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Meditation Programs for Psychological Stress and Well-being

A Systematic Review and Meta-analysis FREE

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ABSTRACT

Importance Many people meditate to reduce psychological stress and stress-related health problems. To counsel people appropriately, clinicians need to know what the evidence says about the health benefits of meditation.

Objective To determine the efficacy of meditation programs in improving stress-related outcomes (anxiety, depression, stress/distress, positive mood, mental health–related quality of life, attention, substance use, eating habits, sleep, pain, and weight) in diverse adult clinical populations.

Evidence Review We identified randomized clinical trials with active controls for placebo effects through November 2012 from MEDLINE, PsycINFO, EMBASE, PsycArticles, Scopus, CINAHL, AMED, the Cochrane Library, and hand searches. Two independent reviewers screened citations and extracted data. We graded the strength of evidence using 4 domains (risk of bias, precision, directness, and consistency) and determined the magnitude and direction of effect by calculating the relative difference between groups in change from baseline. When possible, we conducted meta-analyses using standardized mean differences to obtain aggregate estimates of effect size with 95% confidence intervals.

Findings After reviewing 18 753 citations, we included 47 trials with 3515 participants. Mindfulness meditation programs had moderate evidence of improved anxiety (effect size, 0.38 [95% CI, 0.12-0.64] at 8 weeks and 0.22 [0.02-0.43] at 3-6 months), depression (0.30 [0.00-0.59] at 8 weeks and 0.23 [0.05-0.42] at 3-6 months), and pain (0.33 [0.03- 0.62]) and low evidence of improved stress/distress and mental health–related quality of life. We found low evidence of no effect or insufficient evidence of any effect of meditation programs on positive mood, attention, substance use, eating habits, sleep, and weight. We found no evidence that meditation programs were better than any active treatment (ie, drugs, exercise, and other behavioral therapies).

Conclusions and Relevance Clinicians should be aware that meditation programs can result in small to moderate reductions of multiple negative dimensions of psychological stress. Thus, clinicians should be prepared to talk with their patients about the role that a meditation program could have in addressing psychological stress. Stronger study designs are needed to determine the effects of meditation programs in improving the positive dimensions of mental health and stress-related behavior.

Many people use meditation to treat stress and stress-related conditions and to promote general health.[1,2] To counsel patients appropriately, clinicians

need to know more about meditation programs and how they can affect health outcomes. Meditation training programs vary in several ways, including the type of mental activity promoted, the amount of training recommended, the use and qualifications of an instructor, and the degree of emphasis on religion or spirituality. Some meditative techniques are integrated into a broader alternative approach that includes dietary and/or movement therapies (eg, ayurveda or yoga).

Meditative techniques are categorized as emphasizing mindfulness, concentration, and automatic self-transcendence. Popular techniques, such as transcendental meditation, emphasize the use of a mantra in such a way that it transcends one to an effortless state where focused attention is absent.[3-5] Other popular techniques, such as mindfulness-based stress reduction, emphasize training in present-focused awareness or mindfulness. Uncertainty remains about what these distinctions mean and the extent to which these distinctions actually influence psychosocial stress outcomes.[5,6]

Reviews to date report a small to moderate effect of mindfulness and mantra meditation techniques in reducing emotional symptoms (eg, anxiety, depression, and stress) and improving physical symptoms (eg, pain).[7-26] These reviews have largely included uncontrolled and controlled studies, and many of the controlled studies did not adequately control for placebo effects (eg, waiting list– or usual care–controlled studies). Observational studies have a high risk of bias owing to problems such as self-selection of interventions (people who believe in the benefits of meditation or who have prior experience with meditation are more likely to enroll in a meditation program and report that they benefited from one) and use of outcome measures that can be easily biased by participants' beliefs in the benefits of meditation. Clinicians need to know whether meditation training has beneficial effects beyond self-selection biases and the nonspecific effects of time, attention, and expectations for improvement.[27,28]

An informative analogy is the use of placebos in pharmaceutical trials. A placebo is typically designed to match nonspecific aspects of the “active” intervention and thereby elicit the same expectations of benefit on the part of the provider and patient in the absence of the active ingredient. Office visits and patient-provider interactions, all of which influence expectations for outcome, are particularly important to control when the evaluation of outcome relies on patient reporting. In the situation when double-blinding has not been feasible, the challenge to execute studies that are not biased by these nonspecific factors is more pressing.[28] To develop evidence-based guidance on the use of meditation programs, we need to examine the specific effects of meditation in randomized clinical trials (RCTs) in which the nonspecific aspects of the intervention are controlled.

