



Evidence Map of Mindfulness

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PREFACE

Quality Enhancement Research Initiative's (QUERI) Evidence-based Synthesis Program (ESP) was established to provide timely and accurate syntheses of targeted healthcare topics of particular importance to Veterans Affairs (VA) clinicians, managers and policymakers as they work to improve the health and healthcare of Veterans. The ESP disseminates these reports throughout the VA, and some evidence syntheses inform the clinical guidelines of large professional organizations.

QUERI provides funding for four ESP Centers and each Center has an active university affiliation. The ESP Centers generate evidence syntheses on important clinical practice topics, and these reports help:

- develop clinical policies informed by evidence;
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- set the direction for future research to address gaps in clinical knowledge.

In 2009, the ESP Coordinating Center was created to expand the capacity of HSR&D Central Office and the four ESP sites by developing and maintaining program processes. In addition, the Center established a Steering Committee comprised of QUERI field-based investigators, VA Patient Care Services, Office of Quality and Performance, and Veterans Integrated Service Networks (VISN) Clinical Management Officers. The Steering Committee provides program oversight, guides strategic planning, coordinates dissemination activities, and develops collaborations with VA leadership to identify new ESP topics of importance to Veterans and the VA healthcare system.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at Nicole.Floyd@va.gov.

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EVIDENCE MAP OF MINDFULNESS

ABSTRACT

This evidence map provides an overview of “mindfulness” intervention research and describes its volume and focus. It summarizes patient outcomes as reported in systematic reviews of randomized controlled trial evidence. We searched 10 electronic databases to February 2014, screened reviews of reviews, and consulted topic experts. We used a bubble plot as a visual overview of the distribution of evidence and synthesized results narratively in an executive summary. In total, 81 systematic reviews met inclusion criteria and the largest review included 109 mindfulness RCTs. Most research is available for general overviews on health benefits or psychological wellbeing. Reviews on chronic illness, depression, substance use, somatization, distress, and mental illness included 10 or more RCTs. Reviews suggest differential effects of mindfulness-based stress reduction (MBSR), mindfulness-based cognitive therapy (MBCT), and other mindfulness-based interventions, and definitions of “mindfulness-based” varied. The most consistent effect was reported for depression but published meta-analyses also indicated effects compared to passive control of MBSR on overall health, chronic illness, and psychological variables; MBCT for mental illness; and mindfulness interventions for somatization disorders. Limited evidence is also available for mindfulness interventions for pain, anxiety, and psychosis compared to passive control groups. More detail is provided for priority areas post-traumatic stress disorder, stress, depression, and wellness. The evidence map provides a broad overview (not detailed or definitive effectiveness evidence) over the existing research to help interpret the state of the evidence to inform policy and clinical decision making.

INTRODUCTION

Many Veterans desire complementary and alternative medicine or integrative medicine modalities, both for treatment and for the promotion of wellness. Given the VA's desire to promote evidence-based practice, this evidence mapping project aims to help provide guidance to VA leadership about the distribution of evidence on mindfulness approaches.

Mindfulness, often translated from Sanskrit to mean “awareness,” is an ancient Buddhist concept and, although many different forms and definitions exist, a central aspect of the practice is the intention to be more aware and engaged in the present moment. Two components can be differentiated: the self-regulation of attention so that it is maintained on immediate experiences (thereby allowing for increased recognition of mental events in the present moment) and adopting a particular orientation toward experiences in the present moment (an orientation that is characterized by curiosity, openness, and acceptance).¹ Kabat-Zinn is often credited with popularizing mindfulness in the US by creating a mindfulness-based stress reduction (MBSR) program for treating chronic disease which created institutional capacity for using mindfulness-approaches in clinical settings.² Evaluations of a large number and variety of mindfulness interventions have been published, there is only limited agreement on how to define mindfulness interventions, and formats and components vary across interventions.³⁻⁵

KEY QUESTIONS/SCOPE OF PROJECT

The project deliverables are:

- An Evidence Map that provides a visual overview of the distribution of evidence (both what is known and where there is little or no evidence base) for mindfulness; and
- A set of executive summaries that would help stakeholders interpret the state of the evidence to inform policy and clinical decision making.

METHODS

This evidence map provides a visual overview of the existing evidence on mindfulness intervention research. Given the breadth of the research field and diversity of interventions, we used systematic reviews to estimate the research volume and research focus. Systematic reviews follow a standardized and resource-intensive approach that aims to identify all pertinent studies to answer a particular research or policy question. Systematic reviews search multiple sources to identify studies, screen potentially relevant studies in detail against specified inclusion and exclusion criteria, and summarize results across individual studies. Studies may be synthesized in a meta-analysis, a statistical technique to pool data across published studies. Meta-analysis is instrumental in detecting treatment effects across individual, often small and statistically underpowered, studies. To give a very broad indication of the clinical effectiveness, we used the results reported across randomized controlled trials (RCTs). RCTs represent a rigorous research design which can provide strong evidence for the effectiveness of mindfulness interventions.

DATA SOURCES AND SEARCHES

We searched the electronic databases PubMed (using the systematic review clinical query), the Database of Abstracts of Reviews of Effects (DARE, a database dedicated to cataloguing systematic reviews in healthcare), the Cochrane Library of Systematic Reviews (which keeps a record of all ongoing and completed Cochrane reviews), the Campbell Collaboration database (covering reviews on social interventions in crime and justice, education, international development, and social welfare), AMED (the Allied and Complementary Medicine database), CINAHL (which indexes the nursing and allied health literature), and PsycInfo (which is directed at psychological research) to identify English-language systematic reviews published without date restriction focusing on mindfulness interventions to February 2014. In addition, we screened published reviews of reviews and consulted with topic experts.

STUDY SELECTION

To be included in the evidence map, publications had to meet the following criteria:

- **Design:** Systematic reviews focusing on mindfulness interventions and summarizing primary research studies were eligible for inclusion in the evidence map. We defined systematic reviews as reviews that either self-identified as a “systematic review” or reviews that reported the search sources and accounted for identified studies.
- **Participants:** Systematic reviews including adults participating in a mindfulness intervention for any health-related indication were eligible for inclusion. Systematic reviews of adults or unspecified age groups were included; systematic reviews exclusively focusing on children and adolescents were excluded. Systematic reviews were not limited to “patients” and may have targeted staff or non-clinical participants, but the intervention had to be associated with a health-related indication.
- **Intervention:** Systematic reviews of the effects of mindfulness interventions for any clinical indication were eligible for inclusion. Systematic reviews addressing mindfulness and other approaches were eligible if the term “mindfulness” was part of the search strategy. Systematic reviews with search strategies that did not specify any intervention (*eg*, focused on an outcome) and that identified mindfulness studies were also included. Systematic reviews that included mindfulness intervention studies but did not systematically search for these (*eg*, by reviewing “meditation” interventions where only

those mindfulness studies were found that used the descriptive term “meditation”), and broad reviews on complementary and alternative medicine approaches without a systematic strategy to identify mindfulness interventions were excluded. We accepted the authors’ definition of “mindfulness intervention,” which may include a number of interventions, but publications had to refer to “mindfulness” to be considered.

- Outcome: Patient outcomes were eligible for inclusion. Publications of prevalence, use, costs, study design features, intervention features, or mechanistic outcomes (*eg*, neurobiological changes, EEG reaction) and not reporting patient health outcomes were excluded.
- Timing: Any intervention duration and any followup point were eligible for inclusion.
- Setting: The setting was not limited to healthcare-related settings, but interventions had to be associated with a health-related indication to be eligible for inclusion.
- Other limiters: Systematic reviews regardless of the publication date were eligible for inclusion. English-language systematic reviews, regardless of the language of the included studies, were eligible.

