

**Type of participant**. The specific groups that participants were categorised into were inputted into SPSS as follows:

1= "university students";

2= “workers”;

3= “athletes";

4= “inpatients”;

5= “health professionals”;

6= “oncology patients”;

7= “males”;

8= “females”;

9= “African Americans”;

10= “children”;

11= “outpatients”;

12= “no morbidity” ie having no clinical problem

13= “elderly”;

14= “school students”;

15= “general population”;

16= “other”.

Number of supervised sessions: Encoded into SPSS numerically.

**Instructions by recording only**. Whether participants were given instructions exclusively through a recording or not was extracted. This was encoded into SPSS as 1= “Yes”, 2= “No”.

**Measurements used**. The measurements that the study used to assess the changes in conditions between groups were extracted and recorded in SPSS. Most measurements were given a single column with a 1= “yes”, 2=”no” style of encoding except for the first two items.

i. Blood pressure: As multiple types of blood pressure were used as measurements, blood pressure was encoded as follows:

1= "physiological";

2= "hypertension";

3= "stressor task";

4= "no".

ii. Lab Stressor: As there were different stressors used, the lab stressor was encoded as follows:

1= "pain tolerance";

2= "cognitive challenge";

3= "physical exercise";

4= "no".

iii. Cognitive tests or exam performance

iv. Other objective, not listed elsewhere;

v. Clinician assessment;

vi. Other depression measure, not listed elsewhere;

vii. Other mood, not listed elsewhere;

viii. Other stress measure, not listed elsewhere;

ix. Self actualisation;

x. Exercise;

xi. Disease specific symptom;

xii. Cardiometabolic risk factors;

xiii. Other anxiety, not listed elsewhere;

xiv. Hypertension blood pressure;

xv. Endocrine;

xvi. Immunity;

xvii. Other physiological measure, not listed elsewhere;

xviii. Stressor task;

xix. Physiological heart rate;

xx. Cognitive challenge stressor;

xxi. Symptom diary;

xxii. Noxious stimulus stressor;

xxiii. Physical exercise stressor;

xxiv. Medication consumption;

xxv. Symptom Checklist-90 (SCL90);

xxvi. Positive and Negative Affect Scale (PANAS);

xxvii. Hospital Anxiety/ Depression Scale (HADS);

xxviii. State-Trait Anxiety Inventory (STAI);

xxix. Profile of Mood States Questionnaire (POMS).

**Methodological issues**. Potential methodological issues that some articles presented were analysed and inputted into SPSS. They were encoded as 1= “yes”, 2= “no” unless otherwise stated.

1. Randomisation method described: randomisation was examined, with the level of description in the article being recorded. Randomisation was encoded as:
    a. 1= “f” if the article completely described randomisation including the specific method of randomisation;
    b. 2=”p” if the article only partially described the randomisation and failed to describe the actual method used in the process;
    c. 3=”n” if the article failed to describe the randomisation method in any detail.

2. Compliance with treatment assessed: whether the article described the participants compliance rate with meditation.
3. Expectancy/credibility of comparator: whether the expectancy or credibility of the participants was assessed or not.
4. Blinding to full hypothesis (or group allocation): whether the article described attempts to blind parts of the study.
    a. raters: whether raters were reported to be blind to the group allocation and study hypothesis;
    b. participants: whether participants were reported to be blind to the group allocation and study hypothesis;
    c. statistician: whether statisticians were reported to be blind to the group allocation and study hypothesis;
    d. trainers: whether trainers of the meditation technique were reported to be blind to the group allocation and study hypothesis;
5. Sample size calculation: whether the article reported calculating the sample size
6. Baseline comparisons/ randomisation check: whether the article reported a check between as an indicator of successful randomisation. This was encoded into SPSS as follows:
    i. "YND" if the article reported carrying out baseline comparisons however did not detect significant differences;
    ii. "YD" if the article reported carrying out baseline comparisons and significant differences were detected;
    iii. "N" if the article did not report carrying out baseline comparisons.

7. Dropouts compared to completers: whether the article reported comparing the scores from participants who dropped out to participants who completed the study. This was encoded as follows:
    i. "YS" if dropouts were compared to completers and no significant differences detected;
    ii. "YD" if dropouts were compared to completers and significant differences were detected;
    iii. "N" if the article not report comparing dropouts and completers.
8. Data checked for normal distribution: if the article reported the participant baseline data being checked against what is expected under the normal distribution.
9. Intention to treat analysis: whether the article reported an intent to treat analysis being carried out and used this analysis as the basis for its results, discussion and conclusion.
10. Bonferroni or other adjustment for multiple comparisons: whether the article reported applying a bonferroni or equivalent analysis on someone.
11. Appropriate analysis: which analysis the article reported carrying out on the data acquired. This was encoded as follows:
    i. "reg" for if the data is reported to be analysed using regression analysis;
    ii. "rmA" if the data is reported to be analysed using repeated measures analysis of variance (ANOVA)
    iii. "rmAC" if the data is reported to be analysed using repeated measures analysis of covariance (ANCOVA);

iv. "rmM" if the data is reported to be analysed using repeated measures multiple analysis of variance (MANOVA);

v. "rmMC" if the data is reported to be analysed using repeated measures multiple analysis of covariance (MANCOVA);

vi. "rmNP" if the data is reported to be analysed using repeated measures non-para (metric);

vii. "tcs" if the data is reported to be analysed using change score, t test;

viii. "Acs" if the data is reported to be analysed using change score, ANOVA;

ix. "ACcs" if the data is reported to be analysed using change score, ANCOVA;

x. "Mcs" if the data is reported to be analysed using change score, MANOVA;

xi. "MCcs" if the data is reported to be analysed using change score, MANCOVA;

12. Inappropriate analysis.

i. "uA" univariate ANOVA;

ii. "uAC" if the data is reported to be analysed using univariate ANCOVA;

iii. "uM" if the data is reported to be analysed using univariate MANOVA;

iv. "uMC" if the data is reported to be analysed using univariate MANCOVA;

v. "nbgc" if the data is reported to have had not been analysed using between groups comparisons;

vi. "NCD" if the description of the data analysis is unclear or confusing;

vii. "OIT" if the data is reported to be analysed using another inappropriate technique not listed;

viii. "NR" If no data analysis is reported.

**Reported Outcomes:** The results found by the articles were analysed and the number of positive, negative and neutral outcomes were extracted. These were entered into SPSS numerically in the following categories:

a. Meditation vs control: number of outcomes in the cases of a meditation technique being compared to a control technique
    a. Positive significant difference, number of outcomes;
    b. No significant differences, number of outcomes;
    c. Negative significant differences, number of outcomes.
b. Meditation vs meditation: number of outcomes in the case of a meditation technique being compared to another meditation technique
    a. Positive significant difference, number of outcomes;
    **b.** No significant differences, number of outcomes;
    **c.** Negative significant differences, number of outcomes.

