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# Clinical Trials of Meditation Practices in Health Care: Characteristics and Quality

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## Abstract

***Objective:*** To provide a descriptive overview of the clinical trials assessing meditation practices for health care.
***Design:*** Systematic review of the literature. Comprehensive searches were conducted in 17 electronic bibliographic databases through September 2005. Other sources of potentially relevant studies included hand searches, reference tracking, contacting experts, and gray literature searches. Included studies were clinical trials with 10 or more adult participants using any meditation practice, providing quantitative data on health-related outcomes, and published in English. Two independent reviewers assessed study relevance, extracted the data, and assessed the methodological quality of the studies.
***Results:*** Four hundred clinical trials on meditation (72% described as randomized) were included in the review (publication years 1956–2005). Five broad categories of meditation practices were identified: mantra meditation, mindfulness meditation, yoga, *t'ai chi*, and *qigong*. The three most studied clinical conditions were hypertension, miscellaneous cardiovascular diseases, and substance abuse. Psychosocial measures were the most frequently reported outcomes. Outcome measures of psychiatric and psychological symptoms dominate the outcomes of interest. Overall, the methodological quality of clinical trials is poor, but has significantly improved over time by 0.014 points every year (95% CI, 0.005, 0.023).
***Conclusions:*** Most clinical trials on meditation practices are generally characterized by poor methodological quality with significant threats to validity in every major quality domain assessed. Despite a statistically significant improvement in the methodological quality over time, it is imperative that future trials on meditation be rigorous in design, execution, analysis, and the reporting of results.

## Introduction

Meditation has been used as a spiritual and healing practice for more than 5000 years.[1,2] Over the past 40 years, both secular and spiritual forms of meditation have interested clinicians, researchers, and the general public in Western countries. They have gained acceptance as mind–body interventions within the integrative medicine movement. With an estimated 10 million practitioners in the United States and hundreds of millions worldwide,[3] meditation practices have been advocated as mind–body therapies to alleviate health-related problems and to attain or maintain general wellness. They have been widely adopted by mainstream health care providers and incorporated into a variety of therapeutic programs in hospitals and clinics in the United States and abroad.[4]

Meditation is an umbrella term that encompasses a wide range of techniques that have been described, assessed for therapeutic efficacy, and reported in the scientific literature. The complex nature of these techniques and the coexistence of many perspectives adopted to describe their characteristics have contributed to large variations in the reports of their

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This study is based on a comprehensive evidence-based report available online at www.ahrq.gov: Ospina MB, Bond TK, Karkhaneh M, et al. Meditation practices for health: State of the research. Evid Rep Technol Assess (Full Rep) 2007;155:1–263.

therapeutic effects across studies. Researchers have used a variety of methodological approaches. Numerous authors have asserted that most of the studies in this area are methodologically flawed and often have small sample sizes.[5–14] Formal evaluation of the methodological quality of this broad body of evidence has not been previously conducted. Therefore, there is a need to evaluate the evidence that has emerged within the past several decades on the effects of meditation practices in health care.

The main objective of this review was to produce an overview of the clinical trials conducted on the therapeutic use of meditation practices in health care. Secondary objectives were to systematically synthesize the characteristics of clinical trials of meditation practices in terms of the control groups used, the populations most frequently studied, and the type of outcome measures reported.

## Methods

The methods of the main study have been discussed in detail elsewhere.[15] Comprehensive literature searches were conducted in 17 electronic bibliographic databases from inception to September 2005. Extended systematic search methods (e.g., hand searching non-indexed journals, tracking reference lists, and contacting experts) were also used to identify potentially relevant studies. The gray literature was searched to identify unpublished studies and works in progress. Scientific abstracts from the Society of Behavioral Medicine (2005) and the American Psychosomatic Society (1999–2005) annual scientific meetings were reviewed. The National Research Register from the National Health Service was searched for ongoing trials. Four independent reviewers screened titles and abstracts against specific criteria to assess their potential relevance. The full text of potentially relevant studies was retrieved and assessed for eligibility by two independent reviewers using a standard form that outlined the selection criteria. To be included in the review, the studies had to: be clinical trials with a concurrent control group for comparison (randomized controlled clinical trials [RCTs] or controlled clinical trials [CCTs]) employing a meditation technique, include 10 or more adults, provide data on health-related outcomes, and be published in English. For this review, we based our definition of meditation on a set of criteria outlined by Cardoso et al.[16]—a practice that 1) utilizes a specific and clearly defined technique; 2) involves muscle relaxation somewhere during the process; 3) involves logic relaxation (i.e., not "to intend" to analyze the possible psychophysical effects, not "to intend" to judge the possible results, not "to intend" to create any expectation regarding the process); 4) is a self-induced state; and 5) involves the use of a self-focus skill or "anchor" for attention.

The criteria for concealment of allocation[17,18] and the Jadad scale[19] were used to assess the methodological quality of the trials. The former is based on evidence that indicates that neglecting to conceal the sequence of treatment allocation may likely undermine randomization, and consequently bias study results.[17] The Jadad scale consists of three items pertaining to randomization, double-blinding, and withdrawals and dropouts. The Jadad scores range from 0 to 5 points, with higher scores (≥3 points) indicating better quality.[19] The validity and reliability of the Jadad scale has been thoroughly evaluated in several studies that provide rigorous evidence supporting its use.[19,20] Given the difficulties in interpreting overall quality scores,[21] we reported both the quality score and the rating of studies on individual components of the Jadad scale. Finally, information on the source of funding was collected.[22] The methodological quality of the studies was assessed independently by two reviewers. Disagreement about the selection of studies and assessment of their methodological quality was resolved by reviewer consensus.

Study data were extracted by one reviewer using a pretested form, with a second independent reviewer verifying accuracy and completeness. Information regarding the study (e.g., country and year of publication, type of publication, study design, and source of funding), the characteristics of participants (e.g., type of health problem or health condition), interventions (e.g., type of meditation practice), control groups, and outcome measures were extracted. Two independent researchers classified each study within one of seven descriptive categories. The categories were based on descriptions of each of the techniques in the literature and on consultation with a technical expert panel composed of eight researchers with broad expertise in meditation practices and methodological issues:

1. *Mantra meditation*. This category includes meditation practices in which repeating a mantra (i.e., a word, sound, or symbol) is the main component. We classified in this group practices such as the Relaxation Response (RR), Transcendental Meditation (TM™), Clinically Standardized Meditation (CSM), and Acem meditation.
2. *Mindfulness meditation*. Described slightly differently by Eastern and Western practitioners, this category includes meditation practices in which the main component is cultivating awareness, acceptance, nonjudgment, and attention to the present moment.[23–25] This category includes Mindfulness-Based Stress Reduction (MBSR), Mindfulness-Based Cognitive Therapy (MBCT), Vipassana meditation, Zen Buddhist meditation, and other mindfulness meditation practices not further described in reports by the authors.
3. *Qigong*. This category refers to an ancient traditional Chinese medicine practice of self-regulation that combines the coordination of different breathing patterns with various physical postures, bodily movements, and meditation techniques.[26,27] Practices that focused exclusively on external *qigong* were not considered.
4. *T'ai chi*. This category describes a Chinese martial art characterized by soft, slow, flowing exercises that promote posture, flexibility, relaxation, well-being, and mental concentration. *T'ai chi* also involves training the mind, and this has prompted some to consider the practice "moving meditation."[28]
5. *Yoga*. This category includes thousands of different techniques rooted in the ancient yogic tradition that can include a defined combination of physical postures (*asanas*), various eye positions, breathing techniques (*pranayama*), mantras, and potentially four levels of meditation (*pratyahar*, *dharana*, *dhyana*, and *samadhi*). It includes practices from Kundalini yoga, Hatha yoga, and other yogic lineages.[29–32]
6. *Miscellaneous meditation practices*. This category describes techniques that combine different approaches to medita-

tion in a single intervention, without giving prominence to one. It includes combined practices such as yoga plus RR, TM and Buddhist meditation, and RR plus mindfulness meditation. The category was also used to describe meditation practices that do not fall within any of the other categories (e.g., coloring mandalas).