Two independent literature reviewers screened the systematic review search results. Citations deemed potentially relevant or unclear by at least one reviewer were obtained as full text. The full text publications were screened against the specified inclusion criteria by 2 independent reviewers; disagreements were resolved through discussion. The literature flow was documented in an electronic database and reasons for exclusion of full text publications were recorded.

DATA ABSTRACTION AND QUALITY ASSESSMENT

We identified systematic reviews meeting the inclusion criteria and removing data duplicates from the database so that each systematic review entered the dataset only once (this entailed consolidating online-only and final publication of articles, Cochrane reviews published in the Cochrane database and in a journal article, multiple updates of Cochrane reviews, and references to systematic reviews differently indexed in general and specialist databases). Where originals and updates of systematic reviews by the same author group were available, only the most recent version was considered.

From each included systematic review, we extracted the specific clinical indication (*eg*, cancer care) and the main patient outcomes summarized across studies. We extracted the number of included mindfulness RCTs; when randomization information was not available, studies included in the review were retrieved to check their status individually. We extracted whether the review reported statistically significant benefits of mindfulness interventions across included RCTs, the size of the treatment effect for the main patient outcomes together with the comparator, and the number of studies the result was based on. In addition, we abstracted whether the review addressed adverse events.

To address the validity of effects, we documented which particular format of mindfulness intervention (*eg*, MBSR) the review had searched for and which formats the pooled result was primarily based on. To address the validity of the systematic review, we extracted whether the review was published by an organization known for their expertise and high-quality systematic reviews (*eg*, Cochrane review). Data were extracted by a content expert and checked by an experienced systematic reviewer in an online database designed for systematic reviews using a pilot-tested, standardized form.

DATA SYNTHESIS AND ANALYSIS

The evidence base was distilled into a visual overview using a bubble plot format and results were synthesized narratively in an executive summary.

Bubble plots

The bubble plot uses 5 dimensions to display information: the x-axis; y-axis; the number, size, and color of the bubble.

Clinical indications (number of bubbles): We used the topics of the individual systematic reviews as reported by the review authors to categorize the reviews. Reviews focused on outcomes or clinical indications. All identified systematic reviews were allocated to a single content area and did not enter the bubble plot multiple times. Where reviews provided data for multiple content areas, results were described in the narrative synthesis.

Literature size (y-axis): The bubble plots provide an overview of the research volume for the clinical indications. For this estimate we used the number of included RCTs per review, selecting the systematic review with the most included mindfulness RCTs for the topic as the research volume estimate. Reviews vary in their inclusion criteria for study designs (*eg*, whether or not they include observational studies). A well-established research design, such as RCTs, that is likely to be included in all reviews, provides a broad estimate of the research volume.

Effect (x-axis): The bubble plot provides a very broad indication of the clinical effectiveness of mindfulness interventions according to patient health outcomes reported in RCTs. For each clinical topic, all available systematic reviews were reviewed. Most emphasis was given to the largest review (which should provide the most complete literature synthesis), Cochrane reviews (given their methodological quality), or reports from agencies specializing in unbiased systematic reviews such as Agency for Healthcare Research and Quality (AHRQ) reports. For effect size estimates, meta-analytic results were sought to provide a summary effect across individual and often small and underpowered studies. In order to provide information on intervention-specific effects, the effect determination focused on the effectiveness of the mindfulness intervention compared to a control group. Preference was given to passive control groups (*ie*, no intervention, base treatment given to both treatment arms, waitlist group, not further specified usual care, or provider-independent interventions). Comparative effectiveness results and equivalence / non-inferiority demonstrations of mindfulness compared to other active interventions were described in the narrative synthesis.

Reviews (bubble size): We used the size of the bubble to document the number of identified systematic reviews on the topic.

Intervention (color): “Mindfulness” covers a wide range of intervention approaches that are distinctly different, such as MBSR and mindfulness based cognitive therapy (MBCT). In the figure, red indicates the result is primarily based on interventions where mindfulness was only a component of the overall intervention. Pink indicates the result is based on MBSR studies, purple indicates MBCT studies, and yellow indicates the result is based on another selected mindfulness intervention. Blue indicates the result is based on MBSR and MBCT studies, while green indicates the result is based on many different mindfulness-based approaches.

Executive Summary

While the bubble plot can only display very limited information, the narrative synthesis provides more information on the size of the treatment effect, the individual included clinical indications, the assessed outcomes, characteristics of the identified reviews, the comparator against which the treatment effect was estimated, and other pertinent information on the included studies.

VA PRIORITY AREAS

The primary clients and technical expert panel (TEP) determined the outcomes and clinical indications post-traumatic stress disorder (PTSD), stress, depression, and wellness to be VA priority areas. We provided more detail on existing research in these *a priori* identified priority areas, including information on the intervention components, course format, and adverse events of the intervention, where reported.

The published literature continues to grow and new RCTs may challenge existing summaries of the literature. Hence, we have identified recently published RCTs not yet included in published systematic reviews in a scoping review for the identified priority areas. Studies had to be explicitly described as a mindfulness intervention and had to refer to the outcome of interest in the title or the abstract of the citation to be considered. We used the Randomized Controlled Trial filter in PubMed to identify new RCTs. No language restriction was applied.

FUTURE RESEARCH

We identified evidence gaps by documenting topic areas for which systematic reviews exist, but despite a systematic search, the reviews did not identify relevant RCTs (*ie*, high evidence level research studies). In addition, we documented clinical indications for which there is conflicting evidence across identified reviews or where reviews concluded that the existing evidence base is insufficient to come to firm conclusions.

The international review registry PROSPERO and the Cochrane library of Systematic Reviews were screened for ongoing reviews. We documented these registered reviews that will become available to summarize a topic area in the near future.

TECHNICAL EXPERT PANEL

The TEP included Dr. Stephen Ezeji-Okoye, VHA Central Office Field Advisory Committee on Complementary and Alternative Medicine; Laura Krejci, Associate Director Office of Patient Centered Care and Cultural Transformation; Jill Bormann, Associate Nurse Executive/Research and Clinical Nurse Specialist in Adult Psychiatric-Mental Health Nursing with the Veterans Affairs San Diego Healthcare System, San Diego, California; David Kearney, University of Missouri Kansas City Medical School VA Puget Sound Health Care System - Seattle Division; and John (Greg) Serpa, PhD, California School of Professional Psychology VA Greater Los Angeles Healthcare System.