The objective of this systematic review is to evaluate the effects of meditation programs on negative affect (eg, anxiety, stress), positive affect (eg, well-being), the mental component of health-related quality of life, attention, health-related behaviors affected by stress (eg, substance use, sleep, eating habits), pain, and weight among persons with a clinical condition. We include only RCTs that used 1 or more control groups in which the amount of time and attention provided by the control intervention was comparable to that of the meditation program.

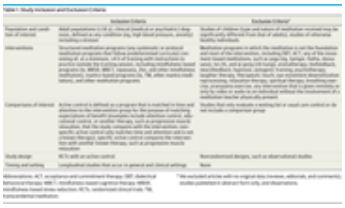
METHODS

We searched the following databases for primary studies: MEDLINE, PsycINFO, EMBASE, PsycArticles, Scopus, CINAHL, AMED, and the Cochrane Library through June 2013. We developed a MEDLINE search strategy using PubMed medical subject heading terms and the text words of key articles that we identified a priori. We used a similar strategy in the other electronic sources. We reviewed the reference lists of included articles, relevant review articles, and related systematic reviews to identify articles missed in the database searches. We did not impose any limits based on

language or date of publication. The protocol for this systematic review is publicly available.[29]

Two trained investigators independently screened titles and abstracts, excluding those that both investigators agreed met at least 1 of the exclusion criteria (Table 1). For those studies included after the first review, a second dual independent review of the full-text article occurred, and differences regarding article inclusion were resolved through consensus.

Table 1. Study Inclusion and Exclusion Criteria



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We included RCTs in which the control group was matched in time and attention to the intervention group. We also required that studies include participants with a clinical condition. We defined a clinical condition broadly to include mental health/psychiatric conditions (eg, anxiety or stress) and physical conditions (eg, lower back pain, heart disease, or advanced age). In addition, because stress is of particular interest in meditation studies, we also included trials that studied stressed populations, although they may not have had a defined medical or psychiatric diagnosis.

We used systemic review software (DistillerSR, 2010; Evidence Partners) to manage the screening process. For each meditation program, we extracted information on measures of intervention fidelity, including dose, training, and receipt of intervention. We recorded the duration and maximal hours of structured training in meditation, the amount of home practice recommended, description of instructor qualifications, and description of participant adherence, if any. Because numerous scales measured negative or positive affect, we chose scales that were common to the other trials and the most

clinically relevant to make comparisons more meaningful.

To display outcome data, we calculated the relative difference in change scores (ie, the change from baseline in the treatment group minus the change from baseline in the control group, divided by the baseline score in the treatment group). We used the relative difference in change scores to estimate the direction and approximate magnitude of effect for all outcomes. We were unable to calculate a relative difference in change score for 6 outcomes owing to incompletely reported data for statistically insignificant findings. We considered a 5% relative difference in change score to be potentially clinically significant because these studies examined short-term interventions and relatively low doses of meditation.

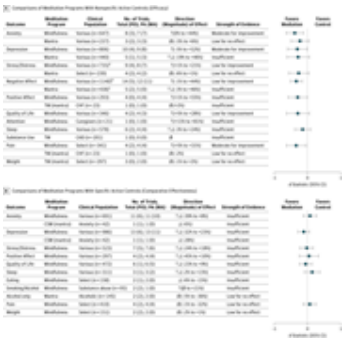
For the purpose of generating an aggregate quantitative estimate of the effect of an intervention and the associated 95% confidence interval, we performed random-effects meta-analyses using standardized mean differences (effect size [ES]; Cohen *d*). We also used these analyses to assess the precision of individual studies, which we factored into the overall strength of evidence. For each outcome, ES estimates are displayed according to the type of control group and the duration of follow-up. Trials did not give enough information to conduct a meta-analysis on 16 outcomes. We display the relative difference in change scores along with the ES estimates from the meta-analysis so that readers can see the full extent of the available data (Figure 1 and Supplement [eFigures 1 to 34]).