7. *Undefined meditation practices*. This category refers to meditation practices that were not described in sufficient detail to allow assignment to a specific category, including techniques that were only vaguely described.

Study selection, methodological quality assessment, and data extraction were managed with the Systematic Review Software (SRS), v. 3.0 (TrialStat!, Ottawa, Ontario, Canada). Extracted data were exported into Excel (Microsoft, Redmond, WA) spreadsheets. Data were analyzed descriptively. Categorical data were summarized using proportions and percentages. Continuous data were summarized using means with standard deviations (SD) or medians with interquartile ranges (IQR) for skewed data. All analyses were performed using the Statistical Package for the Social Sciences for Windows v. 14.1 (SPSS, Chicago, IL).

## Results

### *Characteristics of included studies*

Four hundred clinical trials that met our inclusion criteria examined the therapeutic use of meditation techniques in health care. Figure 1 outlines the study flow for the review. The median year of publication of these 400 trials was 1996 (IQR: 1986, 2003). Most of the trials were published as journal articles (83%), and were conducted in North America (64%). The remaining studies were conducted in Asia (21%), Europe (11%), Australasia (3%), and other regions (2%). We identified 286 RCTs and 114 CCTs. The complete list of references, reasons for exclusion, study characteristics, and quality components of included trials is available upon request.

### *Methodological quality*

Overall, the methodological quality of the clinical trials was poor, with significant threats to validity in every major category of quality measured, regardless of the type of meditation practice studied. The median Jadad score was 2 (IQR, 1 to 2). Only 40 clinical trials (10%) were considered of good quality based on a Jadad score $\geq 3$ points. However, a univariate analysis has shown that there is a statistically significant association between the Jadad score and the time of publication ($F = 1.48$; $p = 0.042$). The methodological quality of clinical trials showed a statistically significant improvement over time by 0.014 points every year (95% CI, 0.005, 0.023).

When the trials were analyzed based on individual components, we found that 72% (286 trials) were described as randomized, but only 11% (45 trials) provided a complete description of an appropriate randomization process to assign participants to treatment groups.

Only 2% (8 trials) of trials reported the use of double-blinding procedures to hide the identity of the assigned interventions, and 49% (196 trials) provided a description of withdrawals and dropouts. The vast majority of trials (95%, 383 trials) failed to describe how they concealed the allocation to the interventions. Finally, 36% (147 trials) explicitly reported whether the trial received funding.

### *Meditation practices*

Mantra meditation practices were the most frequently studied (35%, 141 trials). Studies on mantra meditation assessed the TM technique or the TM-Sidhi program (43%, 60 trials), RR, (32%, 45 trials), mantra practices not described (14%, 20 trials), mantra meditation techniques similar to TM but developed specifically for clinical purposes, including CSM (8%, 11 trials and SRELAX (1%, 1 trial), Acem meditation (i.e., an amalgam of traditional meditation techniques and Western psychological theory and practices) (2%, 3 trials), and Cayce's meditation (1%, 1 trial). The second most frequently studied category of meditation practices was yoga (26%, 105 trials). It included a heterogeneous group of techniques from Hatha yoga, Kundalini yoga, and Sahaja yoga. Mindfulness meditation constituted the third most studied group of practices (19%, 75 trials). Within this category, MBSR (44%, 33 trials) and Zen Buddhist meditation (16%, 12 trials) were studied most. Other mindfulness practices included mindfulness meditation techniques ND (32%, 24 trials), and MBCT (8%, 6 trials). Twelve percent of all trials reported on *t'ai chi* (46 trials) and 3% (13 trials) reported on *qigong*. Finally, 5% did not explicitly describe the components of the meditation intervention (17 trials) or used miscellaneous approaches (3 trials). Table 1 summarizes the type of practices examined in clinical trials on meditation.

### *Control groups*

The number of control groups per study ranged from 1 to 4; 273 trials (68%) used one control group only and 127 (32%) had more than one control group. The majority of trials used conditions of no treatment (30%, 121 trials) and wait-list controls (16% 62 trials) as comparison groups. Table 2 summarizes the type of control groups that were used in the trials.

### *Populations*

Half of the trials (53%, 213 trials) were conducted in healthy populations. Among the 187 trials that were conducted on clinical populations, the conditions studied were: hypertension (27 trials), other cardiovascular diseases (21 trials), substance abuse disorders (17 trials), anxiety disorders (11 trials), depression (10 trials), cancer, asthma (9 trials each), chronic pain, type 2 diabetes (7 trials each), fibromyalgia (6 trials), osteoarthritis, rheumatoid arthritis (4 trials each), heterogeneous patient population, HIV, mood disorders, psoriasis (3 trials each), epilepsy, binge eating disorder, insomnia, irritable bowel syndrome, menopause, miscellaneous psychiatric conditions, schizophrenia, tinnitus (2 trials each), anger management problems, burnout, carpal tunnel syndrome, chronic airway obstruction, chronic fatigue, chronic insomnia, dental problems, infertility, migraine and tension headaches, multiple sclerosis, muscular dystrophy, neurosis, obsessive-compulsive disorder, osteoporosis, parents of children with behavioral problems, personality disorders, pleural effusion, postmenopause, post-traumatic stress disorder, pregnancy, premenstrual syndrome, pulmonary tuberculosis, regional pain syndrome,