**Number of citations:** the relative effect the published article had after its publication was calculated by finding the number of citations the article has on various electronic article databases. This was recorded in SPSS numerically.

**Publication cited in other publications**:

a. Medline;
b. Psycinfo;
c. Scopus;

d. Web of Science.

**Conclusions stated in abstract supported by reported analysis and results**. The results the article claimed to find were compared to the outcomes of the article's data. This was encoded into endnote as 1="yes", 2="no".

# Appendix 2. Summary of systematic literature review.

| Author | Year | n | n per group | Dropouts | Primary Technique† | Comparator†† | Duration | Follow-up | Objective Measures††† | Self report Measures††† | Compliance | Expectancy | Randomised§ | Raters blind | Partic. blind | Stat'n blind | Trainers blind | Sample size calc | Baseline comps‡ | DO vs Compl. ‡‡ | Analysis ‡‡‡ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Alexander[77] | 1989 | 73 | 18 | 25 | TM | RM | 12 | 84 | PBP OO CE CA | STA QOL OD OM | Y | Y | P | Y | N | N | Y | N | N | N | RmA uAC ucd |
| Anderson[37] | 1999 | 91 | 46 | 0 | MMTM | WL | 5 | 9 | - | STA OS | Y | N | N | N | N | N | N | Y | N | N | uMC |
| Astin[32] | 1997 | 28 | 14 | 9 | MBSR | WL | 8 | 0 | - | SCL SA OS | Y | Y | N | N | N | N | N | N | Ynd | N | ACcs |
| Astin[78] | 2003 | 128 | 64 | 50 | MuMo | EC | 8 | 16 | Ex CA | DSS BDI SF OS | N | N | F | Y | N | N | N | Y | Ynd | Ynd | RmA |
| Bahrke[79] | 1978 | 75 | 25 | 0 | RR | EX | 0 | 0 | PBP HR ST OO | STA | N | N | N | N | N | N | N | N | N | N | RmA |
| Barnes[80] | 2001 | 35 | 18 | 2 | TM | EC | 8 | 0 | CMR HR OO | - | Y | N | N | N | N | N | N | N | Ynd | N | RmA |
| Barnes[668] | 2004 | 156 | 78 | 56 | TM | UEM | 16 | 16 | HR | - | Y | N | P | N | N | N | N | N | Ynd | N | RmA RmMC |
| Barnes[669] | 2004 | 89 | 45 | 16 | MBSR | EC | 12 | 0 | HT | OM OS | Y | Y | N | N | N | N | N | N | Ynd | N | Mcs |
| Barnhofer[670] | 2007 | 34 | 17 | 12 | MBSR | ST | 8 | 0 | EEG | BDI PAN | N | N | P | Y | N | N | N | N | YD | N | RmM |

| Author | Year | n | n per group | Dropouts | Primary Technique† | Comparator†† | Duration | Follow-up | Objective Measures††† | Self report Measures††† | Compliance | Expectancy | Randomised§ | Raters blind | Partic. blind | Stat'n blind | Trainers blind | Sample size calc | Baseline comps‡ | DO vs Compl. ‡‡ | Analysis ‡‡‡ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Benson[75] | 1978 | 69 | 35 | 37 | RR | HY | 8 | 0 | PBP HR OO CA | HAD OA | Y | N | N | N | N | N | N | N | N | N | uAC |
| Berger[81] | 1988 | 387 | 97 | 82 | RR | EX | 12 | 0 | - | POM OS | Y | N | P | N | N | N | N | N | Ynd | N | RmM |
| Bormann[82] | 2006 | 93 | 47 | 27 | MM | EC | 10 | 12 | IM OO | STA QOL OD OM SA OS | Y | N | F | N | N | N | N | N | YD | YD | RmA |
| Boswell[83] | 1979 | 80 | 20 | 0 | MMTM | PQ | 2 | 0 | HR EDA | STA | Y | Y | P | N | N | N | N | N | N | N | uA uAC |
| Brazier[84] | 2006 | 62 | - | 15 | MuMo | ST | 3 | 6 | - | DSS QOL OS | N | N | F | N | N | N | N | N | Ynd | N | RmA Tcs |
| Bruning[85] | 1986 | 86 | 29 | 21 | CSM | EX | 10 | 0 | - | OA OS | N | N | N | N | N | N | N | N | N | N | ucd |
| Carlson[86] | 1988 | 36 | 12 | - | other | RM | 2 | 0 | HR EMG ST | STA SCL OM OS | N | N | P | N | N | N | N | N | YD | N | uA uM |
| Carrington[36] | 1980 | 154 | 39 | 6 | CSM | RM | 6 | 22 | - | SCL OS | Y | Y | N | N | N | N | N | N | Ynd | N | uAC |
| Carson[671] | 2005 | 43 | -. | 0 | other | ST | 8 | 12 | - | DSS OM OS | Y | Y | F | N | N | N | N | N | YD | N | nbgc |
| Castillo-Richmond[88] | 2000 | 138 | 69 | 78 | TM | UR | 24 | 36 | CMR HT OO | - | Y | N | P | Y | N | Y | N | N | Ynd | Ynd | - |

| Author | Year | n | n per group | Dropouts | Primary Technique† | Comparator†† | Duration | Follow-up | Objective Measures††† | Self report Measures††† | Compliance | Expectancy | Randomised§ | Raters blind | Partic. blind | Stat'n blind | Trainers blind | Sample size calc | Baseline comps‡ | DO vs Compl. ‡‡ | Analysis ‡‡‡ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Cohen[89] | 2004 | 39 | 20 | 9 | other | WL | 7 | 1 | - | STA<br>OM<br>OD OS | Y | Y | P | Y | N | N | N | Y | Ynd | Ynd | oit |
| Couture[90] | 1994 | 40 | 10 | 0 | RRB | BFB | 2 | 0 | HR | OS | N | N | N | N | N | N | N | N | N | N | uA |
| Credidio[541] | 1982 | 30 | 10 | 3 | CSM | BFB | 6 | 0 | EMG<br>ST | OS | Y | N | N | N | N | N | N | N | N | N | RmAC |
| Curiati[92] | 2005 | 19 | 10 | 4 | MuMo | UEM | 14 | 0 | EC OO | DSS | Y | N | N | N | N | N | N | N | Ynd | N | ucd |
| Davidson[93] | 2003 | 48 | 24 | 7 | MBSR | WL | 8 | 16 | EEG<br>Im | STA<br>PAN | Y | N | N | N | N | N | -. | N | Ynd | Ynd | Mcs |
| Deberry[94] | 1982 | 36 | 12 | 0 | MuMo | WL | 10 | 10 | - | STA<br>OD | N | N | N | N | N | N | N | N | Ynd | N | uA<br>ucd |
| Deckro[95] | 2002 | 128 | 64 | 38 | MuMo | WL | 6 | 0 | - | STA<br>SCL<br>QOL<br>OS | Y | N | N | N | N | N | N | N | Ynd | Ynd | nr |
| Delmonte[96] | 1985 | 40 | 20 | 0 | MMTM | RE | 2 | 0 | PBP<br>HR<br>EMG<br>EDA<br>ST OO | | N | Y | N | N | N | N | N | N | N | N | RmA |
| Dillbeck[97] | 1977 | 33 | 17 | 0 | TM | SM | 2 | 0 | - | STA | Y | N | N | N | N | N | N | N | YD | N | ucd |
| Dua[49] | 1992 | 32 | 8 | 3 | other | BT | 4 | 6 | - | OM | N | N | N | N | N | N | N | N | N | N | RmAC |
| Edelman[98] | 2006 | 154 | - | 32 | MuMo | ST | 40 | 0 | CMR<br>HT CA | - | Y | N | N | Y | N | N | N | N | YD | N | - |