Figure 1.

Strength of Evidence on the Trial Outcomes

Summary across measurement domains of comparisons of meditation programs with nonspecific active controls (efficacy analysis) (A) and specific active controls (comparative effectiveness analysis) (B). CAD indicates coronary artery disease; CHF, congestive heart failure; CSM, clinically standardized meditation (a mantra meditation program); MA, meta-analysis; PA, primary analysis; PO, number of trials in which this was a primary outcome for the trial; and TM, transcendental meditation (a mantra

meditation program). Direction is based on the relative difference in change analysis. ↑ Indicates the meditation group improved relative to the control group (with a relative difference generally ≥5% across trials); ↓, the meditation group worsened relative to the control group (with a relative difference generally ±5% across trials); Ø, a null effect (with a relative difference generally <5% across trials); and ↑↓, inconsistent findings (some trials reported improvement with meditation [relative to control], whereas others showed no improvement or improvement in the control group [relative to meditation]). Magnitude is based on the relative difference in the change score, a relative percent difference, using the baseline mean in the meditation group as the denominator. For example, if the meditation group improves from 10 to 19 on a mental health scale and the control group improves from 11 to 16 on the same scale, the relative difference between groups in the change score is: $\{[(19-10)-(16-11)]/10\}\times 100=40\%$. The interpretation is a 40% relative improvement on the mental health scale in the meditation group compared with the control group. Improvement in all scales is indicated in the positive direction. A positive relative percent difference means that the score improved more in the intervention group than in the control group. The meta-analysis figure (far right) shows the Cohen *d* statistic with the 95% CI.[a]Summary effect size is not shown owing to concern about publication bias for this outcome.[b]Negative affect combines the outcomes of anxiety, depression, and stress/distress and is thus duplicative of those outcomes.[c]We did not perform an MA on this outcome because it would duplicate the anxiety MA for mantra. Anxiety and depression are indirect measures of negative affect and therefore resulted in a lower strength of evidence than that for the outcome of mantra on anxiety.



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We classified the type of control group as a nonspecific active or specific active control (Table 1). The nonspecific active comparison conditions (eg, education or attention control) control for the nonspecific effects of time, attention, and expectation. Comparisons against these controls allow for assessments of the specific effectiveness of the meditation program beyond the nonspecific effects of time, attention, and expectation. This comparison is similar to a comparison against a placebo pill in a drug trial. Specific active controls are therapies (eg, exercise or progressive muscle relaxation) known or expected to change clinical outcomes. Comparisons against these controls

allow for assessments of comparative effectiveness similar to those of drug trials that compare one drug against another known drug. Because these study designs are expected to yield different conclusions (efficacy vs comparative effectiveness), we separated them in our analyses.

We assessed the quality of the trials independently and in duplicate based on the recommendations in the *Methods Guide for Conducting Comparative Effectiveness Reviews*.[30] We supplemented these tools with additional assessment questions based on the Cochrane Collaboration's risk-of-bias tool.[31,32] Two reviewers graded the strength of evidence for each outcome using the grading scheme recommended by the Methods Guide for Conducting Comparative Effectiveness Reviews.[33] This grading was followed by a discussion to review and achieve consensus on the assigned grades. In assigning evidence grades, we considered the following 4 domains: risk of bias, directness, consistency, and precision. We classified evidence into the following 4 basic categories: (1) high grade (indicating high confidence that the evidence reflects the true effect and that further research is very unlikely to change our confidence in the estimate of the effect), (2) moderate grade (indicating moderate confidence that the evidence reflects the true effect and that further research may change our confidence in the estimate of the effect and may change the estimate), (3) low grade (indicating low confidence that the evidence reflects the true effect and that further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate), and (4) insufficient grade (indicating that evidence is unavailable or inadequate to draw a conclusion).