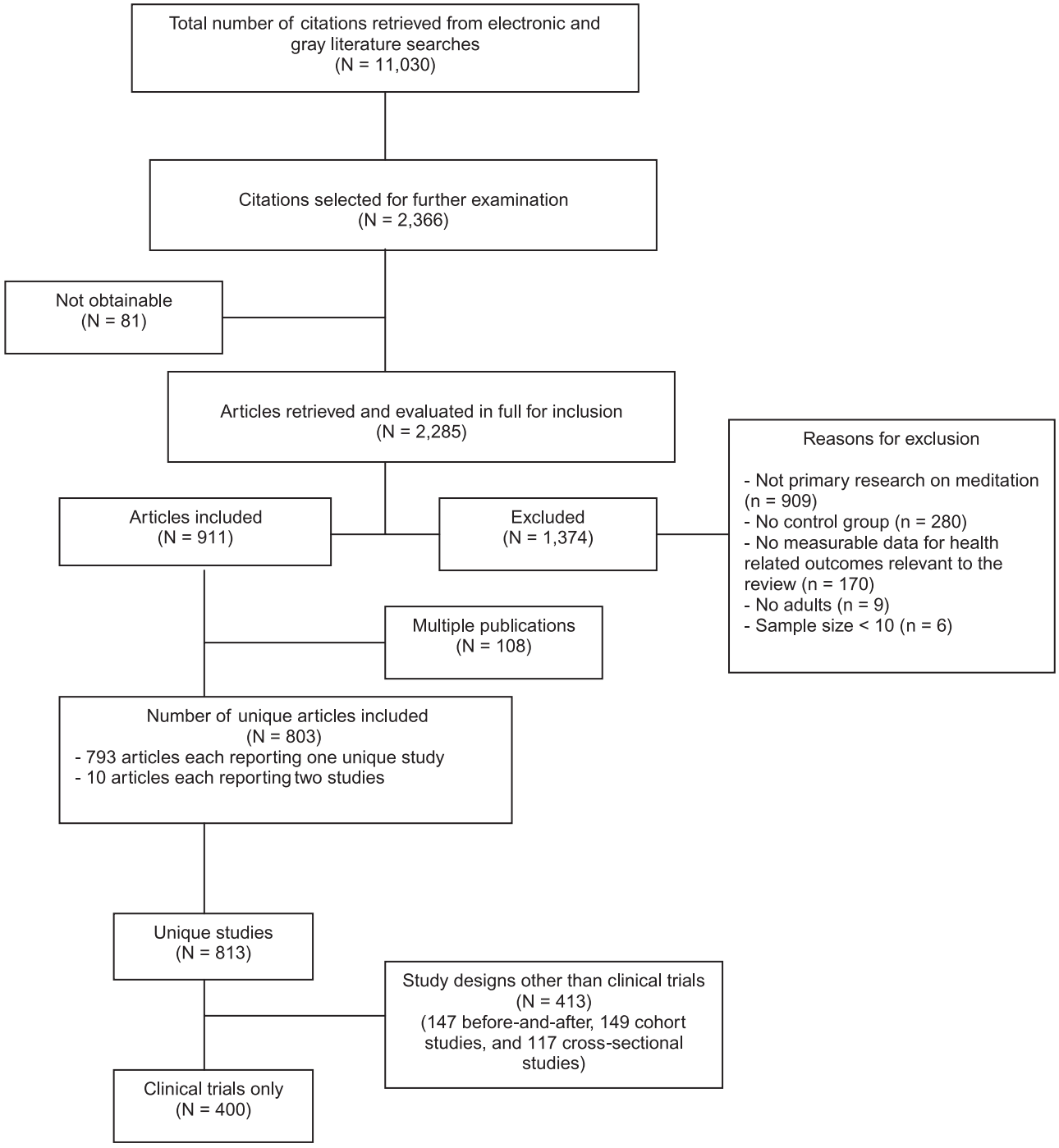


**FIG. 1.** Flow-diagram for study retrieval and selection for the review.

stroke, total hip/knee replacement, traumatic brain injuries, and vestibulopathy (1 trial each). A summary of the type of populations evaluated per meditation practice is presented in Table 3.

### *Outcome measures*

In total, 2,046 outcome measures were reported in 400 trials with a median of 4 per trial (IQR: 2, 6). Psychosocial measures were the most studied, encompassing 733 measures (35.8%). Other measures included physiological functions (711; 34.8%), clinical events and health status measures (433; 21.2%), cognitive and neuropsychological measures (137; 6.7%), and health care utilization outcomes (32; 1.5%). Table 4 summarizes the frequency of reporting of outcome measures by meditation practice.

Among the psychosocial measures, there were 416 measures of psychiatric and psychological symptoms, including anxiety disorders, depression, stress, mood states, irritability and anger expression, and abuse of psychoactive or other

Table 1. Meditation Practices Examined in Clinical Trials

| *Meditation practice* | *RCT* | *CCT* | *Total* | *Sample size (median, IQR)* |
|---|---|---|---|---|
| Mantra meditation | 111 | 30 | 141 | 40 (24, 68) |
| Mindfulness meditation | 50 | 25 | 75 | 39 (23, 73) |
| Undefined meditation practices | 11 | 6 | 17 | 46 (27, 97) |
| Miscellaneous meditation practices | 3 | 0 | 3 | 84 (20, 81) |
| *Qigong* | 13 | 0 | 13 | 36 (22, 73) |
| *T'ai chi* | 29 | 17 | 46 | 39 (25, 65) |
| Yoga | 69 | 36 | 105 | 40 (23, 70) |
| Total | 286 | 114 | 400 | |

CCT, controlled clinical trials; IQR, interquartile range; RCT, randomized controlled trials.

substances causing psychological dependence. Measures of personality (both normal and abnormal) were the second most common measures reported (159 measures). Studies using these measures reported data on either general characteristics of the personality (e.g., personality and psychological profiles, ego strength, and coping styles) or particular traits of the individual psychological functioning (e.g., locus of control, neuroticism, psychoticism, extraversion, self-actualization, self-esteem, and hostility traits). Sixty-two measures of positive psychology outcomes (e.g., measures of processes that contribute to flourishing or optimal functioning of individuals, including empathy, assertive behavior, happiness, spirituality, and autonomy) were reported. Outcomes related to social and interpersonal relationships such as marital adjustment, level of interpersonal conflicts, social adjustment, and social functioning, were examined in 38 measures. There were 29 measures of health-related quality of life. Other psychosocial outcomes included activities of daily living (15 measures), and other miscellaneous and nonspecific behavioral measures not further classified (14 measures), e.g., "level of relaxation" and "hypnotic response."

Cardiovascular outcomes (270 measures) were the most frequently examined among the physiological outcomes. They included changes in systolic and diastolic blood pressure, heart rate, oxygen consumption, and electrocardiogram patterns. Nutritional biochemistry and metabolism outcomes (121 measures) included biochemical and metabolic process measures that are markers of certain diseases or conditions. These measures included serum levels of cholesterol, triglycerides, glucose, lactate, potassium, calcium, sodium, and lipid profile.

Other physiological measures that were frequently reported included pulmonary and respiratory outcomes (95 measures) such as respiratory rate, lung function testing measures (forced expiratory volume [FEV1], forced vital capacity [FVC], peak expiratory flow rate [PEFR]), and carbon monoxide levels. Endocrine and hormone outcomes (57 measures) described changes in substances secreted by the endocrine system to regulate organ activity. They included measures of cortisol, pituitary and neurohormones, catecholamines, endorphins, and aldosterone. There were 39 measures of electrodermal responses (i.e., galvanic skin response, skin conductance, and skin resistance) that reflect sympathetic nervous system activity and levels of emotional arousal and stress. Brain and nervous system measures (23 measures) included electroencephalogram (EEG) profile and P300 latencies. Frontal electromyographic activity, muscle voltage, reflex function, and others were among the 28 muscular physiology measures. There were 25 measures of the immune system that included immunoglobulin (e.g., IgA, IgG, and IgM) concentrations, leukocytes, lymphocytes, monocytes, neutrophil levels, natural killer cell activity, white blood cell count, cytokines, and monoclonal antibodies. There were 14 outcomes related to thermoregulatory function (e.g., skin and body temperature), 13 for blood products and hemodynamic parameters, and 10 for the skeletal system (e.g., bone mineral density). Less frequently reported measures included 6 for renal function, 5 for sensory (e.g., auditory thresholds), 4 for ocular (e.g., intraocular pressure, pupillary dilatation), and 1 for gastric motility.