| Author | Year | n | n per group | Dropouts | Primary Technique† | Comparator†† | Duration | Follow-up | Objective Measures††† | Self report Measures††† | Compliance | Expectancy | Randomised§ | Raters blind | Partic. blind | Stat'n blind | Trainers blind | Sample size calc | Baseline comps‡ | DO vs Compl. ‡‡ | Analysis ‡‡‡ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Elder[99] | 2006 | 60 | 30 | 5 | TM | UEM | 12 | 12 | PBP HR CMR OP | - | Y | N | F | Y | N | N | N | N | N | N | Tcs oit |
| English[100] | 1983 | 36 | 12 | 1 | RR | RM | 5 | 0 | ST HR PT | OM | Y | N | P | N | N | N | N | N | Ynd | N | uAC |
| Fee[101] | 1978 | 54 | 11 | 0 | other | BFB | - | 0 | EMG HR ST EDA RR | STA | N | N | P | N | N | N | N | N | Ynd | N | RmA |
| Fiedler[524] | 1989 | 66 | 33 | 9 | MuMo | WL | 7 | 0 | ST HR EMG CC | SCL OS | Y | Y | N | Y | N | N | N | N | N | N | uAC |
| Fields[672] | 2002 | 57 | 19 | 11 | MuMo | EX | 52 | 0 | PBP CMR | - | Y | N | F | Y | N | N | N | N | Ynd | Ynd | RmNP |
| Galvin[104] | 2006 | 15 | 8 | 0 | RR | ST | 5 | 0 | EC CE | STA BDI | Y | N | N | Y | N | N | N | N | YD | N | RmA |
| Gaston[105] | 1991 | 18 | 6 | 6 | other | WL | 20 | 0 | MC CA | QOL OS | Y | N | N | Y | N | N | N | N | N | N | - |
| Griffiths[106] | 1981 | 50 | 17 | - | NS | BFB | 3 | 0 | EMG STR HR OP | STA | N | N | P | N | N | N | N | N | N | N | uAC |
| Haffner[107] | 1982 | 21 | 7 | 1 | NS | NT | 8 | 12 | HT | OA OD OM OS | Y | N | P | N | N | N | N | N | N | N | RmA |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hager[108] | 1978 | 30 | 15 | 13 | RR | BFB | 4 | 0 | HT | - | N | N | N | N | N | N | N | N | Ynd | N | RmA |
| Hall[109] | 1991 | 30 | 10 | 0 | TM | RM | 7 | 0 | OO | - | N | N | P | N | N | N | N | N | Ynd | N | ucd |
| Harinath[110] | 2004 | 30 | 15 | 0 | MuMo | EX | 12 | 0 | PBP HR RR EC Ex OO | QOL OA OS | N | N | F | N | N | N | N | N | N | N | ucd |
| Hiderley[673] | 2004 | 31 | 16 | 0 | other | UR | 8 | 0 | Im | HAD | N | N | P | N | N | N | N | N | N | N | Tcs |
| Irvin[112] | 1996 | 45 | 15 | 12 | RR | SR | 7 | 0 | - | STA POM SD | Y | N | N | N | N | N | N | N | Ynd | N | nbgc |
| Ditto[674] | 2006 | 32 | -. | 0 | Mind | RM | 4 | 0 | PBP HR OP | - | Y | N | N | N | N | N | N | N | N | N | uA |
| Jain[66] | 2007 | 104 | - | 23 | MBSR | RM | 4 | 0 | - | OA OM SA OS | Y | N | F | N | N | N | N | Y | YD | N | uAC |
| Janowiak[113] | 1994 | 62 | 21 | - | CSM | Bre | 8 | 0 | - | SA OS | Y | N | P | N | Y | N | N | N | Ynd | N | RmA |
| Jayadevappa[114] | 2007 | 23 | - | 0 | TM | EC | 37 | 0 | EC Ex OO | DSS QOL SF OD OS | Y | N | F | Y | Y | Y | Y | N | YD | N | RmAC |
| Kabat-Zinn[115] | 1998 | 37 | 19 | 18 | MBSR | ST | 13 | 0 | CA | STA SCL | Y | Y | N | Y | Y | N | N | N | Ynd | N | Tcs RmA |

| Author | Year | n | n per group | Dropouts | Primary Technique† | Comparator†† | Duration | Follow-up | Objective Measures††† | Self report Measures††† | Compliance | Expectancy | Randomised§ | Raters blind | Partic. blind | Stat'n blind | Trainers blind | Sample size calc | Baseline comps‡ | DO vs Compl. ‡‡ | Analysis ‡‡‡ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Keefer[675] | 2001 | 16 | 8 | 3 | RR | WL | 6 | 12 | - | DSS | Y | Y | P | N | N | N | N | N | Ynd | N | RmA Tcs |
| Kember[676] | 1985 | 20 | 10 | 4 | TM | ST | 24 | 0 | CE | - | N | N | N | Y | N | N | N | N | N | N | RmNP |
| Kindlon[118] | 1985 | 35 | 18 | - | other | RE | 11 | 0 | HR CE CA | OM OS | Y | Y | N | N | N | N | N | N | N | N | nr |
| Kingston[119] | 2007 | 45 | 23 | 3 | MuMo | Vis | 3 | 0 | ST HR PT | PAN SA | Y | Y | P | N | N | N | N | Y | Ynd | Ynd | RmA |
| Kirkland[120] | 1980 | 60 | 15 | 10 | RR | RM | 2 | 0 | HR CE OO | OA OS | N | N | P | N | N | N | Y | N | N | N | uA uAC |
| Kirsch[121] | 1979 | 38 | 19 | 0 | RR | BT | 3 | 0 | HR CA | OA | Y | Y | P | Y | N | N | N | N | Ynd | N | RmA |
| Klein[122] | 1985 | 74 | 25 | 32 | other | GT | 12 | 36 | CA | SCL DSS QOL OD OM OS | N | N | N | N | N | N | N | N | Ynd | Ynd | uAC |
| Koszyki[67] | 2007 | 53 | - | 13 | MBSR | BT | 8 | 0 | CA | DSS BDI QOL | Y | N | N | N | N | N | N | N | N | Ynd | uAC |
| Kumar[123] | 2002 | 67 | 34 | 0 | KM | WL | 7 | 0 | - | QOL | N | N | N | N | N | N | N | N | YD | N | RmA ucd nr |
| Paula-Labrador[677] | 2007 | 103 | 52 | 19 | TM | EC | 16 | 0 | PBP Ex CMR | OA OD OM OS | Y | N | P | Y | N | Y | N | N | YD | N | Tcs RmNP |