RESULTS

We screened 18 753 unique citations (Figure 2) and 1651 full-text articles. Forty seven trials met our inclusion criteria.[34-80]

Figure 2.

Summary of the Literature Search

[a]Total exceeds the number in the exclusion box because reviewers were allowed to mark more than 1 reason for exclusion.

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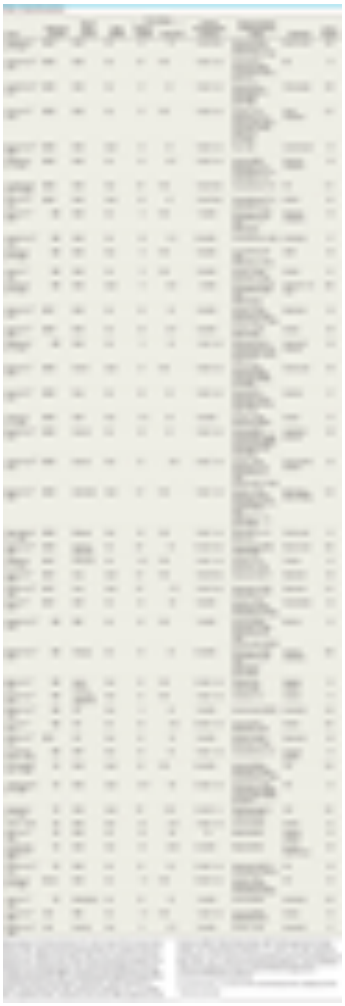
Most trials were short-term but ranged from 3 weeks to 5.4 years in duration (Table 2). Not all trials reported the amount of training or home practice recommended. Mindfulness-based stress reduction programs typically provided 20 to 27.5 hours of training during 8 weeks. The other mindfulness meditation trials provided about half this amount. Transcendental meditation trials were estimated to provide 16 to 39 hours in 3 to 12 months, whereas other mantra meditation programs provided about half this amount. Only 5 of the trials reported the trainers' actual meditation experience (ranging from 4 months to 25 years), and 6 reported the trainers' actual teaching experience (ranging from 0-15.7 years). Fifteen trials studied psychiatric populations, including those with anxiety, depression, stress, chronic worry, and insomnia. Five trials studied smokers and alcoholics, 5 studied populations with chronic pain, and 16 studied populations with diverse medical problems, including those with heart disease, lung disease, breast cancer, diabetes mellitus, hypertension, and human immunodeficiency virus infection.

Table 2. Study Descriptions



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The strength of evidence concerning the outcomes is shown in Figure 1. We found it difficult to draw comparative effectiveness conclusions owing to the large heterogeneity of type and strength of the many comparators. Therefore, we present our results first for all the comparisons with nonspecific active controls (efficacy) and then for those with specific active controls (comparative effectiveness).

The direction and magnitude of effect is derived from the relative difference between groups in the change score. In our efficacy analysis (Figure 1A), we found low evidence of no effect or insufficient evidence that mantra meditation programs had an effect on any of the psychological stress and well-being outcomes we examined. Mindfulness meditation programs had moderate evidence of improved anxiety (ES, 0.38 [95% CI, 0.12- 0.64] at 8

weeks and 0.22 [0.02-0.43] at 3-6 months), depression (0.30 [0.00-0.59] at 8 weeks and 0.23 [0.05-0.42] at 3-6 months), and pain (0.33 [0.03-0.62]) and low evidence of improved stress/distress and mental health–related quality of life.We found low evidence of no effect or insufficient evidence of an effect of meditation programs on positive mood, attention, sleep, and weight. We also found insufficient evidence that meditation programs had an effect on health-related behaviors affected by stress, including substance use and sleep.

In our comparative effectiveness analyses (Figure 1B), we found low evidence of no effect or insufficient evidence that any of the meditation programs were more effective than exercise, progressive muscle relaxation, cognitive-behavioral group therapy, or other specific comparators in changing any outcomes of interest. Few trials reported on potential harms of meditation programs. Of the 9 trials reporting this information, none reported any harms of the intervention.