Measures examining physical functions such as balance, strength, flexibility, mobility, and postural stability were the most frequently reported types of clinical outcomes (146 measures). Second were discrete clinical events or indicators of symptom improvement, which included 108 condition-specific measures (e.g., fibromyalgia symptoms, asthmatic episodes, and angina pectoris symptoms). Nutritional status or body composition included 53 measures for body weight, body mass index, and diet and nutritional patterns. General health status and well-being accounted for 44 measures, pain symptoms for 32, sleep characteristics for 23, and frequency of falls or falls-related behaviors for 14. Other clinical measures included adherence (9 measures) and mortality (4 measures).

Sensory perception and motor function (45 measures) were the most frequently examined cognitive and neuropsychological outcomes. These measures included psychomotor performance, perceptual motor skills, field independence, absorption, autonomic arousal, and visual-spatial ability. Other cognitive and neuropsychological measures less frequently examined included reasoning and executive function (28 measures) such as cognitive flexibility, logical reasoning, thought categorization, and associative learning. General cognitive outcomes (26 measures) included global measures of intelligence, cognitive status, spatial and verbal skills, and neuropsychological functioning. Attention functions (e.g., concentration, sustained focusing capacity, attention switching) were each reported by 14 measures. Finally, memory functions (e.g., short- and long-term, verbal and visual, declarative and procedural) and language skills (e.g., verbal fluency, vocabulary, language comprehension, and reading skills) were each reported by 12 measures.

Table 2. Types of Control Groups for Intervention Studies on Meditation Practices

| *Type of control* | *Mantra meditation* | *Mindfulness meditation* | *Undefined meditation practices* | *Miscellaneous practices* | Qigong | T'ai chi | *Yoga* | *Total* |
|---|---|---|---|---|---|---|---|---|
| NT (Inactive control) | 42 (24 TM, 8 Mantra NS; 6 RR, 2 CSM, 1 Acem, 1 Cayce's meditatiion) | 22 (9 MBSR, 7 MM NS, 5 Zen Buddhist, 1 MBCT) | 6 | 1 | 2 | 19 | 29 | 121 |
| WL (Inactive control) | 24 (10, 5 CSM, 5 RR, 3 Mantra NS, 1 SRELAX) | 21 (11 MBSR, 6 MM NS, 2 MBCT, 2 Zen Buddhist) | 3 | — | 2 | 2 | 10 | 62 |
| Exercise/physical activity | 10 (3 Mantra NS, 3 RR, 2 TM, 1 Acem, 1 CSM) | 1 MBSR | 1 | — | 1 | 14 | 18 | 45 |
| Rest and states of relaxation | 28 (14 RR, 9 TM, 3 Mantra NS, 2 CSM) | 6 (3 Zen Buddhist, 2 MM NS, 1 MBSR) | 2 | — | — | — | 9 | 45 |
| Education | 17 (9 TM, 5 RR, 2 Mantra NS, 1 CSM) | 10 (5 MBSR, 3 Zen Buddhist, 2 MM NS) | 2 | 1 | — | 6 | 8 | 44 |
| PMR | 27 (10 TM, 8 RR, 5 Mantra NS, 3 CSM, 1 Acem) | 5 (2 MBSR, 2 MM NS, 1 Zen Buddhist) | 1 | — | — | — | 6 | 39 |
| Usual care | 2 (1 RR, 1 TM) | 9 (3 MBSR, 3 MBCT, 2 MM NS, 1 Zen Busshist) | 1 | 1 | 3 | 4 | 16 | 36 |
| Cognitive behavioral techniques | 9 (3 TM, 3 RR, 2 CSM, 1 Mantra NS) | 7 (4 MM NS, 3 MBSR) | 2 | — | — | — | 2 | 20 |
| Miscellaneous active control | 6 (3 RR, 2 Mantra NS, 1 TM) | 4 (2 MBSR, 1 Zen Buddhist, 1 MM NS) | 1 | 1 | — | 1 | 6 | 19 |
| Sham meditation | 9 (3 TM, 3 Mantra NS, 2 RR, 1 SRELAX) | 1 Zen Buddhist | 3 | — | 2 | 1 | 2 | 18 |
| Group therapy | 6 (3 RR, 2 TM, 1 Acem) | 3 (1 MBSR, 2 MM NS) | — | — | — | 2 | 2 | 13 |
| BF | 11 (6 RR, 3 Mantra NS, 2 TM) | — | — | — | — | — | 1 | 12 |
| Reading | 6 (4 RR, 2 TM) | — | — | — | — | 1 | 1 | 8 |
| Pharmacological interventions | — | — | — | — | 2 | — | 6 | 8 |
| Control groups (ND) | 2 (1 RR, 1 TM) | 1 MM NS | — | — | 2 | 1 | — | 6 |
| Hypnosis | 2 TM | — | 2 | — | — | — | — | 4 |
| Psychotherapy | 1 TM | 1 MBSR | — | — | — | — | 1 | 3 |
| Massage | 1 RR | 1 MBSR | — | — | — | — | — | 2 |
| Acupuncture | — | — | — | — | — | 1 | — | 1 |
| Yoga | 4 (3 TM, 1 Mantra NS) | — | 1 | — | — | — | — | 5 |
| Mantra | — | — | — | — | — | — | 3 | 3 |
| Mindfulness | 2 (1 TM, 1 Mantra NS) | — | 1 | — | — | — | — | 3 |
| Meditation ND | 2 (1 RR, 1 TM) | — | — | — | — | — | — | 2 |
| *T'ai chi* | 1 RR | — | — | — | — | — | — | 1 |
| Yoga | — | — | — | — | — | — | 14 | 14 |
| Mantra | 9 (5 TM, 2 RR, 1 CSM, 1 Mantra NS) | — | — | — | — | — | — | 9 |
| Mindfulness | — | 4 (2 MBSR, 1 Zen Buddhist, 1 MM NS) | — | — | — | — | — | 4 |
| Undefined meditation practices | — | — | 2 | — | — | — | — | 2 |

CSM, clinically standardized meditation; MBCT, mindfulness-based cognitive therapy; MBSR, mindfulness-based stress reduction; MM, mindfulness meditation; NS, not specified; NT, no treatment; PMR, progressive muscle relaxation; RR, relaxation response; TM™, Transcendental Meditation; WL, waitlist.