| Author | Year | n | n per group | Dropouts | Primary Technique† | Comparator†† | Duration | Follow-up | Objective Measures††† | Self report Measures††† | Compliance | Expectancy | Randomised§ | Raters blind | Partic. blind | Stat'n blind | Trainers blind | Sample size calc | Baseline comps‡ | DO vs Compl. ‡‡ | Analysis ‡‡‡ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lee[125] | 2007 | 46 | - | 5 | MuMo | EC | 8 | 0 | - | STA<br>SCL<br>BDI<br>OD | N | N | P | N | N | N | N | N | Ynd | N | RmA |
| Lehrer[126] | 1983 | 61 | 20 | 11 | CSM | RM | 5 | 24 | HR<br>EMG<br>EDA<br>EEG<br>NS | STA<br>SCL<br>OA OS | N | Y | P | N | N | N | N | N | YD | N | RmAC<br>ACcs |
| Linden[678] | 1973 | 90 | 30 | 0 | other | EC | 18 | 0 | CE CA | STA | N | N | P | N | N | N | N | N | Ynd | N | uA |
| Malcolm[128] | 2007 | - | - | - | MBSR | WL | - | - | - | PAN<br>OS | - | - | - | - | - | - | - | - | - | - | - |
| Mandel[129] | 1990 | 45 | 15 | 0 | RR | RE | 0 | 0 | PBP<br>HR<br>MC<br>CA | STA<br>OS | N | N | N | Y | Y | N | N | N | Ynd | N | uA |
| Mccarberg[130] | 1999 | 353 | 177 | 108 | MuMo | UR | 24 | 24 | | OS | N | N | F | N | N | N | N | N | YD | YD | uA |
| Mccomb[131] | 2004 | 20 | 10 | 2 | MBSR | WL | 8 | 0 | HR<br>RR<br>EC Ex<br>OO | STA<br>SF | N | N | F | N | N | N | N | N | Ynd | N | RmA |
| Mcmillan[132] | 2002 | 145 | 48 | 15 | Mind | EX | 4 | 48 | CE<br>CA | HAD<br>QOL | Y | N | N | Y | N | N | N | N | Ynd | N | nr |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Moadel[679] | 2007 | 128 | - | 36 | MuMo | ST | 12 | 0 | - | SD OM SA | Y | N | N | N | N | N | N | Y | YD | N | Reg |
| Moritz[680] | 2006 | 165 | 55 | 18 | MBSR | Vis | 8 | 4 | - | POM SF | Y | N | F | N | N | N | N | Y | YD | N | RmA |
| Murphy[133] | 1986 | 60 | 20 | 17 | CSM | EX | 8 | 6 | Ex | SD | Y | Y | P | N | N | N | N | N | Ynd | N | RmA |
| Oken[134] | 2004 | 69 | 23 | 12 | MuMo | EX | 24 | 0 | EEG Ex CE | STA POM DSS SF OS | N | N | F | Y | N | Y | N | Y | Ynd | Ynd | uAC |
| Oktedalen[135] | 2001 | 29 | 15 | - | ACEM | ST | 24 | 0 | EC PE PT Ex OO | - | Y | N | N | N | N | N | N | N | N | N | uA |
| Oman[136] | 2006 | 61 | 31 | 3 | other | WL | 8 | 8 | - | SF OS | Y | N | N | N | N | N | N | N | N | Ynd | oit |
| Ottens[137] | 1975 | 57 | 18 | 3 | TM | BT | 10 | 0 | - | SD | Y | N | N | N | N | N | N | N | Ynd | N | RmA |
| Panjwani[681] | 2000 | 32 | 11 | 0 | SY | PQ | 24 | 0 | EDA EEG EC | SD | N | N | N | N | N | N | N | N | Ynd | N | uA |
| Parker[139] | 1978 | 30 | 10 | 0 | RR | RM | 3 | 0 | PBP HR EDA | STA | N | N | F | N | N | N | N | N | N | N | uA |
| Patel[140] | 1981 | 204 | 102 | 12 | MuMo | UEM | 8 | 32 | HT HR EC | - | N | N | N | N | N | N | N | N | Ynd | N | Tcs |
| Puente[141] | 1980 | 60 | 15 | 3 | TM | BT | 3 | 0 | HR | - | N | N | P | N | N | N | N | N | N | N | uA |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Puente[65] | 1981 | 47 | 16 | 3 | TM | ST | 1 | 0 | HR EMG EDA EEG RR | OS | N | N | N | Y | Y | N | N | N | YD | N | uA |
| Puryear[682] | 1976 | 218 | 109 | 59 | other | ST | 4 | 0 | - | OA OS | Y | N | P | N | N | N | N | N | Ynd | N | RmA |
| Rausch[683] | 2006 | 387 | - | 0 | CSM | RM | 1 | 0 | - | OA OS | N | N | N | N | N | N | Y | N | Ynd | N | RmAC |
| Sawada[38] | 1988 | 24 | 12 | 6 | other | RM | 0 | 0 | ST HR EDA OP PT CC | STA OM | N | Y | N | N | N | N | - | N | N | N | RmA |
| Schneider[684] | 1995 | 127 | 42 | 16 | TM | RM | 12 | 12 | HR | - | Y | Y | F | Y | N | Y | N | N | - | - | RmA |
| Schneider[685] | 2005 | 197 | 66 | 47 | TM | RM | 12 | 52 | HT HR MC | - | Y | N | F | Y | N | N | N | N | Ynd | Ynd | RmAC |
| Seer[686] | 1980 | 41 | 14 | 3 | MMTM | PQ | 5 | 12 | HT HR | STA SCL QOL OM | Y | Y | P | Y | N | N | N | N | N | N | RmA |
| Sephton[146] | 2007 | 91 | 46 | 23 | MBSR | WL | 8 | 8 | - | DSS BDI OS | Y | N | P | Y | Y | N | N | Y | Ynd | YD | oit |