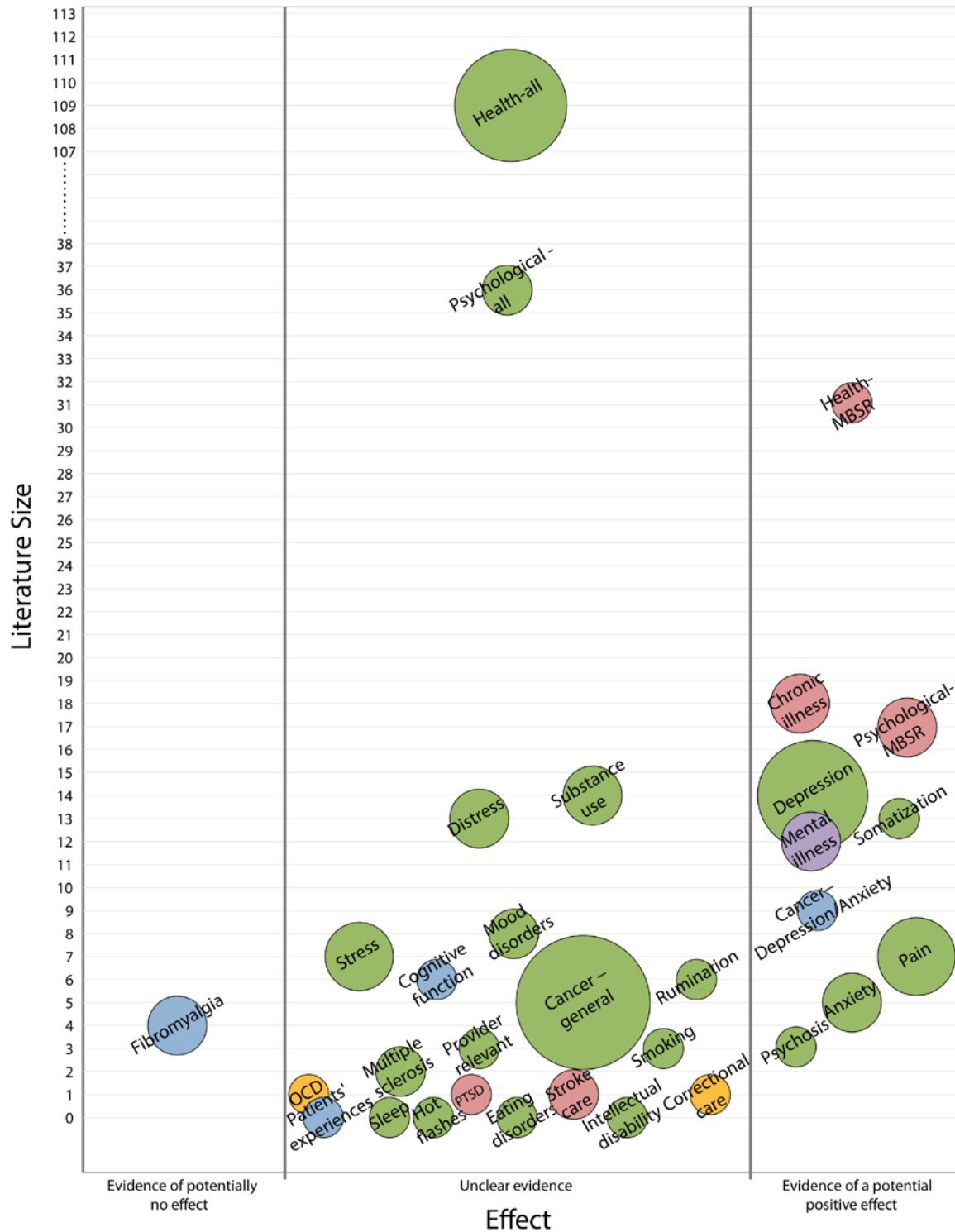
PEER REVIEW

A draft version of the deliverables was reviewed by technical experts, as well as clinical leadership. Reviewer comments were addressed in the final product and are documented in the appendix.

RESULTS

The systematic review search identified 332 citations. This included 81 unique systematic reviews meeting the inclusion criteria.⁶⁻⁸⁶ The results are presented in a bubble plot and a text summary.

Evidence Map of Mindfulness



The bubble plot broadly summarizes mindfulness intervention systematic reviews published to February 2014 and shows the clinical conditions addressed in reviews (bubbles), the estimated size of the literature (y-axis), the effectiveness trend according to reviews (x-axis), and the number of reviews (bubble size) per clinical condition. Colors: green (various mindfulness interventions), pink (MBSR), purple (MBCT), blue (MBSR+MBCT), yellow (unique mindfulness-based intervention)

EXECUTIVE SUMMARY

The evidence map used the clinical topics addressed in existing systematic reviews. Reviews varied widely in scope. While some reviews evaluated specific interventions, such as MBSR following the original 8-week structured program, others included a large range of mindfulness-based interventions such as MBCT, mindfulness meditation, or complex interventions where mindfulness was one of many components. In addition, review authors varied in their definition of “mindfulness intervention.” The evidence map displays the topics of systematic reviews; primary research studies may have contributed to multiple systematic reviews. All depicted dimensions are estimates and can only provide a broad overview of the evidence base.

Areas with the Largest Research Base

We identified 9 systematic reviews that addressed health benefits of mindfulness interventions (**health-all**) and the largest review included 109 RCTs. The largest review, a comprehensive meta-analysis of 209 mindfulness-based therapy studies, reported positive effects in pre-post comparisons and across controlled studies but not effects seen in RCTs specifically (*ie*, the most robust research design).⁴⁷ The review included mindfulness meditation-based interventions and excluded studies that examined mindfulness as part of another treatment, such as cognitive behavior protocol, Acceptance and Commitment Therapy, Dialectical Behavior Therapy, and Loving-Kindness Meditation. An AHRQ report on meditation practices included 50 RCTs evaluating mindfulness-based approaches, including mindfulness meditation techniques not further described, Zen Buddhist meditation, MBCT, and Vipassana meditation.⁸⁷ Individual study results varied, the quality of included studies was rated as poor, and no pooled result across studies was reported. The report stated further that in cardiovascular diseases, indirect comparisons showed that there were no significant differences in measures of anxiety between yoga and MBSR. A 2004 meta-analysis included 7 RCTs and reported a positive effect for mental health (Cohen’s *d* 0.54; 95% confidence interval (CI) 0.35, 0.74; $p < 0.001$; 7 RCTs) but physical health estimates were not pooled separately from other study designs and the statistical significance of the individual study results was not reported.⁴⁴ Six additional reviews included between 26 and zero mindfulness-based intervention RCTs, with varying individual study results, and did not report a pooled treatment estimate for RCTs.

A Campbell Collaboration systematic review addressed health benefits of MBSR (**health-MBSR**) and included 31 RCTs.⁸ The review only included training programs based on the protocol elements specified by Kabat-Zinn (body-scan exercises, mental exercises focusing attention on breathing, physical exercises focusing on the awareness of bodily sensations, and the practice of being fully aware during everyday activities). The review reported positive effects on the combined outcome mental health (SMD 0.53; 95% CI -0.43, 0.64; 26 RCTs), measures of personal development (0.50; 95% CI 0.35, 0.66; 12 RCTs), quality of life (0.57; 95% CI 0.17, 0.96; 4 RCTs), mindfulness (0.70; 95% CI 0.05, 1.34; 7 RCTs), and somatic health (0.31; 95% CI 0.10, 0.52; 10 RCTs) compared to waitlist and usual care control groups. The review concluded that MBSR has a moderate and consistent effect on a number of measures of mental health for a wide range of target groups and appears to improve measures of personal development such as empathy and coping, enhances mindfulness and quality of life, and improves some aspects of somatic health. The review also noted that there is a lack of data on social function, work ability, and long-term effects.