We could not conduct any quantitative tests (eg, funnel plots) for publication bias because few studies were available for most outcomes, and many were excluded from the meta-analysis owing to missing data. We reviewed the clinicaltrials.gov registration database to identify trials completed 3 or more years ago that prespecified our outcomes of interest and did not publish at all or did not publish all prespecified outcomes. We found 5 trials that appeared to have been completed before January 1, 2010, that did not publish all the outcomes they had prespecified and 9 trials for which we could not find an associated publication. Because only 6 outcomes were excluded from the analyses of the relative difference in change scores between groups, whereas 16 outcomes were excluded from the meta-analyses, our findings from the primary analyses are less likely than the meta-analyses to be affected by publication bias.

DISCUSSION

Our review indicates that meditation programs can reduce the negative dimensions of psychological stress. Mindfulness meditation programs, in particular, show small improvements in anxiety, depression, and pain with moderate evidence and small improvements in stress/distress and the mental health component of health-related quality of life with low evidence when compared with nonspecific active controls. Mantra meditation programs did not improve any of the outcomes examined, but the strength of this evidence varied from low to insufficient. Although meditation programs generally seek to improve the positive dimensions of health, the evidence from a small number of studies did not show any effects on positive affect or well-being for any meditation program. We found no evidence of any harms of meditation programs, although few trials reported on harms. One strength of our review is the focus on RCTs with active controls, which should give clinicians greater confidence that the reported benefits are not the result of nonspecific effects (eg, attention and expectations) that are seen in trials using a waiting list or usual-care control condition.

Anxiety, depression, and stress/distress are different components of negative affect. When we combined each component of negative affect, we saw a small and consistent signal that any domain of negative affect is improved in mindfulness programs when compared with a nonspecific active control. The ESs were small but significant for some of these individual outcomes and were seen across a broad range of clinical conditions (Table 2). During the course of 2 to 6 months, the mindfulness meditation program ES estimates ranged from 0.22 to 0.38 for anxiety symptoms and 0.23 to 0.30 for depressive symptoms. These small effects are comparable with what would be expected from the use of an antidepressant in a primary care population but without the associated toxicities. In a study using patient-level meta-analysis, Fournier et al[81] found that for patients with mild to moderate depressive symptoms, antidepressants had an ES of 0.11 (95% CI, –0.18 to 0.41), whereas for those with severe depression, antidepressants had an ES

of 0.17 (–0.08 to 0.43) compared with placebo.

Among the 9 RCTs[43,44,47,54,55,63,64,73,74] evaluating the effect on pain, we found moderate evidence that mindfulness-based stress reduction reduces pain severity to a small degree when compared with a nonspecific active control, yielding an ES of 0.33 from the meta-analysis. This effect is variable across painful conditions and is based on the results of 4 trials, of which 2 were conducted in patients with musculoskeletal pain,[55,64] 1 trial in patients with irritable bowel syndrome,[43] and 1 trial in a population without pain.[44] Visceral pain had a large and statistically significant relative 30% improvement in pain severity, whereas musculoskeletal pain showed 5% to 8% improvements that were considered nonsignificant.

Overall, the evidence was insufficient to indicate that meditation programs alter health-related behaviors affected by stress, and low-grade evidence suggested that meditation programs do not influence weight. Although uncontrolled studies have usually found a benefit of meditation, very few controlled studies have found a similar benefit for the effects of meditation programs on health-related behaviors affected by stress.[17- 19]

In the 20 RCTs examining comparative effectiveness,[34,36,37,40,45,46,48,49,51,53,54,57,61- 63,66,70,71,73- 75,77,80] mindfulness and mantra programs did not show significant effects when the comparator was a known treatment or therapy. A lack of statistically significant superiority compared with a specific active control (eg, exercise) only addresses the question of equivalency or noninferiority if the trial is suitably powered to detect any difference. Sample sizes in the comparative effectiveness trials were small (mean size of 37 per group), and none appeared adequately powered to assess noninferiority or equivalence.

A number of observations provide context to our conclusions. First, very few mantra meditation programs met our inclusion criteria. This lack significantly

limited our ability to draw inferences about the effects of mantra meditation programs on psychological stress–related outcomes, which did not change when we evaluated transcendental meditation separately from other mantra training.