| Author | Year | n | n per group | Dropouts | Primary Technique† | Comparator†† | Duration | Follow-up | Objective Measures††† | Self report Measures††† | Compliance | Expectancy | Randomised§ | Raters blind | Partic. blind | Stat'n blind | Trainers blind | Sample size calc | Baseline comps‡ | DO vs Compl. ‡‡ | Analysis ‡‡‡ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Shannahoff-Khalsa[687] | 1999 | 21 | 11 | 7 | KM | - | 12 | 60 | - | POM<br>SCL<br>DSS<br>OS | N | N | F | N | N | N | N | Y | Ynd | N | Tcs<br>ucd |
| Shapiro[688] | 1998 | 78 | 39 | 5 | MBSR | WL | 8 | 0 | - | STA<br>SCL<br>SA OS | Y | N | P | Y | N | Y | N | N | Ynd | N | RmM<br>RmMC |
| Sharma[149] | 2006 | 30 | - | 0 | SY | WL | 8 | 0 | CE | OD | N | N | N | N | N | N | N | N | Ynd | N | Tcs |
| Sheppard[150] | 1997 | 44 | 22 | 12 | TM | SM | 12 | 140 | PBP | STA<br>OD OS | Y | N | N | Y | Y | N | N | N | Ynd | N | uAC |
| Smith[4] | 1976 | 139 | 46 | 61 | TM | PQ | 24 | 0 | - | STA<br>OS | Y | N | F | N | Y | N | Y | N | N | N | uAC |
| So[152] | 2001 | 99 | 50 | 0 | TM | ST | 52 | 0 | CE | STA<br>OS | N | N | N | N | N | N | N | N | N | N | uAC |
| Solberg[153] | 1996 | 25 | 13 | 0 | ACEM | NT | 7 | 52 | OO | OS | Y | Y | P | Y | N | N | N | N | N | N | Tcs<br>Acs |
| Solberg[154] | 2000 | 39 | - | 8 | ACEM | BFB | 24 | 0 | Ex<br>OO | STA | Y | N | N | N | N | N | N | N | N | N | uA<br>ucd |
| Speca[155] | 2000 | 109 | 55 | 6 | MBSR | WL | 7 | 24 | - | POM<br>OS | Y | N | F | N | N | N | N | N | Ynd | Ynd | RmM |
| Targ[156] | 2002 | 181 | 91 | 51 | MuMo | EC | 12 | 0 | - | POM<br>DSS<br>SA | N | N | P | N | N | N | N | N | Ynd | Ynd | RmA<br>RmM |

| Author | Year | n | n per group | Dropouts | Primary Technique† | Comparator†† | Duration | Follow-up | Objective Measures††† | Self report Measures††† | Compliance | Expectancy | Randomised§ | Raters blind | Partic. blind | Stat'n blind | Trainers blind | Sample size calc | Baseline comps‡ | DO vs Compl. ‡‡ | Analysis ‡‡‡ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Taub[157] | 1984 | 250 | 63 | 132 | TM | BFB | 24 | 52 | - | POM OS | Y | N | P | N | N | N | N | N | N | N | uA |
| Taylor[158] | 1995 | 10 | 5 | 0 | MuMo | NT | 10 | 4 | IM | STA POM OS | Y | N | N | N | N | N | N | N | N | N | Acs |
| Teasdale[159] | 2000 | 145 | 73 | 13 | MBSR | NT | 60 | 52 | OO CA | BDI OM | N | N | P | Y | N | N | N | Y | YD | Ynd | oit |
| Tlozcynski[160] | 1997 | 7 | 4 | 0 | NS | HY | 3 | 0 | - | OS | Y | N | N | N | N | N | N | N | N | N | oit |
| Tlozcynski[161] | 1998 | 75 | 25 | 13 | Zen | RM | 6 | 3 | - | OA OS | Y | N | P | N | N | N | N | N | N | N | RmA Acs |
| Tsai[162] | 1996 | 137 | 69 | - | MuMo | EC | 1 | 3 | - | QOL OS | Y | N | F | N | N | N | N | Y | N | N | RmAC |
| Vedanthan[163] | 1998 | 17 | 9 | 0 | MuMo | WL | 16 | 0 | MC OO | SD | Y | N | N | Y | Y | N | N | N | N | N | oit |
| Wachholtz[689] | 2005 | 84 | 28 | 16 | other | RM | 2 | 0 | HR | STA PAN SA OS | Y | N | N | N | N | N | N | N | Ynd | Ynd | Tcs Acs |
| Weinstein[164] | 1992 | 76 | 26 | 24 | NS | RM | 5 | 0 | PT | OA OS | N | N | N | Y | Y | N | Y | N | N | N | uA |
| Weissbecker[165] | 2002 | 91 | 46 | 23 | MBSR | WL | 8 | 0 | - | DSS BDI OS | N | N | N | N | N | N | N | N | Ynd | YD | RmM Tcs |
| Wenk-Sormaz[166] | 2005 | 132 | - | 12 | Zen | RE | 2 | 0 | EDA CE | - | Y | N | P | N | N | N | N | N | N | N | RmAC |

| Author | Year | n | n per group | Dropouts | Primary Technique† | Comparator†† | Duration | Follow-up | Objective Measures††† | Self report Measures††† | Compliance | Expectancy | Randomised§ | Raters blind | Partic. blind | Stat'n blind | Trainers blind | Sample size calc | Baseline comps‡ | DO vs Compl. ‡‡ | Analysis ‡‡‡ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Wenneberg[167] | 1997 | 66 | 33 | 27 | TM | UR | 16 | 0 | ST HR CC PE | - | Y | N | N | Y | N | N | N | N | Ynd | Ynd | ACcs |
| Williams[168] | 2001 | 103 | 52 | 28 | other | UR | 8 | 12 | - | SCL QOL OS | Y | N | N | N | N | N | N | Y | YD | Ynd | RmA |
| Williams[169] | 2005 | 58 | 15 | 17 | MuMo | O | 8 | 60 | - | QOL | N | N | P | Y | N | N | N | Y | YD | N | RmA |
| Wilson[170] | 1975 | 25 | 13 | 4 | TM | UEM | 12 | 12 | EDA MC OO CA | SD DSS | N | N | N | N | N | N | N | N | N | N | nbgc |
| Wolf[50] | 2003 | 93 | 31 | 32 | MM | PQ | 4 | 4 | - | OD OS | N | N | N | N | N | N | N | N | N | N | RmM |
| Woolfolk[171] | 1976 | 32 | 11 | 8 | Zen | RM | 4 | 6 | - | SD DSS | Y | Y | P | N | N | N | N | N | Ynd | N | Acs |
| Woolfolk[172] | 1981 | 60 | 30 | 0 | MM | - | 0 | 0 | PBP EDA CA | OS | N | Y | N | N | N | N | N | N | N | N | ACcs uA |
| Wood[173] | 1986 | 32 | 16 | 3 | TM | RE | 0 | 0 | ST HR EMG Ex OP | - | N | N | P | N | N | N | N | N | N | N | - |
| Yen[174] | 1996 | 392 | 98 | 93 | MuMo | O | 8 | 0 | HT | - | N | N | P | Y | N | N | N | N | Ynd | YD | Acs RmNP |
| Yuille[175] | 1980 | 136 | 34 | 34 | TM | PQ | 12 | 0 | CE | - | Y | Y | P | Y | N | N | N | N | N | YD | uA |
| Zuroff[176] | 1978 | 61 | 20 | 1 | TM | RM | 9 | 104 | HR | OA OS | Y | Y | P | Y | N | N | N | N | N | N | RmA |