TABLE 3. TYPE OF POPULATIONS EXAMINED IN CLINICAL TRIALS ON MEDITATION PRACTICES

| *Meditation technique* | *Population examined* |
|---|---|
| Mantra meditation | Healthy (98 studies): 44 TM™, 29 RR, 14 Mantra NS, 7 CSM, 3 Acem, 1 Cayce's meditation |
| | Clinical conditions (43 studies): |
| | 11 hypertension (5 TM, 4 RR, 1 Mantra NS, 1 SRELAX) |
| | 9 substance abuse (5 TM, 2 RR, 1 CSM, 1 Mantra NS) |
| | 6 anxiety disorders (3 Mantra NS, 1 CSM, 1 RR, 1 TM) |
| | 4 other cardiovascular diseases (3 RR, 1 TM) |
| | 2 asthma (TM) |
| | 2 cancer (1 RR, 1 TM) |
| | 1 chronic insomnia (CSM) |
| | 1 epilepsy (Mantra NS) |
| | 1 irritable bowel syndrome (RR) |
| | 1 menopause (RR) |
| | 1 post-traumatic stress disorders (TM) |
| | 1 premenstrual syndrome (RR) |
| | 1 schizophrenia (CSM) |
| | 1 schizophrenia and antisocial personality disorders (RR) |
| | 1 total hip and knee replacement (RR) |
| Mindfulness meditation | Healthy (29 studies): 11 MM NS, 9 MBSR, 8 Zen Buddhist, 1 MBCT |
| | Clinical conditions (46 studies): |
| | 6 cardiovascular diseases (3 MM NS, 2 MBSR, 1 Zen Buddhist) |
| | 4 cancer (2 MBSR, 2 MM NS) |
| | 4 fibromyalgia (2 MM NS, 1 MBCT, 1 MBSR) |
| | 3 anxiety disorders (2 MBSR, 1 MM NS) |
| | 3 chronic pain (MBSR) |
| | 3 depression (MBCT) |
| | 3 psoriasis (2 MBSR, 1 MM NS) |
| | 3 substance abuse (2 MBSR, 1 MM NS) |
| | 2 binge eating disorder (MM NS) |
| | 2 heterogeneous conditions (MBSR) |
| | 2 hypertension (Zen Buddhist) |
| | 2 mood disorders (MBSR) |
| | 1 burnout (MBSR) |
| | 1 chronic fatigue (MBSR) |
| | 1 HIV (MBSR) |
| | 1 infertility (MM NS) |
| | 1 insomnia (Zen Buddhist) |
| | 1 parents of children with behavioral problems (MBSR) |
| | 1 personality disorders (MBSR) |
| | 1 tinnitus (MBCT) |
| | 1 traumatic brain injuries (MBSR) |
| Undefined meditation practices | Healthy (11 studies) |
| | Clinical conditions (6 studies): |
| | 1 anger management |
| | 1 dental problems |
| | 1 hypertension |
| | 1 insomnia |
| | 1 mood disorders |
| | 1 substance abuse |
| Miscellaneous meditation practices | Healthy (2 studies) |
| | Cancer (1 study) |
| *Qigong* | Healthy (2 studies) |
| | Clinical conditions (11 studies): |
| | 4 hypertension |
| | 1 fibromyalgia |
| | 1 heterogeneous conditions |
| | 1 muscular dystrophy |
| | 1 cardiovascular diseases |
| | 1 regional pain syndrome |
| | 1 substance abuse |
| | 1 type 2 diabetes |
| *T'ai chi* | Healthy studies (25 studies) |
| | Clinical conditions (21 studies): |
| | 3 cardiovascular diseases |

(*continued*)

Table 3. Type of Populations Examined in Clinical Trials on Meditation Practices (Cont'd)

| *Meditation technique* | *Population examined* |
|---|---|
| | 3 osteoarthritis<br>2 chronic pain<br>1 rheumatoid arthritis<br>1 cancer<br>1 depression<br>1 HIV<br>1 hypertension<br>1 menopause<br>1 miscellaneous psychiatric conditions<br>1 osteoporosis<br>1 postmenopause<br>1 stroke<br>1 type 2 diabetes<br>1 vestibulopathy |
| Yoga | Healthy (46 studies)<br>Clinical conditions (59 studies):<br>8 hypertension<br>7 asthma<br>7 other cardiovascular diseases<br>6 depression<br>5 type 2 diabetes<br>3 substance abuse<br>2 anxiety disorder<br>2 chronic pain<br>2 rheumatoid arthritis<br>1 cancer<br>1 carpal tunnel syndrome<br>1 chronic airway obstruction<br>1 epilepsy<br>1 fibromyalgia<br>1 HIV<br>1 irritable bowel syndrome<br>1 migraine and tension headaches<br>1 miscellaneous psychiatric conditions<br>1 multiple sclerosis<br>1 neurosis<br>1 obsessive-compulsive disorder<br>1 osteoarthritis<br>1 pleural effusion<br>1 pregnancy<br>1 pulmonary tuberculosis<br>1 tinnitus |

CSM, Clinically Standardized Meditation; MBCT, mindfulness-based cognitive therapy; MBSR, Mindfulness-based stress reduction; MM, mindfulness meditation; NS, not specified; RR, Relaxation Response; TM, Transcendental Meditation™.

Factors related to the use of health care resources, such as medication use (21 measures), length of hospital stay, medical utilization rates, number of sick leaves, and payments to the health care system (11 measures) were occasionally reported. The reporting of the remaining outcome measures varied across the categories of meditation.

## Discussion

This study was a systematic and comprehensive review of clinical trials indexed in the scientific literature that have evaluated the effects of meditation techniques. To our knowledge, there has been no other review that covers the range of meditation practices, populations, and outcomes that are examined here. The majority of trials on meditation identified for this review have been conducted in Western countries and published as journal articles within the past 15 years. A similar bibliometric analysis on the clinical application of yoga revealed an increase in publication frequency over the past three decades, with a substantial and growing use of RCTs.[33]

We summarized a vast body of evidence from clinical trials over a very broad range of techniques. We have seven defined groups that are each heterogeneous, and all of these practices have been included under the umbrella term "meditation." Determining a working definition of "meditation" for the selection of studies in the review was a particularly challenging process that has been described elsewhere.[15] Although we acknowledge the limitations of the chosen approach, expert consensus resulted in the inclusion of the var-