Second, differences may exist between trials for which the outcomes are a primary vs a secondary focus, although we did not find any evidence of this. The samples included in these trials resembled a general primary care population, and there may not be room to measure an effect if symptom levels of the outcomes are low to start with (ie, a floor effect). This limitation may explain the null results for mantra meditation programs because 3 transcendental meditation trials[47,59,65] enrolled patients with cardiac disease, whereas only 1 enrolled patients with anxiety.[69]

Third, the lack of effect on stress-related outcomes may relate to the way the research community conceptualizes meditation programs, the challenges in acquiring such skills or meditative states, and the limited duration of RCTs. Historically, meditation was not conceptualized as an expedient therapy for health problems.[3,6,82] Meditation was a skill or state one learned and practiced over time to increase one's awareness and through this awareness to gain insight and understanding into the various subtleties of one's existence. Training the mind in awareness, in nonjudgmental states, or in the ability to become completely free of thoughts or other activity are daunting accomplishments. The interest in meditation that has grown during the past 30 years in Western cultures comes from Eastern traditions that emphasize lifelong growth. The translation of these traditions into research studies remains challenging. Long-term trials may be optimal to examine the effect of meditation on many health outcomes, such as those trials that have evaluated mortality.[65] However, many of the studies included in this review were short term (eg, 2.5 h/wk for 8 weeks), and the participants likely did not achieve a level of expertise needed to improve outcomes that depend on mastery of mental and emotional processes.

Finally, none of our conclusions yielded a high strength-of-evidence grade for a positive or null effect. Thus, further studies in primary care and disease-specific populations are indicated to address uncertainties caused by inconsistencies in the body of evidence, deficiencies in power, and risk of bias.

Some of the trials we reviewed were implemented before modern standards for clinical trials were established. Thus, many did not report key design characteristics to enable an accurate assessment of the risk of bias. Most trials were not registered, did not standardize training using trainers who met specified criteria, did not specify primary and secondary outcomes a priori, did not power the trial based on the primary outcomes, did not use CONSORT recommendations for reporting results, or did not operationalize and measure the practice of meditation by study participants.[83]

We could not draw definitive conclusions about effect modifiers, such as dose and duration of training, because of the limited details provided in the publications of the trials. Despite our focus on RCTs using active controls, we were unable to detect a specific effect of meditation on most outcomes, with the majority of our evidence grades being insufficient or low. These evidence grades were mostly driven by 2 important evaluation criteria: the quality of the trial and inconsistencies in the body of evidence. Trials primarily had the following 4 biases: lack of blinding of outcome assessment, high attrition, lack of allocation concealment, and lack of intention-to-treat analysis. The reasons for inconsistencies in the body of evidence may have included the differences in the particular clinical conditions and the type of control groups the studies used. Another possibility is that the programs had no real effect on many of the outcomes that had inconsistent findings.

Despite the limitations of the literature, the evidence suggests that mindfulness meditation programs could help reduce anxiety, depression, and pain in some clinical populations. Thus, clinicians should be prepared to talk

with their patients about the role that a meditation program could have in addressing psychological stress.

Future research in meditation would benefit by addressing the remaining methodological and conceptual issues. All forms of meditation, including mindfulness and mantra, imply that more time spent meditating will yield larger effects. Most forms, but not all, present meditation as a skill that requires expert instruction and time dedicated to practice. Thus, more training with an expert and practice in daily life should lead to greater competency in the skill or practice, and greater competency or practice would presumably lead to better outcomes. However, when compared with other skills that require training, such as writing, the amount of training or the dose afforded in the trials was quite small, and generally the training was offered during a fairly short period. These 3 components—trainer expertise, amount of practice, and skill—require further investigation. We were unable to examine the extent to which trainer expertise influences clinical outcome because teacher qualifications were not reported in detail in most trials. Trials need to document the amount of training instructors provide and patients receive and the amount of home practice patients complete. These measures will allow future investigators to examine questions about dosing related to outcome.

ARTICLE INFORMATION

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