† **Technique: ACEM** = ACEM meditation, **CSM** = clinical standard meditation, **KM** = *Kundalini* Meditation, **MBSM** = MBSM & similar, **Mind** = mindfulness only, **MM** = mantra mediation, **MMTM** = mantra meditation TM based, **MuMo** = multimodal, **NS** = not specified, **Other** = Other, **RR** = relaxation response, **RRB** = relaxation response based, **SY** = *Sahaja* yoga, **TM** = Transcendental meditation, **Zen** = Zen Buddhism meditation.

†† **Comparator: BFB** = biofeedback, **Bre** = breathing, **BT** = behavioural therapy, **EC** = educational classes, **EX** = exercise, **GT** = group therapy, **HY** = hypnosis, **NT** = no treatment, **O** = other, **PQ** = pseudo, quasi-, anti-meditation, **RE** = rest/napping, **RM** = relaxation method, **SM** = stress management, **SR** = structured reading, **ST** = standard treatment, **UEM** = educational materials- unstructured, **UR** = community resources/unstructured reading, **Vis** = visualisation, **WL** = waiting list.

††† **Measures**: **BDI** = Beck Depression Anxiety Index, **CA** = clinician assessment, **CC** = Cognitive challenge stressor, **CE** = cognitive exams, **CMR** = cardiometric risk, **DSS** = disease specific symptom, **EC** = endocrine, **EC** = endocrine, **EDA** = electrodermal activity, **EEG** = electroencephalography, **EMG** = electromyogram, **HAD** = HADS, **HR** = heart rate, **HT** = hypertension blood pressure, **IM** = immunity, **MC** = med consumption, **NS** = Noxious stimulus stressor, **OA** = other anxiety, **OD** = other depression measure, **OM** = other mood, **OP** = other physiological measure, **OO** = other objective, **OS** = other stress measure, **PAN** = PANAS, **PBP** = physiological blood pressure, **PE** = Physical exercise stressor, **POM** = POMS, **PT** = pain tolerance, **QOL** = QOL, **SA** = self actualisation, **SCL** = SCL90, **SD** = Symptom diary, **SF** = social function, **ST** = stressor task, **STA** = STAI.

§ **Randomisation method: F** = full, **P** = partial, **N** = none reported.

‡ **Baseline comparison: Ynd** = yes, no differences found, **YD** = yes, differences found, **N** = not reported.

‡‡ **Dropouts vs completers: Ynd** = yes, no differences found, **YD** = yes, differences found, **N** = not reported.

‡‡‡ **Appropriate analysis: ACcs** = ANCOVA change scores, **Acs** = ANOVA change scores, **MCcs** = MANCOVA change scores, **Mcs** = MANOVA change scores, **Reg** = regression, **RmA** = rmANOVA, **RmAC** = rmANCOVA, **RmM** = rmMANOVA, **RmMC** = rmMANCOVA, **RmNP** = rm non parametric, **Tcs** = *t*-test change scores.

‡‡‡ **Inappropriate analysis: nbgc** = no between group comparisons, **NR** = not reported, **OIT** = other inappropriate description, **uA** = univariate ANOVA, **uAC** = univaritate ANCOVA, **UCD** = unclear/ confusing description, **uM** = univariate MANOVA, **uMC** = univariate MANCOVA.

# Appendix 3. Meditator Survey Forms

The 2 meditator survey demo data frontsheets for:

1. *Sahaja Yoga* meditators
2. Non-*Sahaja Yoga* meditators

are found in this Appendix.

**NSW, ACT, VIC, QLD, WA**

**1. Age ___ yrs**

THANKYOU for helping us by answering this survey

PLEASE PUT A TICK IN THE CIRCLE "O" NEXT TO THE ANSWER THAT MOST APPLIES TO YOU

**2. Gender**

1. O male
2. O female

**3. Relationship status**

1. O Single
2. O Married
3. O defacto

**4. Ethnicity**

1. O White/Caucasian Australian: having been born in Australia
2. O White/Caucasian emigrant (not of Hispanic origin): person having origins in any of the original peoples of Europe, north Africa, middle east
3. O Aboriginal: native australian
4. O Black (not hispanic origin): person having origins in any black racial groups of Africa or America
5. O Asian or Pacific Islander: person having origin in any of t he peoples of the Far East, Southeast Asia, Indian Subcontinent, Pacific Islands.

**5. Level of Education**

1. O Completed primary school
2. O Completed secondary school
3. O Completed diploma/tertiary
4. O Completed undergraduate
5. O Completed postgraduate
6. O Completed doctorate

**6. History of Mental Illness**

1. O No known history
2. O History of minor mental illness (break down, anxiety/panic disorder, depression)
3. O History of major mental illness (eg schizophrenia)
4. O Current mental illness

**7. Annual pre-tax salary (or equivalent)**

1. O less than $20,000pa
2. O $20,000 to $35,000pa
3. O $35,000- $50,000pa
4. O $65,000-$80,000pa
5. O more than $95,000

**8. How long have you been a practicing SY Meditation?**
**___ yrs**

**9. Do you meditate regularly?**

1. O Yes
2. O No

Formal meditation is when you are not doing any other simultaneous activity except meditation

**10. How often do you use FORMAL meditation?**

1. O more than twice a day
2. O twice a day
3. O Once a day
4. O Most days
5. O About once a week
6. O Once every two or three weeks
7. O Once a month
8. O Less than once a month

Informal meditation is when you experience meditation in conjunction with other mundane activities such as shopping, housework etc

**11. How often do you use INFORMAL meditation?**

1. O more than twice a day
2. O twice a day
3. O Once a day
4. O Most days
5. O About once a week
6. O Once every two or three weeks
7. O Once a month
8. O Less than once a month

**12. How often do you participate in formal collective meditation?**

1. O more than twice a day
2. O twice a day
3. O Once a day
4. O Most days
5. O About once a week
6. O Once every two or three weeks
7. O Once a month
8. O Less than once a month

**13. How often do you attend social gatherings which mostly involve other meditators (BUT does not involve a formal group meditation)?**

1. O more than twice a day
2. O twice a day
3. O Once a day
4. O Most days
5. O About once a week
6. O Once every two or three weeks
7. O Once a month
8. O Less than once a month

**14.How often do you smoke tobacco?**

1. O Never
2. O once a month
3. O once a week
4. O most days
5. O everyday

**15.How often do you consume alcoholic drinks?**

1. O Never
2. O once a month
3. O once a week
4. O most days
5. O everyday

**16.How often do you use marijuana or other recreational drugs?**

1. O Never
2. O once a month
3. O once a week
4. O most days
5. O everyday

**17. How often do you attend the main collective meeting? eg Burwood on Saturday evenings or equivalent**

1. O usually every week
2. O every second week
3. O every few weeks
4. O about once a month
5. O occasionally
6. O Never

**1. What is your AGE?.....YRS**

Start here!