We identified 2 systematic reviews that addressed psychological wellbeing (**psychological-all**) and the largest review included 36 RCTs. The largest review was based on an AHRQ report on meditation programs for psychological stress and wellbeing, which classified MBSR, MBCT, Vipassana, Zen, and other mindfulness meditation as mindfulness-based. The review reported positive effects for anxiety (Cohen's d 0.38; 95% CI 0.12, 0.64; at 8 weeks; 0.22; 95% CI 0.02, 0.43; at 3-6 months; 8 RCTs total), depression (0.30; 95% CI -0.00, 0.59; at 8 weeks; 0.23; 95% CI 0.05, 0.42; at 3-6 months; 10 RCTs total); and pain (0.33; 95% CI, 0.03 to 0.62; 4 RCTs) compared to control interventions matched in time and attention.⁴³ The AHRQ report also showed a positive effect on negative affect (general anxiety, stress/distress, and depression outcomes combined; standardized mean difference (SMD) -0.34 (95% CI -0.53, -0.14; 10 RCTs).³ Data on stress/distress varied by comparator, the pooled results for the outcomes mental health related quality of life, positive affect, and sleep were negative, and there was insufficient evidence for positive mood, attention, substance use, eating habits, and weight. There was no evidence that meditation programs were better than any active treatment (*ie*, drugs, exercise, and other behavioral therapies). The review concluded that meditation programs can result in small to moderate reductions of multiple negative dimensions of psychological stress. An additional review evaluated the effects of mindfulness meditation in non-clinical samples.⁹ The pooled effect across psychological variables was statistically significant for MBSR (r 0.29; 12 RCTs) and for mindfulness meditation (r 0.22; 5 RCTs) compared to inactive control groups. The review's conclusions were centered on differences in effects between MBSR and "pure" mindfulness meditation interventions seen across the multitude of included studies; the authors suspected that effect sizes in MBSR might be partly inflated by effects not attributable to the mindfulness meditation component.

Two systematic reviews addressed MBSR and psychological variables (**psychological-MBSR**) and the largest included 17 RCTs. The largest review reported across all psychological outcomes an effect size of Cohen's d 0.396 (95% CI 0.19, 0.61; $p < 0.001$; 17 RCTs) compared, primarily, to waitlist.²⁰ Stratified by comparator, active treatments (progressive muscle relaxation, cognitive behavioral group therapy, or massage) were not statistically significantly better than MBSR (-0.249; 95% CI -0.731, 0.234; 3 RCTs). MBSR was not statistically significantly better than minimal contact (0.258; 95% CI -0.192, 0.709; 2 RCTs). The effect size estimate of MBSR compared to waitlist was 0.542 (95% CI 0.334, 0.749; 12 RCTs). The review considered 48 different psychological variables and reported positive pooled effects for stress (0.792; 95% CI 0.371, 1.123; 4 RCTs), distress (0.547; 95% CI 0.193, 0.901; 6 RCTs), depression (0.512; 95% CI 0.164, 0.861; 5 RCTs), and anxiety (0.435; 95% CI 0.141, 0.729; 3 RCTs). The review concluded that MBSR compared to waitlist is effective across a broad range of psychological outcomes but comparisons with other forms of treatment are less favorable. A second review addressed anxiety and mood symptoms across a range of populations but did not report a summary effect estimate for the 10 included RCTs and individual study results varied. The more general systematic review by the Campbell Collaboration on MBSR reported positive results for individual as well as a combined mental health outcome (SMD 0.53; 95% CI 0.46, 0.61; 26 RCTs), measures of personal development (0.50; 95% CI 0.35, 0.66; 12 RCTs), quality of life (0.57; 95% CI 0.17, 0.96; 4 RCTs), and mindfulness (0.70; 95% CI 0.05, 1.34; 7 RCTs).⁸ A review in cancer patients, described in more detail below, reported a positive effect of MBSR on mental health (Cohen's d 0.37; 95% CI 0.10, 0.64; $p < 0.003$, 4 RCTs).⁵⁵

Three systematic reviews addressed mindfulness interventions in **chronic illness**; the largest included 18 RCTs. The largest (MBSR) review did not pool across studies and the statistical

significance of individual studies was not reported.⁶¹ A systematic review in adults with a chronic medical disease (defined as conditions that involve some disability caused by irreversible pathological change or illnesses that cause enduring disability) reported SMD 0.32 (95% CI 0.13, 0.50; 3 RCTs) for psychological distress, 0.26 (95% CI 0.18, 0.34; 6 RCTs) for depression, and 0.47 (95% CI 0.11, 0.83; 4 RCTs) for anxiety comparing MBSR to waitlist and support groups.²⁵ The review concluded that MBSR has small effects on depression, anxiety, and psychological distress in people with chronic somatic diseases and speculated that integrating MBSR in behavioral therapy may enhance the efficacy of mindfulness based interventions. A third MBSR review found mixed results in individual studies and did not report an estimate across all studies.

We identified 8 systematic reviews focusing specifically on **depression** and the largest included 14 RCTs. The largest review addressed depressive symptoms in people with mental disorders treated with MBCT (12 RCTs), MBSR (1 RCT) or dialectical behavioral therapy with mindfulness training (1 RCT) and found a positive pooled effect (SMD 0.39; 95% CI 0.23, 0.55; $p < 0.001$; 14 RCTs) either alone or in combination with usual care or medication, primarily compared to treatment as usual.⁴⁹ The review concluded that mindfulness-based interventions are efficacious for alleviating depressive symptoms in adults with mental disorders and suggested the interventions could be used in conjunction with other treatments in clinical settings. A review on MBCT based on the manual by Segal et al tailored for depression in recurrent major depressive disorder found a significantly reduced risk of relapse/recurrence with a risk ratio (RR) of 0.66 (95% CI 0.53, 0.82; 5 RCTs) compared to treatment as usual or placebo controls.⁶⁴ MBCT did not show a statistically significant difference compared to maintenance antidepressant medication across 2 RCTs. The authors concluded that MBCT is an effective intervention for relapse prevention in patients with recurrent major depressive disorder in remission, at least for patients with 3 or more previous episodes. A review on cognitive behavioral group therapy included MBCT RCTs; individual study results varied and no pooled was reported. A systematic review included 2 MBCT RCTs (both statistically significantly positive compared to treatment as usual only / no add-on MBCT therapy) but the authors concluded that because of the nature of the control groups the findings cannot be attributed to MBCT-specific effects.⁷ The Canadian Network for Mood and Anxiety Treatments Clinical Guidelines for the management of major depressive disorder in adults concluded that MBCT does not yet have significant evidence as acute treatment but considers it a second-line treatment for the maintenance phase of major depressive disorder in adults.⁶³ Three additional reviews on depression did not report between group effects or did not find any relevant RCT for the specific review question. The Campbell Collaboration review reported a pooled effect of MBSR of SMD 0.54 (95% CI 0.35, 0.74; 9 RCTs) compared to waitlist or treatment as usual for the outcome depression.⁸ As shown, the AHRQ report on mindfulness meditation programs reported positive effects for depression (SMD 0.30; 95% CI 0.00, 0.59; at 8 weeks; 0.23; 95% CI 0.05, 0.42 at 3–6 months; 10 RCTs total).⁴³ An MBSR-specific review reported a positive effect on depression (SMD 0.512; 95% CI 0.164, 0.861; 5 RCTs).²⁰ Furthermore, reviews on cancer patients and survivors,⁶⁵ chronic illness,²⁵ somatization disorders,⁵¹ anxiety,⁷⁷ and two reviews on mental illness^{33,41} also reported statistically significant pooled effects for the outcome depression.