Table 4. Frequency of Reported Outcome Measures by Category of Meditation

| | *Mantra meditation* | *Mindfulness meditation* | *Undefined meditation practices* | *Miscellaneous practices* | Qigong | T'ai chi | *Yoga* | *Total* |
|---|---|---|---|---|---|---|---|---|
| Activities of daily living/events impact | 4 | 5 | — | — | 1 | 3 | 2 | 15 |
| Adherence behavior | 3 | 2 | — | — | — | 3 | 1 | 9 |
| Clinical events/symptoms improvement | 22 | 22 | 1 | — | 4 | 12 | 47 | 108 |
| Cognitive-neuropsychological (attention) | 6 | 3 | | — | — | — | 5 | 14 |
| Cognitive-neuropsychological (general) | 11 | 5 | 1 | 1 | — | 2 | 5 | 25 |
| Cognitive-neuropsychological (language) | 4 | 1 | — | — | — | — | 7 | 12 |
| Cognitive-neuropsychological (memory) | 5 | 3 | 2 | — | — | — | 2 | 12 |
| Cognitive-neuropsychological (reasoning/executive) | 12 | 11 | 3 | — | — | — | 2 | 28 |
| Cognitive-neuropsychological (sensory perceptual and motor functions) | 14 | 12 | 3 | 1 | — | 4 | 11 | 45 |
| Falls occurrence/behavior | — | — | — | — | 1 | 13 | — | 14 |
| Health care utilization/economic outcomes | 5 | | — | — | — | — | 3 | 11 |
| Health status/well being | 9 | 10 | 1 | — | 2 | 9 | 13 | 44 |
| Health-related quality of life | 3 | 6 | 2 | 1 | 3 | 7 | 7 | 29 |
| Medication use | 4 | 1 | — | — | 1 | 1 | 14 | 21 |
| Mortality | 4 | — | — | — | — | — | 1 | 5 |
| Nutritional status/body composition/weight | 15 | 7 | — | — | 7 | 7 | 17 | 53 |
| Other behavioral | 5 | 2 | — | 2 | — | 1 | 4 | 14 |
| Pain/pain-related behavior | 5 | 9 | — | — | 2 | 8 | 8 | 32 |
| Physical function | 11 | 6 | 1 | — | 7 | 83 | 38 | 146 |
| Physiological (blood) | 3 | 1 | — | — | 3 | 1 | 5 | 13 |
| Physiological (brain/nervous system) | 9 | 1 | — | — | — | — | 13 | 23 |
| Physiological (cardiovascular) | 111 | 15 | 9 | — | 12 | 36 | 87 | 270 |
| Physiological (electrodermal responses) | 28 | 3 | 1 | — | — | — | 7 | 39 |
| Physiological (endocrine/hormonal) | 15 | 7 | 1 | — | 8 | 7 | 19 | 57 |
| Physiological (gastric) | — | — | — | — | — | — | 1 | 1 |
| Physiological (lymphatic/immunological) | 2 | 6 | — | — | 15 | 1 | 1 | 25 |
| Physiological (muscular) | 17 | 1 | 2 | — | — | 4 | 4 | 28 |
| Physiological (nutritional biochemistry and metabolism) | 18 | 5 | — | — | 13 | 15 | 70 | 121 |
| Physiological (ocular) | 1 | — | — | — | — | — | 3 | 4 |
| Physiological (pulmonary/respiratory) | 20 | 10 | 1 | — | 2 | 16 | 46 | 95 |
| Physiological (renal/excretory) | — | — | 2 | — | 2 | 1 | 1 | 6 |
| Physiological (sensory) | — | — | — | — | — | — | 5 | 5 |
| Physiological (skeletal) | — | — | — | — | — | 9 | 1 | 10 |
| Physiological (thermoregulatory) | 6 | 1 | 1 | — | 1 | — | 5 | 14 |
| Physiological (psychological symptoms) | 144 | 125 | 18 | 2 | 12 | 23 | 92 | 416 |
| Physiological (personality) | 73 | 36 | 9 | 1 | 3 | 13 | 24 | 159 |
| Physiological (positive psychology) | 21 | 245 | 2 | 1 | — | 3 | 11 | 62 |
| Sleep | 6 | 7 | 2 | — | — | 2 | 6 | 23 |
| Social/interpersonal relationships | 16 | 14 | — | — | — | 2 | 6 | 38 |
| Total | 632 | 364 | 62 | 9 | 99 | 286 | 594 | 2046 |

ious categories of meditation described in this review. This review may be criticized for ignoring important differences between meditation techniques by using categories that include "single entities" (e.g., TM, RR, MM, and CSM). Even if other reasonable categorizations had been used, the overall conclusions regarding the quality and breadth of this literature would not have been substantially altered.

The clinical trials that have evaluated meditation techniques vary widely in many aspects. Some authors have declared that meditation poses a considerable challenge for the principles of evidence-based medicine.[34] Meditation is a complex and multifaceted practice, difficult to standardize compared to pharmacological interventions, and for which specific effects are difficult to distinguish.[34] Therefore, it is not surprising that there is no single or shared theoretical framework. Instead, there are many different types of trials that have been conducted that focus on different physiological, cognitive, behavioral, and cognitive-behavioral outcome measures. There appear to be different schools of thought on the best theories, meditation techniques, and outcome measures that should be studied in this area, as evidenced by this overview of the literature. There is a need for more collaboration among researchers of various schools of thought in order to benefit from different perspectives, and ultimately improve the quality of research in this area.

The appropriate selection of controls is of paramount importance if progress is to be made with respect to determining the effects of meditation techniques. The problem of the inadequacy of control groups in meditation trials is not new.[35] A wide array of control groups was used in the trials included in this review. They have not been standardized and it is unknown how comparable they are across the studies. Almost half of the trials used wait-list or no treatment groups as controls rather than a comparator that would more fully control for experimenter attention and contact. For good reason some authors have argued that the use of a wait list as a control group in clinical trials is clearly inappropriate as no one expects to improve while they are waiting to begin treatment.[36] The same critique may be directed to studies employing a no treatment control. This situation may also create a negative expectation of improvement that may spuriously amplify the difference in treatment effects between the intervention and the control.[36] Therefore, extreme caution should be exercised when interpreting studies comparing the effects of meditation practices to no treatment or wait-list groups.

The need for appropriate controls has been described by some researchers as the most difficult conundrum for designing research trials in meditation.[37,38] Selection of appropriate control groups and consistency of inherently individualized interventions are challenging issues that need extensive evaluation.[39] We are unaware of assessment tools developed to specifically address this issue as it pertains to meditation practices. However, the comprehensive categorization of the control groups presented in this study allows a starting point for examining the appropriateness of these controls to assess the benefits of various therapeutic meditation practices. Such an examination is especially important given the imperative to control for the expectation effects of meditation per se in the design of any meditation trial.

The vast majority of trials included in this review were conducted in healthy populations. It can be argued that trials with healthy participants are useful to assess how meditation practices may prevent certain clinical conditions and enhance wellness and well being. However, simply focusing on healthy subjects does not provide a clear picture of the effectiveness of meditation practices as therapeutic interventions. Clinical trials of meditation practices have addressed conditions with high mortality and morbidity rates or burden of disease, including hypertension, cardiovascular disorders, substance abuse, anxiety disorders, cancer, asthma, chronic pain, type 2 diabetes, and fibromyalgia. The first three of these conditions were among the six leading causes of premature death and disability in the United States projected for the mid-1900s to 2020, as measured by disability-adjusted life years (DALYs).[40] However, it may be argued that the choice of appropriate clinical populations for whom meditation trials should be conducted is an overlooked area of research. Without some biologically plausible mechanisms of action to direct selection of the appropriate clinical populations, results from studies of meditative practices may be difficult to interpret. An open debate among meditation researchers would certainly help to establish consensus on priorities in the research agenda for meditation as a therapeutic intervention for clinical populations.