**2. Gender**
1. O male
2. O female

PLEASE PUT A TICK IN THE CIRCLE "O" NEXT TO THE ANSWER THAT MOST APPLIES TO YOU

**3. Relationship status**
1. O Single
2. O Married
3. O defacto

**4. Ethnicity**
1. O White/Caucasian Australian: born in Australia
2. O White/Caucasian emigrant
3. O Aboriginal: native australian
4. O Black (not hispanic origin):
5. O Asian or Pacific Islander: (the Far East, Southeast Asia, Indian Subcontinent, Pacific Islands).

**5. Level of Education**
1. O Completed primary school
2. O Completed secondary school
3. O Completed diploma/ tertiary/undergraduate
4. O Completed postgraduate

**7. Annual pre-tax salary (or equivalent)**

5. O less than $20,000pa
6. O $20,000 to $35,000pa
7. O $35,000- $50,000pa
8. O $50,000-$65,000pa
9. O more than $65,000

**6. History of Mental Illness**
1. O No known history
2. O History of minor mental illness (break down, anxiety/panic disorder, depression)
3. O History of major mental illness (eg schizophrenia, manic depression)
4. O Current mental illness

**7.How often do you smoke tobacco?**
1. O Never
2. O occasionally
3. O most days/everyday

**8.How often do you consume alcoholic drinks?**
1. Never
2. occasionally
3. most days/everyday

**9.How often do you use marijuana or other recreational drugs?**
1. Never
2. occasionally
3. most days/everyday

**10. in general, over the past few months,Did you meditate regularly?**
1. O Yes
2. O No

Formal meditation is when you are not doing any other simultaneous activity except meditation

**11. in general, over the past few months, how often did you use FORMAL meditation?**
1. O twice a day or more
2. O Once a day
3. O Most days
4. O About once a week
5. O Once every two or three weeks
6. O once a month or less

**12. How often do you participate in formal *group* meditation (this should involve at least 3 meditators)?**
1. twice a day or more
2. Once a day
3. Most days
4. About once a week
5. Once every two or three weeks
6. once a month or less

**13. How often do you attend social gatherings which mostly involve other meditators (BUT does not involve a formal group meditation)?**
1. twice a day or more
2. Once a day
3. Most days
4. About once a week
5. Once every two or three weeks
6. once a month or less

Informal meditation is when you use meditation techniques in conjunction with other mundane activities such as shopping, housework etc

**14. How often do you use informal meditation**
1. O all day
2. O most of the day
3. O several times a day
4. O about twice a day
5. O about once a day
6. O once every few days
7. O About once a week
8. O about once every two or three weeks
9. O about once a month
10. O about once every few months
11. O about once a year
12. O almost never

**15. How long have you been practicing Meditation?**

**..........YRS**

16.Which meditation technique do you mostly use?

..................................

# Appendix 4. ADHD Follow-up Questionaires

The 2 ADHD follow-up questionaires for:

3. Week 4
4. Week 6

are found in this Appendix.

**ADHD Meditation Clinic, Natural Therapies Unit, Royal Hospital for Women**

Please complete the following questions, based on your experiences since beginning the Sahaja Meditation Program. Some questions provide set answers to circle and others ask for your own response. Please take the time to write in detail about your experiences as these will help us to assess the value of the program.

Your Name: ______________________________________ Date ___________

1. Do you feel your child is getting more out of life since starting the program?

yes no not sure

2. Have you been able to reduce your child's level of medication and still maintain an acceptable level of behaviour?

yes no N/A (child not on medication)

If yes, by what proportion has the dose been changed?

reduced by less than half by half by more than half

3. In general, has the program been beneficial for your child?

yes no not sure

If yes, in what ways? Please circle the number that best described the degree of benefit.

little benefit a lot of benefit

| | | | | | | |
|---|---|---|---|---|---|---|
| less anxious | 1 | 2 | 3 | 4 | 5 | not sure |
| less angry | 1 | 2 | 3 | 4 | 5 | not sure |
| more confident in him/herself | 1 | 2 | 3 | 4 | 5 | not sure |
| improved memory | 1 | 2 | 3 | 4 | 5 | not sure |
| improved sleep pattern | 1 | 2 | 3 | 4 | 5 | not sure |
| more cooperative | 1 | 2 | 3 | 4 | 5 | not sure |
| more able to settle down/be quiet for some period of time | 1 | 2 | 3 | 4 | 5 | not sure |
| more able to manage negative feelings | 1 | 2 | 3 | 4 | 5 | not sure |
| other? _________________ | 1 | 2 | 3 | 4 | 5 | not sure |

anything else?

4. In general, has the Sahaja Meditation Program been beneficial for you?

yes no not sure

If yes, in what ways? please circle the number that best describes the benefit you have felt

| | little benefit | | | a lot of benefit | |
|---|---|---|---|---|---|
| happier | 1 | 2 | 3 | 4 | 5 | not sure |
| less stressed | 1 | 2 | 3 | 4 | 5 | not sure |
| more able to manage stress | 1 | 2 | 3 | 4 | 5 | not sure |
| less angry | 1 | 2 | 3 | 4 | 5 | not sure |
| more able to manage anger | 1 | 2 | 3 | 4 | 5 | not sure |
| improved memory | 1 | 2 | 3 | 4 | 5 | not sure |
| other? __________________ | 1 | 2 | 3 | 4 | 5 | not sure |

anything else?

5. Has the program made a change to your relationship with your child?

yes no not sure

if yes, in what ways? please circle the number that best describes the level of benefit

| | little benefit | | | a lot of benefit | | |
|---|---|---|---|---|---|---|
| more warmth/affection | 1 | 2 | 3 | 4 | 5 | not sure |
| less conflict | 1 | 2 | 3 | 4 | 5 | not sure |
| more able to manage conflict | 1 | 2 | 3 | 4 | 5 | not sure |
| less anxiety | 1 | 2 | 3 | 4 | 5 | not sure |
| more open communication | 1 | 2 | 3 | 4 | 5 | not sure |
| less exhausting | 1 | 2 | 3 | 4 | 5 | not sure |
| other? __________________ | 1 | 2 | 3 | 4 | 5 | not sure |

anything else?

6. If your child has brothers or sisters, has the program made a change to these relationships?

yes no not sure

if yes, in what ways?