Three systematic reviews addressed the role of mindfulness-based interventions in **substance use** treatment and the largest included 14 RCTs. Results of studies included in the largest review varied and no treatment estimate across all RCTs was reported.³⁴ Two additional reviews also did not provide summary treatment estimates and results varied across studies and across outcomes. Three systematic reviews addressed psychological **distress** and the largest included 13

RCTs. The largest review evaluated bio-psychological training programs for the self-management of emotional stress for military personnel; the results of MBSR varied across studies or were not described in detail and the summary treatment estimate is not known.³⁷ Two further reviews did not report pooled effects compared to a control group for RCTs and individual study results varied. A review on psychological outcomes reported positive results for the outcome distress (0.547; 95% CI 0.193, 0.901) but included only 6 MBSR RCTs.²⁰ As reported, the chronic illness review reported positive effects on psychological distress (SMD 0.32; 95% CI 0.13, 0.50) but included only 3 relevant RCTs.²⁵ The Campbell Collaboration and the AHRQ report on mindfulness meditation pooled the outcomes stress and distress and did not provide separate analyses for psychological distress^{8,43}

One systematic review addressed **somatization** disorders and included 13 RCTs in patients with a diagnosis of fibromyalgia, chronic fatigue syndrome, irritable bowel syndrome, and nonspecified somatization disorder.⁵¹ The review reported positive effects for mindfulness-based therapies for the primary outcome symptom severity (SMD -0.40; 95% CI -0.54, -0.26; 10 RCTs) compared to waitlist or support group. Positive effects were also reported for the outcomes pain (-0.21; 95% CI -0.38, -0.03; 7 RCTs), quality of life (0.39; 95% CI 0.19, 0.59; 5 RCTs), and depression (-0.23; 95% CI -0.40, -0.07; 8 RCTs), but not for anxiety. Stratified by mindfulness intervention, only MBSR and MBCT pooled results were statistically significant, but not eclectic/unspecified mindfulness-based therapy interventions. The authors concluded that preliminary evidence suggests that mindfulness-based therapies may be effective in treating at least some aspects of somatization disorders but there is a need for further research. We identified 3 systematic reviews on **mental illness** and the largest review included 12 RCTs. The largest review investigated MBCT in patients suffering from psychiatric disorders and reported a favorable effect of MBCT plus treatment as usual for the primary review outcome relapse prevention of major depression (odds ratio (OR) 0.36; 95% CI 0.19, 0.48, $p < 0.0003$; 4 RCTs) compared to treatment as usual alone.³³ Results for anxiety varied and were not pooled across studies. A further review also found positive pooled results for the relapse rate of patients with 3 or more previous episodes of depression at one year followup (RR 0.61; 95% CI 0.48, 0.79; 5 RCTs), depression measured with HAM-D (weighted mean difference WMD -2.46; 95% CI -4.36, -0.56; 3 RCTs at 1-year followup; WMD -10.39; 95% CI -15.66, -5.12; 2 RCTs post-intervention), depression measures with Beck depression inventory (WMD -10.39; 95% CI -15.66, -5.12; 2 RCTs at 1-year followup; WMD -7.33; 95% CI -12.12, -2.54; 6 RCTs post-intervention), and anxiety (different scales) at post-intervention (SMD -2.42; 95% CI -0.74, -0.09; 2 RCTs) comparing MBCT plus treatment as usual to treatment as usual alone, or MBCT plus support to discontinue or reduce antidepressants to maintenance antidepressants.⁴¹ The review concluded that MBCT is an effective intervention for patients with 3 or more previous episodes of major depression. A review on mindfulness-based treatment in people with severe mental illness did not find any RCTs.

Areas with a Smaller Research Base

Fewer research studies (*ie*, fewer than 10 RCTs identified in existing systematic reviews) are available for a large number of clinical indications and outcomes.

We identified one review specific to the effect of mindfulness-based therapy on anxiety and depression in adult cancer patients (**cancer-depression/anxiety**) and survivors and it included 9 RCTs. The review reported positive effects for anxiety (SMD 0.37; 95% CI 0.24, 0.50; $p < 0.001$; 9 RCTs), depression (0.44; 95% CI 0.24, 0.64; $p < 0.001$; 9 RCTs), and mindfulness (0.39; 95%

CI 0.20, 0.58; $p < 0.001$; 5 RCTs) of MBSR conducted according to Kabat-Zinn or MBCT conducted according to Segal compared to waitlist or treatment as usual.⁶⁵ The review concluded that there appears to be some positive evidence from relatively high-quality RCTs to support the use of mindfulness-based therapy for cancer patients and survivors with symptoms of anxiety and depression. In contrast, 11 systematic reviews addressed the role of mindfulness interventions in cancer care in general (**cancer-general**) and the largest review included 5 RCTs. The largest review did not provide separate analyses for RCTs or a description of individual studies.⁶⁰ One review in cancer patients reported a positive effect of MBSR for mental health outcomes (Cohen's d 0.37; 95% CI 0.10, 0.64; $p < 0.003$, 4 RCTs) across a range of outcomes measures (distress, quality of life, mental health, sleep measures, sense of control, anxiety, depression, sense of coherence, mood) but not for physical health (measured through SF-36, symptoms of stress inventory physical health components).⁵⁵ One review on complementary and alternative medicine on quality of life of cancer survivors included 3 mindfulness intervention RCTs and reported positive results (SMD 0.32; 95% CI 0.06, 0.57; 2 RCTs) for breast cancer survivors at 6 months but the exact mindfulness intervention and comparator were not specified.⁷³ The remaining 8 reviews did not provide summary effect estimates for RCTs, and did not report individual study results, or reported conflicting results across studies and outcomes.

Two systematic reviews addressed patients with **mood disorders** and the largest one included 8 RCTs. The largest review concentrated on pre-post changes, not effects relative to a control group.⁴⁵ The second review did not report a summary estimate across studies, and individual study results varied or comparative effects to the control group were not stated. We identified 4 systematic review addressing **stress** and the largest one included 7 RCTs. The largest review, targeting stress management in healthy people, did not pool studies in a formal meta-analysis and the statistical significance of the individual study results was not reported.³⁰ The other reviews specific to stress pooled RCT results with other study designs, or identified only one or no RCTs relevant for the particular review question. A review on psychological outcomes reported positive effects on stress (0.792; 0.371, 1.213; 4 RCTs) but the review was limited to MBSR interventions.²⁰ The Campbell Collaboration review and the AHRQ report on meditation programs combined the outcome stress and distress.^{8,43}

Five systematic reviews addressing **pain** were identified and the largest review included 7 RCTs. The largest review pooled across study designs and all included acceptance-based interventions.⁷⁶ Other reviews that addressed pain specifically did not provide summary estimates and results of individual study reviews varied, or only one RCT was identified for the particular review question, which was not analyzed for effects compared to the control group. The AHRQ report on mindfulness meditation reported a positive pooled effect on pain (Cohen's d 0.33; 95% CI 0.03, 0.62; 4 RCTs) compared to non-specified active control groups but not across 4 control groups with a specific active control group such as massage or yoga. The report concluded that there is moderate evidence of improved pain associated with mindfulness interventions.⁴³ The review on somatization disorders reported positive effects for the outcome pain (WMD -0.21; 95% CI -0.38, -0.03; 7 RCTs) compared to waitlist or support group⁵¹ while 2 reviews on fibromyalgia found no effects on pain across studies.^{24,52}

One systematic review addressed treatments used to reduce **ruminatio**n and/or worry and included 6 mindfulness RCTs. Results of individual studies evaluating MBSR, MBCT, mindfulness meditation, and mindful breathing RCTs varied and no overall treatment estimate

was reported.⁶⁷ A review on mindfulness training to improve **cognitive functioning** included 6 RCTs. Results of individual studies varied across studies, outcomes, and interventions.²⁹