The trials evaluated a wide variety of outcome measures. Psychosocial outcomes, particularly those of psychiatric and psychological symptoms, were the most frequently evaluated. Physiological outcomes, particularly cardiovascular measures, and outcomes related to clinical events were also frequently assessed. Few clinical trials focused on cognitive and neuropsychological functions. Since hypertension and cardiovascular disorders rank as the two most studied conditions, it is not surprising that physiological outcomes were so prominently assessed. However, if psychiatric disorders and psychological factors are studied more, it is likely that the number of evaluations of psychosocial outcome measures will continue to increase. There is also great diversity in the measures used to assess similar psychosocial constructs, which often prevents comparisons across studies. Researchers would be well advised to attempt consensus on a core battery of outcome questionnaires that may be appropriate for this type of research in specific patient populations.

We assessed the quality of clinical trials on meditation published between 1956 and 2005. Overall, the methodological quality of most of the trials on meditation is poor, with significant threats to validity in every major category of quality measured. This finding is not unique to the area of meditation research, and the quality of reporting is a frequent problem in other areas of complementary and alternative medicine (CAM) research[41] and related therapy research domains.[42]

The findings of this report are also supported in general by other recent systematic reviews.[9–14] A 2004 meta-analysis on mindfulness studies for a wide variety of disorders found 64 empirical studies where only 20 reports met criteria of acceptable quality or relevance to be included and only 13 studies included control groups.[9] Of these 13, 6 employed forms of active controls with a mean effect size of almost 0.49, which was similar to the mean effect size observed in 4 wait-list control groups ($d = 0.58$). The authors concluded that "most studies reviewed suffered from methodological deficiencies beyond merely the type of design as randomized, quasiexperimental or observational. Insufficient considera-

tion or information was typically given about participant dropout rate, other concurrent interventions during the mindfulness training period, therapist adherence to intervention program, evaluation of therapist training and competence, description of interventions, adequate statistical power to calculate intervention effects, or the clinical relevance of results. Additionally, the construct of mindfulness itself, although central to all interventions, was neither operationalized nor evaluated for change in any study."[9] A 2007 review of 15 MBSR controlled studies published in peer-reviewed journals with outcomes related to changes in depression and anxiety concluded: "Evidence for a beneficial effect of MBSR on depression and anxiety was equivocal. When active control groups were used, MBSR did not show an effect on depression and anxiety. Adherence to the MBSR program was infrequently assessed. Where it was assessed, the relation between practising mindfulness and changes in depression and anxiety was equivocal."[14] The authors further stated that "MBSR does not have a reliable effect on depression and anxiety."[14] A 2005 systematic review on MBSR for cancer patients found three RCTs and seven uncontrolled clinical trials.[13] The authors stated: "A lack of relevant qualitative research studies was identified. Studies report positive results, including improvements in mood, sleep quality and reductions in stress. A dose-response effect has been observed between practice of MBSR and improved outcome. A number of methodological limitations were identified. Modifications to the traditional MBSR programme make comparison between studies difficult and a lack of controlled studies precludes any firm conclusion on efficacy."[13] A 2005 systematic review on the effectiveness of eight yoga studies for the treatment of anxiety and anxiety-related disorders reported "positive results, although there were many methodological inadequacies. Owing to the diversity of conditions treated and poor quality of most of the studies, it is not possible to say that yoga is effective in treating anxiety or anxiety disorders in general. However, there are encouraging results, particularly with obsessive compulsive disorder. Further well conducted research is necessary which may be most productive if focused on specific anxiety disorders."[11] Another systematic review by the same group was conducted on yoga studies for treating depression.[12] They located five RCTs that all used different forms of yoga interventions and the severity of the depression ranged from mild to severe. They stated that "All trials reported positive findings but methodological details such as method of randomisation, compliance and attrition rates were missing. No adverse effects were reported with the exception of fatigue and breathlessness in participants in one study . . . Overall, the initial indications are of potentially beneficial effects of yoga interventions on depressive disorders. Variation in interventions, severity and reporting of trial methodology suggests that the findings must be interpreted with caution."[12] Finally, a 2006 systematic review of meditation techniques for medical illness found 82 studies of which 20 RCTs met their criteria, included 958 subjects total (397 experimentally treated, 561 controls), and no reported serious adverse events.[10] Their results suggested that "The strongest evidence for efficacy was found for epilepsy, symptoms of the premenstrual syndrome and menopausal symptoms. Benefit was also demonstrated for mood and anxiety disorders, autoimmune illness, and emotional disturbance in neoplastic disease." They concluded that "The results support the safety and potential efficacy of meditative practices for treating certain illnesses, particularly in nonpsychotic mood and anxiety disorders. Clear and reproducible evidence supporting efficacy from large, methodologically sound studies is lacking."[10]

Research on meditation techniques has developed mostly over the past two decades. We found a small but statistically significant improvement in the methodological quality of clinical trials over time. Future reviews should examine what factors are associated with an improvement in the quality of meditation trials over time. The publication of the Consolidated Standards of Reporting Trials (CONSORT)[43] in 1996 was aimed at the improvement of the quality of research reports of RCTs. It is unknown how the quality of reporting of RCTs of meditation practices has changed after the dissemination of these guidelines in the CAM community.

We described the methodological quality of the meditation trials using the individual components of the scales. By this approach, we found that only 11% of the RCTs identified in the review provided a complete description of an appropriate randomization process to assign participants to treatment groups, 2% reported the use of double blinding procedures to hide the identity of the assigned interventions, and 95% failed to describe how they concealed the allocation to the interventions. Finally, less than half of the trials (49%) provided a description of withdrawals and dropouts.

The lack of double-blinding has been a particularly controversial topic not only in meditation trials, but also in other areas of CAM,[39] in surgical interventions,[44] and in behavioral treatments.[36] The idea that it is possible to design high-quality trials in meditation and implement double-blind procedures by selecting appropriate control groups, and include clinician raters who are blinded to the subject's intervention, has had little support in the field of meditation research, as indicated by the 2% of the trials that successfully implemented a double blind procedure. Although it may not always be possible to prevent the participants in a trial from identifying what technique they are employing, other strategies, such as blinding subjects to the study hypothesis and blinding outcome assessors, may alleviate this problem. However, this can be problematic in clinical trials for a specific disorder, in which recruited patients will have expectations that a technique may be efficacious for that disorder.

Some authors have called for a paradigm shift, suggesting that the quality of CAM research should be evaluated by other methodological standards.[45,46] They have asserted that the scientific techniques of treatment protocols, randomization, double-blind conditions, and use of placebo controls distort the holistic therapeutic milieu of CAM. However, the distinction of holistic interventions as opposed to traditional medicine may be artificial. Just as CAM does, traditional interventions provide treatments within a symbolic healing context by using nonspecific therapeutic attention and expectations.[47] Empirical evidence and theoretical considerations support that there are some basic characteristics that should always be considered when evaluating the quality of any RCT: randomization, blinding, handling of patient attrition in the analysis, and allocation concealment.[17,19,48–50] There is some agreement that behavioral interventions are different than trials on pharmaceutical therapies in some respects, and it may not be appropriate to always evaluate

them by identical standards. New developments such as an extension of the CONSORT guidelines for reporting trials of behavioral interventions constitute a step in the right direction.[51] In addition, the question of the relative efficacy of various meditation techniques can only be answered by comparing a variety of different techniques under highly controlled conditions. It has been suggested that "it is timely and very important to compare TM, the Relaxation Response, Mindfulness Meditation, Kundalini Yoga meditation techniques, and other yogic meditation techniques from various lineages in RCTs run by the best experts in the field, and to use all the blinding possible for assessment."[52] An alternative hypothesis is that there is a common element or elements shared across the various meditative approaches.