**ADHD Meditation Clinic, Natural Therapies Unit, Royal Hospital for Women**

**Review – Week 6**

Your Name: ______________________________________ Date ___________

Please circle the responses, or numbers, that best reflect your experience of the Sahaja Meditation Program. Please give full written responses to the open-ended questions and feel free to give us any other information about how the program has helped you and your child.

1. In general, do you feel your child has benefited from the Sahaja Meditation program?

yes no not sure

little benefit a lot of benefit

If yes, to what extent? 1 2 3 4 5

In what ways? Please circle the number that best described the degree of benefit.

little benefit a lot of benefit

| | | | | | | |
|---|---|---|---|---|---|---|
| less anxious | 1 | 2 | 3 | 4 | 5 | not sure |
| less angry | 1 | 2 | 3 | 4 | 5 | not sure |
| more confident in him/herself | 1 | 2 | 3 | 4 | 5 | not sure |
| improved memory | 1 | 2 | 3 | 4 | 5 | not sure |
| improved sleep pattern | 1 | 2 | 3 | 4 | 5 | not sure |
| more cooperative | 1 | 2 | 3 | 4 | 5 | not sure |
| more able to settle down/be quiet for some period of time | 1 | 2 | 3 | 4 | 5 | not sure |
| more able to manage negative feelings | 1 | 2 | 3 | 4 | 5 | not sure |
| other? _________________ | 1 | 2 | 3 | 4 | 5 | not sure |
| anything else? | | | | | | |

2. Have you been able to reduce your child's level of medication and still maintain an acceptable level of behaviour?

yes no N/A (child not on medication)

If yes, by what proportion has the dose been changed?

reduced by less than half by half by more than half

3. Do you feel the meditation has been beneficial for how your child copes at school?

yes no not sure

little benefit / a lot of benefit

If yes, to what extent? 1 2 3 4 5

In what ways? Please circle the number that best described the degree of benefit.

little benefit / a lot of benefit

| | | | | | | |
|---|---|---|---|---|---|---|
| positive about going to school | 1 | 2 | 3 | 4 | 5 | not sure |
| less difficulty with other children | 1 | 2 | 3 | 4 | 5 | not sure |
| less difficulty with the teacher | 1 | 2 | 3 | 4 | 5 | not sure |
| more able to manage schoolwork | 1 | 2 | 3 | 4 | 5 | not sure |
| more able to do homework | 1 | 2 | 3 | 4 | 5 | not sure |
| other? _________________ | 1 | 2 | 3 | 4 | 5 | not sure |

anything else?

4. In general, has the Sahaja Meditation Program been beneficial for you?

yes no not sure

little benefit / a lot of benefit

If yes, to what extent? 1 2 3 4 5

In what ways? please circle the number that best describes the benefit you have felt

little benefit / a lot of benefit

| | | | | | | |
|---|---|---|---|---|---|---|
| happier | 1 | 2 | 3 | 4 | 5 | not sure |
| less stressed | 1 | 2 | 3 | 4 | 5 | not sure |
| more able to manage stress | 1 | 2 | 3 | 4 | 5 | not sure |
| less angry | 1 | 2 | 3 | 4 | 5 | not sure |
| more able to manage anger | 1 | 2 | 3 | 4 | 5 | not sure |
| improved memory | 1 | 2 | 3 | 4 | 5 | not sure |
| other? _________________ | 1 | 2 | 3 | 4 | 5 | not sure |

anything else?

Please tell us about some specific examples about your relationship with your child over the past week

Describe a time when things went well between you and your child.

Describe a time when things did not go well between you and your child.

How did a difficult time get resolved?

# Appendix 5. Personal Account of the Sahaja State

The following is an account of the state of consciousness experienced under *sahaja* meditation by Metta Zetty[690]:

> Suddenly, an invisible, but significant, shift occurred internally: it felt as if any residual or latent energy block-ages within my body had been instantly and completely released. Before I knew or could understand what was happening, the top of my head opened up, and a flood of brilliant white light poured over me, flowing into and through my entire body. Overwhelmed by the intensity of this flooding energy and light, my knees buckled beneath me, and I awakened abruptly. Now wide awake and in utter amazement, I felt the surging energy continuing to flow through my entire body! As it moved through me, flooding through the very essence of my being, the energy rapidly began changing — transforming into an wave of complete and absolute euphoria, an indescribable contentment that extended far beyond the bounds of human expression.
> Suddenly I realized, with indisputable certainty, that the world is absolutely complete and perfect, exactly as it is. I recognized that there is nothing we need to do or achieve beyond the fullness of the present moment. Everything within the entire universe felt whole, complete and integrated, and any sense of fundamental separateness or anxiety was completely gone. At the same time, I was delightfully surprised to discover that "I" — the little identity I recognize as "me" — did not disappear or extinguish. I was astonished that "I" did not have to die in order to "experience" this magnificent Wholeness! "I" remained conscious and aware, but now "I" was contained within, and not separate from, the Presence and Essence of this vast, infinite and integrated Wholeness. This was a moment of overwhelming revelation, of pure and absolute joy.

I realized that it is at an intuitive level that we have our deepest moments of "knowingness" and insight, and with this dawning realization came a deepening recognition that:

• "Mistakes," as we know them, are not possible.

• "Whatever happens is the only thing that could have."

• Our most fundamental freedom is our freedom to choose within the present moment.

• The present moment and the human soul are a converging nexus point of the Infinite.

• The past and future are pale shadows and faint echoes of the luminescent present.

• Bliss is recognizing the absolute, complete perfection of the universe, exactly as it is, within the infinite present.

• The perfection of the universe lies within its complete integrity and wholeness. Within this larger context, there is room for all the smaller, diverse "imperfections" of our daily, human experience.

• All suffering in the universe ultimately is not absurd because it is contained within an Infinite Benevolence that extends far beyond the limits of all imaginable suffering.

In this Awakening, I discovered that my restless seeking and ceaseless longing were suddenly resolved within the Perfection of the present moment. With a sense of incredible delight and relief, I discovered that my search for meaning and purpose was finally over. I realized that our common, "ordinary" human/experience is indistinguishable from the Fullness and Essence of Reality. And, I finally understood that nothing ever needs to be done to achieve or obtain this Great Perfection. It is already absolute and complete, within the present moment.

I realized that this shift in Awareness is not about a change in perspective or position: it is about a sudden integration into Beingness. I realized that this shift is both gradual and sudden: it happens suddenly, and it exists outside of time. And, it emerges gradually, both in and over time. I also realized that this shift is not about arriving somewhere; it is simply borne of a contentment that no longer feels the need to go anywhere. I realized that part of the Great Mystery of the universe is that the Infinite is continuously manifesting in and through our individual, personal experiences of the finite. And, I realized that throughout history saints and sages have always supported and encouraged us until this experience of Awareness and insight is one we recognize, and accept, as our own.

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