We identified 3 systematic reviews that specifically addressed **anxiety** and the largest one included 5 RCTs. The largest review reported a positive effect across RCTs for anxiety symptoms at post-treatment (SMD -0.83, 95% CI -1.62, -0.04) and for depression symptoms (-0.72; 95% CI -1.20, -0.24) in patients with a diagnosis of anxiety disorders receiving MBSR, MBCT, or Acceptance and Commitment Therapy with a distinct mindfulness component; control group details were not reported.⁷⁷ The review concluded that mindfulness- and acceptance-based interventions are associated with robust and substantial reductions in symptoms of anxiety and comorbid depressive symptoms and more research is needed to determine the efficacy relative to current treatments of choice. A Cochrane review on meditation therapy for anxiety disorders included one mindfulness RCTs comparing the effects of a relaxation/mindfulness meditation intervention and Kundalini Yoga; no statistically significant differences in obsessive compulsive symptoms were found between groups.⁵⁰ A review on anxiety in bipolar disorders included one MBCT RCT (statistically significant positive effects on anxiety scores reported). The Campbell Collaboration review reported a treatment effect of SMD 0.53 (95% CI 0.43, 0.63; 10 RCTs) for anxiety comparing MBSR and waitlist or treatment as usual.⁸ The AHRQ report on meditation programs reported a positive pooled effect on anxiety (SMD 0.38; 95% CI 0.12, 0.64 at 8 weeks; 0.22; 95% CI 0.02, 0.43 at 3-6 months) comparing mindfulness meditation programs to a control group matched in time and attention to the intervention group across a number of anxiety outcome measures. A MBSR review reported a positive pooled effect on anxiety (0.435; 95% CI 0.141, 0.729; 3 RCTs).²⁰ As shown above, pooled positive effects were also reported in a review on chronic medical diseases comparing MBSR to waitlist and support groups²⁵; a review on mental health comparing MBCT plus treatment as usual to treatment as usual alone or MBCT plus support to discontinue or reduce antidepressants to maintenance antidepressants⁴¹; and a review on cancer patients; but a review on somatization disorders did not find effects on anxiety associated with mindfulness-based interventions compared to waitlist or support group across 5 RCTs.⁵¹

Three systematic reviews evaluated treatments for **fibromyalgia** and the largest one included 4 RCTs. The largest review did not find statistically significant differences between MBSR and waitlist or usual care, or active control interventions, for quality of life or pain (number of studies per comparison not reported).⁵² A review on cognitive behavioral therapy approaches included 3 mindfulness RCTs and reported no statistically significant difference across 2 RCTs for the outcome pain at post-treatment compared to waitlist or an attention control group.²⁴ A further review included 2 mindfulness intervention RCTs but only one assessed pain or functional status.

One systematic review addressed **psychosis** and included 3 mindfulness RCTs. The review reported a positive effect of MBCT, mindfulness and metacognitive insight therapy, or mindfulness-based psychoeducation in patients with schizophrenia, schizophrenia spectrum, or outpatients with distressing voices (SMD 0.55; 95% CI 0.36, 0.75; 3 RCTs) compared to waitlist or usual care across all outcome measures (CORE, PSYRAT, BAVQ-r, SMQ, SMVQ, CGI-SCH, AAQ-II, SMQ, ITAQ, BPRS, SSQ-6, SLOF, rehospitalization).⁴⁸ The authors concluded that mindfulness interventions are moderately effective in treating negative symptoms and can be useful adjunct to pharmacotherapy but more research is needed to identify the most effective elements of mindfulness interventions.

A review on mind-body practices on **smoking** cessation included 3 mindfulness RCTs. Individual studies evaluated mindfulness training and cue-exposure plus mindfulness; individual study results varied and no overall estimate specific to mindfulness-based interventions was reported.²⁶ One review addressed the effects of mindfulness training on health care provider outcomes (**provider-relevant**) and included 3 RCTs. The statistical significance of training effects and/or the effects relative to a control group were not reported and no overall effect estimate was provided.¹⁰ We identified 2 systematic reviews on mindfulness-based interventions in **multiple sclerosis** and the larger one included 2 RCTs. The largest review did not find data for the primary outcome perceived stress and results for other outcomes were not reported in comparison to control group results.⁷⁴ The other review did not include additional RCTs. Two systematic reviews evaluated mindfulness interventions in **stroke care** and both included (the same) one RCT. Both reviews did not report the effects of the mindfulness intervention relative to the effects of the control group.^{53,54} One systematic review evaluated mind-body practices for posttraumatic stress disorder (**PTSD**) and included one mindfulness intervention RCT. The RCT in cancer patients that assessed posttraumatic stress symptoms found no significant differences between intervention and control group in assessed outcomes, apart from in the outcome mindfulness, and continued meditation was associated with a reduction in avoidance symptoms.¹¹ One review evaluated mindfulness and other Buddhist-derived interventions in correctional settings (**correctional care**) and included one RCT. The review reported a significant increase in negative outcome expectancies associated with a mindfulness-based relapse prevention program compared to a substance abuse educational program, but the effects on the other outcomes (depression and refusal self-efficacy) were not reported in comparison to a control group.¹⁹ One systematic review addressed complementary medicine, self-help, and lifestyle interventions for obsessive compulsive disorder (**OCD**) and the OCD spectrum and included one mindfulness intervention RCT. The review reported that the small RCT found a significant reduction in OCD symptom complaints with a large effect size in favor of a mindfulness training intervention compared to waitlist but stated that effects of other outcome measures (“letting go,” rumination) were not clearly reported.⁷⁰

We identified systematic reviews on **patients’ experiences, eating disorders, intellectual disability, sleep disturbance, and hot flashes** that systematically searched for mindfulness intervention but did not find any relevant RCTs.

Most promising areas

The most consistent effect was shown for the outcome depression compared to treatment as usual or waitlist. All reviews that reported a pooled analysis showed a positive effect.^{7,8,25,33,41,43,49,51,63-65,77}

Positive effects were also shown for an overall effect on health and on psychological variables, but the analysis was limited to MBSR compared to passive control groups.⁸ Positive effects compared to waitlist and support groups were shown in the area of chronic illness but reviews only included MBSR studies and only considered the outcomes anxiety, depression, and psychological distress.²⁵ Positive results were also found for somatization disorders analyzing symptom severity compared to waitlist or support group; however, stratified by intervention, only MBSR and MBCT pooled results were statistically significant, not eclectic/unspecific mindfulness-based therapies.⁵¹ Mental illness showed positive effects compared to treatment as usual alone, but reviews analyzed only MBCT studies and most data were available for the outcome depression.³³

Positive effects were shown for MBSR or MBCT compared to waitlist or treatment as usual for the outcomes depression and anxiety of cancer patients or survivors but fewer than 10 RCTs were available.⁶⁵ The comprehensive AHRQ report on meditation practices concluded that there is moderate evidence of improved pain associated with mindfulness interventions; not all reviews reported statistically significant positive effects for the outcome pain, and reviews identified fewer than 10 relevant RCTs. Although several reviews reported effects on anxiety compared to passive control, only a limited number of original studies (5 RCTs) was available and estimates of the size of the effect varied widely across reviews.^{8,25,41,43,50,51,77} Another area with limited research (3 RCTs) was psychosis treatment, which identified a review that reported overall positive effects across a variety of mindfulness-based interventions compared to waitlist or usual care, but the authors' conclusions were limited to negative, not positive, psychosis symptoms.⁴⁸

VA priority areas

PTSD

As shown, we identified one systematic review that systematically searched for and evaluated effects of mindfulness-based interventions on PTSD.¹¹ The review included 16 randomized and non-randomized studies evaluating a variety of mind-body practices, including studies in Veterans, and concluded that mind-body practices are increasingly used in the treatment of PTSD and are associated with positive impacts on stress-induced illnesses such as depression and PTSD in most studies. The review included one explicit mindfulness intervention RCT⁸⁸ that found no differences between intervention and control group in symptoms of stress in 71 cancer patients but an association with continued meditation and a reduction in avoidance symptoms. The PTSD RCT reported that no adverse events or side effects were reported. The review discussed the safety of the interventions but did not report on adverse events in individual studies.