While there is a clear need and place for RCTs to evaluate the efficacy of meditation interventions, it may be that mixed approaches to meditation research are justified. Other research methods that were beyond the scope of this review are also appropriate for answering different research questions. For example, qualitative methods provide insight into participants' experience of the techniques, and while these methods cannot prove efficacy in a traditional sense, they are useful for achieving other research objectives, such as describing processes of change and providing rich examples of how meditation practices may be integrated into individuals' lives.

The assessment of methodological quality is one of the strengths of this review. A model for quality assessment based on stringent criteria was adopted.[53] Our approach focused on the internal validity of the studies, as recommended by several researchers.[19,54–56] We chose two assessment tools that have well-established face validity, and for which a relationship with bias has been proven in empirical studies.[17,48] The Jadad scale is the most commonly used quality scale for RCTs in pharmacological and nonpharmacological reviews.[57] The Jadad scale uses a simple and easy-to-understand approach that incorporates the most important individual components of internal validity: randomization, blinding, and handling of patient attrition. The scale, however, may be criticized as being unsuited for the evaluation of nonpharmacological interventions such as meditation, where blinding of the subjects to the identity of the treatment they are receiving is likely to interfere with treatment effectiveness. Likewise, the Jadad scale does not evaluate the effectiveness of treatment implementation. Though various criteria to assess methodological quality of studies are available in the scientific literature,[58] there is no consensus on which quality assessment tool can be recommended without reservation.[59] The approach adopted for this review serves to indicate important potential methodological weaknesses in meditation research, thereby tempering the conclusions that may be drawn from meditation clinical trials and highlighting areas for improving future research.

In our approach to quality assessment, we have not addressed other important aspects that contribute to the external validity of a trial (e.g., how representative the participants are, how the treatment providers compare to intended eventual users of the intervention). Certainly, the external validity of a trial is an important concept that is worthy of consideration in future reviews. It may be the case that many studies on meditation techniques have compromised their internal validity, as seen in this report, for the sake of external validity. However, this cannot be gauged from the scope of this analysis and it is unknown how factors related with external validity may bias study results and, therefore, the results of a systematic review.

Despite the comprehensive nature of our search strategies (i.e., electronic searches supplemented by a search for relevant gray literature, abstracts from scientific meetings, dissertations and theses, reference lists, and trial registries), there are inevitable gaps with respect to the gray literature. Although 17% of the trials were identified from nonelectronic sources, it is unlikely that all of the clinical trials meeting our inclusion criteria have been identified and acquired. In particular, a number of Indian journals, including yoga specialty journals, have not been indexed and are difficult to acquire. We also did not contact religious or spiritual organizations for unpublished studies. Nevertheless, it is likely that the vast majority of publications that satisfy our inclusion criteria have been examined and that the general trends reported in this study are sufficiently representative of the research on meditation at large.[33] The restriction to English-language publications is of special concern because many of these meditation techniques originate in non-English-speaking countries. In light of a recent bibliometric study on yoga that reported that there is a large amount of research by Indian researchers,[33] it is possible that some yoga trials were not included in this review. In addition, it is likely that an unknown number of trials on *t'ai chi*[60] and *qigong* have been published in Asian languages and, therefore, are not included in this review. Nonetheless, it is unlikely that the results of this review would have been significantly altered by inclusion of these other studies.

Future research studying the efficacy of meditation techniques faces several challenges. The most important concern is to compare various meditation techniques with each other in well-controlled trials conducted by highly trained individuals that are skilled with the selected population(s). Special attention to the appropriate selection of controls in trials where only a single technique or protocol is tested is also of paramount importance. Forthcoming trials would also benefit by including larger sample sizes, using disease-specific outcome measures, and providing clearer descriptions of intervention components. Many different types of meditation techniques have been subjected to trial and have included a wide variety of healthy and clinical populations using various study designs. Therefore, it is very difficult to assess the effects for the umbrella term "meditation" as a generalized therapy under a given set of circumstances. It is especially important that investigators make an effort to clearly define and report the details of the intervention procedures and exactly how it was employed, as well as details of the population, controls, and outcomes.

Blinded allocation to treatment may be difficult to implement in meditation trials, especially since many techniques are now openly described on the internet. Methods that have been proposed for blinding participants, health care providers, or other caregivers consist mainly of blinding participants to the hypothesis and the nature of the placebo or the use of sham procedures such as similar attention-control interventions (as has been done in psychotherapy research). One critical factor in meditation research is the expectation effect that patients may have when entering the trial or when practicing the meditation intervention. When testing a med-

itation technique with a specific clinical population, it is unlikely that patients could be recruited and retained without knowing the intent of the trial. The strength of a patient's motivation to attend the treatment training sessions and to practice routinely on their own depends on having a positive expectation of benefits. It may be useful to add manipulation checks into study designs in order to gauge the degree to which participants feel they are engaging in authentic and efficacious treatments. This remains an important area for future research. Some modifications of the traditional double-blind methodology, such as the "dual-blinding" approach (in which the participant and an external evaluator, but not the person administering treatment, are blind to treatment), have also been proposed.[61]

Key methodological issues in the study of meditation using an evidence-based approach should be further explored through the analysis of important factors such as the impact of publication bias in meditation research (including positive outcome bias and time to publication bias); empirical evidence of relationships between study quality and effect estimates; the impact of language bias in systematic reviews of meditation practices; the impact of year of publication of primary studies on pooled estimates; trends of quality of primary studies and systematic reviews on meditation; and use of quality assessment tools in meditation research. The relationship between report of funding and disclosure of conflict of interest and positive outcomes also merits formal evaluation. Although it is important to suggest conducting more high quality studies based on the standards for RCTs, it is also important to develop alternative study designs that can incorporate the special features of meditation practices to fully investigate their therapeutic effects while minimizing the risk of bias.

## Conclusions

The field of research on meditation techniques and their therapeutic applications has been clouded by a lack of methodological rigor, although rigor is improving. Further research needs to be directed to distinguishing the relative efficacy of techniques through head-to-head trials, as is commonly seen in studies of pharmaceutical agents. In addition, the potentially different elements of these techniques should be explored in the laboratory. The dearth of high-quality evidence highlights the need for greater care in defining and describing the interventions and in choosing the appropriate controls, populations, and outcomes that permit comparison of studies across techniques. More care in these choices will allow effects to be estimated with greater reliability and validity. More randomized trials that draw on the experience of investigators or consultants with a strong background in clinical and basic research should be conducted. It is imperative that future trials on meditation be more rigorous in design, execution, analysis, and reporting of results. In particular, greater importance should be placed on the reporting of study methods and providing detailed descriptions of the training of the participants, qualifications of meditation instructors, and the criteria and methods used to determine a successful meditation practice.

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