An additional literature search identified 4 PTSD-relevant RCTs indexed in PubMed. One RCT assessed acceptability, not patient health outcomes or adverse events; it concluded that implementing a manualized protocol is feasible in female Veterans and interviews showed positive responses.⁸⁹ A pilot RCT assessed PTSD symptoms in Veterans with self-reported sleep disturbance and found a significant reduction associated with a mind-body bridging program for sleep management that was designed to increase mindfulness; adverse events were not assessed.⁹⁰ A 16-session mindfulness-based stretching and deep breathing exercise intervention for nurses investigated effects on subclinical features of PTSD and found superior outcomes compared to no intervention; the presence or absence of adverse events were not reported.⁹¹ One RCT assessed the effect of MBSR plus treatment as usual compared to treatment as usual alone in 47 Veterans with PTSD.⁹² MBSR classes followed the original 8-week format and were taught by experienced instructors in groups of 20 to 30 male and female participants. Intention to treat analyses found improved but not statistically significant different scores comparing MBSR and treatment as usual alone. A post-hoc power analysis indicated more than 4 times as many participants are needed to demonstrate statistically significant effects. No participants withdrew due to worsening of PTSD symptoms or other difficulties with the intervention.

Stress

The mindfulness literature includes reviews on stress and on distress, and some reviews combined the outcomes in a stress/distress analysis. The majority of reviews did not define these outcome categories and a large variety of individual measures was included in the analyses,

including Global Severity Index of the Symptom Checklist 90 Revised (SCL-90), Psychological Distress subscale of the SCL-90, Brief Symptom Inventory, Perceived Stress Scale, State-Trait Anxiety Inventory, Anxiety scale of the Profile of Mood States, and Differential Stress Inventory. As outlined, results on distress were not described in detail, varied across studies, or were clinical condition-specific, summarizing only a fraction of all relevant studies. Several systematic reviews have addressed the outcome stress in healthy people; however, study effects were not pooled in a formal meta-analysis, or identified only one study relevant to the particular review question.

The AHRQ report on meditation programs for psychological stress and wellbeing reported on the combined outcome stress/distress. The report differentiated unspecific active control and specific control interventions (*eg*, yoga). The report stated that 8 RCTs with unspecific active control groups were identified; however, only 6 could be pooled in a meta-analysis, excluding the RCT with the lowest risk of bias while one large RCT with a high risk of bias dominated the analysis. Hence no pooled result was reported. Compared to specific control interventions, mindfulness-based approaches were not statistically significantly different from control. The authors reported low strength of evidence of improved stress/distress in mindfulness meditation programs.^{3,43} The Campbell Collaboration combined the outcome stress and distress and the analysis included 20 RCTs, all evaluating MBSR. The review reported a positive effect for the combined outcome (SMD 0.56; 95% CI 0.44, 0.67) comparing MBSR and waitlist or treatment as usual.⁸ No information was given on which specific measures were combined in this analysis. A MBSR review based on 17 studies in a variety of clinical and non-clinical samples reported positive results for the outcome distress measured with the General Severity Index of the SCL-90 (SMD 0.547; 95% CI 0.193, 0.901; 6 RCTs) and stress measured as Symptoms of Stress Inventory or Perceived Stress Scale scores, or laboratory tests of stress hormones and other biological markers of stress (0.792; 95% CI 0.371, 1.1213; 4 RCTs).²⁰ The review specified that the average length of MBSR class sessions was 120 minutes (standard deviation (SD) 38.24), the average number of sessions was 7 (SD 1.22), 88% of studies referred to meditation or breath awareness as part of the intervention, 88% included yoga or body movement, 82% homework, 71% body scan meditation, 65% specified a didactic training element, and 35% included a day-long retreat, but these numbers refer to all included studies, and are not limited to those reporting on stress or distress. A review in adults with a chronic medical disease reported SMD 0.32 (95% CI 0.13, 0.50; 3 RCTs) for psychological distress for MBSR but the comparator was not specified.²⁵

Only one review out of 3 on emotional or psychological distress addressed adverse events, and the review did not report individual events reported in included studies but stated that there are very few to no adverse effects associated with the evaluated self-management skill programs when properly learned and practiced.³⁷ Only one out of 4 reviews on the outcome stress addressed adverse events and that one only reported it for one included study (no reported adverse effects of the intervention).¹⁸ Safety was a key question in the AHRQ report on meditation practices that addressed the outcome category stress/distress. The report stated that few RCTs reported on potential harms of meditation programs. Of 9 RCTs that reported on harms, none reported any harms of the intervention. One trial specified that the researchers looked for toxicities of meditation to hematologic, renal, and liver markers and found none. The remaining 8 trials did not specify the type of adverse event they were looking for, 7 reported that they found no significant adverse events, while one did not comment on the encountered adverse events. The remaining 32 RCTs did not report whether they monitored for adverse events.³ The

Campbell Collaboration review that addressed the area stress/distress stated that no explicit reporting on possible adverse effects was provided.⁸

Judging from a scoping search, more than 35 mindfulness-based intervention RCTs have been published after the completion of the literature search of the most comprehensive review, the AHRQ report on meditation interventions (updated for a journal publication in November 2012). These new RCTs report on the outcome stress or psychological distress, or describe an intervention that is explicitly applied to reduce stress.⁹¹⁻¹²⁷ Individual study results varied and it is unclear which studies would meet inclusion criteria of the report, and whether the conclusion of low strength of evidence for improved stress/distress continues to be correct in a reanalysis.

Depression

Judging from existing systematic reviews, the most consistent effect of mindfulness-based interventions, including MBSR designed for stress reduction, was not found for the outcome “stress” but for the outcome “depression.” The outcome has received substantial research attention and all reviews that pooled across individual studies found positive effects of mindfulness-based interventions compared to passive control groups. This effect was not limited to MBSR or MBCT: positive effects were shown across all included interventions. However, a large number of existing studies had used these 2 more formalized programs.

Estimates of the size of the treatment effect varied across reviews, ranging from Cohen’s *d* 0.23,⁴³ Hedges’ *g* 0.23,⁵¹ Hedges’ *g* 0.26,⁶¹ Cohen’s *d* 0.30,⁴³ Cohen’s *d* 0.39,⁴⁹ Hedges’ *g* 0.44 in cancer patients,⁶⁵ Cohen’s *d* 0.51,²⁰ Hedges’ *g* 0.54,⁸ to Hedges’ *g* 0.72,⁷⁷ indicating a small to medium effect. WMD estimates for common depression measures ranged from -2.46 (HAM-D, 1 year post-intervention),⁴¹ -4.31 (HAM-D post-intervention),⁴¹ -7.33 (BDI post-intervention),⁴¹ and -10.39⁴¹ (BDI, 1 year post-intervention). RR 0.66⁶⁴ and 0.61⁴¹ were estimated for the dichotomous outcome relapse/recurrence and one study reported OR 0.36 favoring the mindfulness-based intervention.³³ Included reviews evaluated effects on the outcome depression in a variety of populations ranging from patients with recurrent major depressive disorder^{39,64} or a history of depression⁷ to a range of clinical indications not limited to depression.^{8,33,43}

The majority of studies included in systematic reviews estimated the effect of the intervention compared to a passive control group (some reviews only searched for this type of study). A common comparator in reviewed studies was waitlist or treatment as usual. Some reviews suggested that mindfulness interventions could be used in conjunction with other treatments.⁴⁹ However, in many systematic reviews it was not clearly stated whether all participants in the RCT had received treatment as usual, with the difference between the groups being that one received a mindfulness intervention while the other did not (mindfulness intervention as add-on treatment). Several reviews, including depression-specific reviews, stated that the existing studies are not designed to determine whether the mindfulness component is responsible for the effectiveness of the interventions (in particular in MBCT interventions because MBCT was not compared to traditional CBT), or whether there are mindfulness-based-specific intervention effects given that the intervention group was compared to a passive control group.^{7,13} Pooled comparative effectiveness effects were reported in 2 reviews. One review concluded that MBCT was at least as effective as maintenance antidepressant medication because the pooled result showed no statistically significant difference between groups in a pooled analysis (RR 0.80; 95% CI 0.60, 1.08; favoring mindfulness; *p*=0.15; 2 RCTs); both individual included studies did not report a statistical power analysis.⁶⁴ The AHRQ report on meditation interventions differentiated specific and non-specific active control interventions and compared to specific active controls; a

combination of the interventions MBSR, MBCT, mindfulness meditation, and other mindfulness intervention did not show statistically significant differences compared to spirituality, relaxation, pain control, Vinyasa yoga, cognitive behavioral group therapy, antidepressants, or aerobic exercise control groups. Results in individual studies varied by comparators and showed no statistically effect between groups or favored the non-mindfulness-based intervention. However, a positive treatment effect was shown compared to unspecific active control groups that were at least matched in time and attention to the intervention group to control for the nonspecific effects of time, attention, and expectation (SMD 0.30; 95% CI -0.00, 0.59; at 8 weeks; SMD 0.23; 95% CI 0.05, 0.42 at 3–6 months; 10 RCTs total).³

Few reviews included a detailed description of the intervention. The AHRQ report that reported effect size estimates of 0.23 to 0.30 for depression included only structured meditation programs (defined as systematic or protocolized meditation programs that follow predetermined curricula) consisting of at least 4 hours of training with instructions to practice outside the training session.⁴³ A review on psychiatric disorders that reported a positive OR of depression relapse in favor of MBCT reported that in 5 out of the 12 included studies the instructor was one of the founders of MBCT, was supervised by one of the founders, or had been trained by one of the founders of MBCT.³³ The review on anxiety and depression effects in patients with cancer specified that all effects that reported a positive effect on anxiety and depression specified that interventions were based on MBSR conducted according to the program by Kabat-Zinn and MBCT according to Segal et al.⁶⁵ A review reporting a positive effect on relapse prevention specified that included interventions were limited to MBCT based on the manual by Segal et al tailored for depression in recurrent major depressive disorder.⁶⁴ The interventions in the studies contributing to a positive result on depression in anxiety disorders were all based on a group format.⁷⁷ As outlined, even reviews limited to a specific program such as MBSR indicated variation in the intervention implementation, and information was summarized across all included studies and characteristics of studies reporting on stress or depression.²⁰ A review on depressive symptoms in mental health reported a mean number of sessions of 10 (SD 3.3), total intervention hours mean 21 (SD 5.36), session duration mean 124 minutes (SD 25.8), and different therapist background (*eg*, CBT therapist) across interventions but data were not reported separately for mindfulness interventions.⁴⁹ Information on the intervention components, implementation characteristics, and the training of the mindfulness instructor was rarely documented in the included reviews, independent from the clinical area.

Of 7 depression-specific reviews that included mindfulness intervention RCTs, 3 commented on adverse events. One review that included 14 RCTs reported that adverse effects were not addressed in any of the included studies.⁴⁹ A second review stated that adverse events were not summarized because the data were sparse, inconsistent, and uninformative.⁸⁴ A third review did not assess adverse events but stated that MBSR is a psychological alternative with no adverse medical side-effects.⁶⁴ We did not identify summary estimates on suicide and suicide ideation. Reviews on depression,⁴⁹ mental illness,⁴¹ and mood disorders⁶ explicitly included RCTs in patients with depression and suicide ideation; however patient groups were, in most cases, explicitly described as in recovery at the time of the trial, and results on the outcome were not reported. The mood disorder review suggested, based on an individual case study, that MBCT possibly decreases cognitive vulnerability to suicidality.⁶

A scoping search indicated that since the AHRQ report on meditation programs, at least 17 new RCTs have been published that addressed the outcome “depression,” including comparative effectiveness studies comparing the effects of mindfulness interventions to other

treatments.^{92,96,97,105,107,108,114,121,127-135} Without careful assessment it is not possible to establish whether studies may challenge the summary of moderate evidence for improved depression³; however, only 6 RCTs included more than 100 participants and none included more than 350.^{97,107,114,119,121,130,135} The RCTs evaluated very different populations and study results varied across studies.

Wellness

Some included systematic reviews addressed the effects of mindfulness-based interventions in healthy adults, not clinical samples with a medical diagnosis. A review on psychological variables included 17 RCTs and reported a small effect ($r = .22$; 5 RCTs) for mindfulness meditation, and $r = 0.29$ (12 RCTs) for MBSR in nonclinical samples.⁹ The review's conclusion focused on the difference seen for MBSR and mindfulness meditation across all included studies, not RCTs specifically, and did not report recommendations for practice. Reviews in workplace setting interventions,²¹ stress management in healthy people,³⁰ stress-management programs for medical students,^{17,18} and stress reduction in university students,¹⁶ did not provide between-group meta-analytic effect estimates.

One systematic review provided a subgroup analysis for nonclinical / community samples and estimated Cohen's $d = 0.664$ (95% CI 0.37, 0.96; 6 RCTs) as the effect of MBSR across a variety of psychological outcomes compared to waitlist control.²⁰ As outlined previously, intervention characteristics were summarized across all 17 included MBSR studies, not separately for the nonclinical samples. The Campbell Collaboration review reported positive effects for outcomes in the wellness domain (personal development 0.50; 95% CI 0.35, 0.66; 12 RCTs; quality of life 0.57; 95% CI 0.17, 0.96; 4 RCTs) but results were based on a combination of clinical and non-clinical samples.⁸

Adverse events were only addressed in 2 of the 8 systematic reviews. As discussed, one review reported for one study that there were no adverse events¹⁸; the Campbell Collaboration review noted that reports on adverse events were missing from all included studies.

New RCTs in healthy adult participants, published since the comprehensive review that included non-clinical samples (search end date March 2010),⁹ address cognitive-affective neural plasticity¹³⁶; acute respiratory infection prevention¹³⁷; online stress interventions^{120,121}; loneliness¹³⁸; worry¹³⁹; pre-session centering for therapists¹⁴⁰; emotional response to film clips¹⁴¹; repetitive thoughts¹⁴²; emotional benefits in older adults¹²⁹; spatial abilities¹⁴³; cognitive rigidity¹⁴⁴; stress during pregnancy⁹³; job satisfaction¹⁴⁵; telomerase activity¹⁴⁶; experimentally induced pain^{109,147-149}; attention^{150,151}; postural balance¹⁵²; subjective effects and cognitive costs¹⁵³; intrinsic brain connectivity¹⁵⁴; body image¹⁵⁵; weight loss¹⁵⁶; experimental behavior modification¹⁵⁷; stimulus over-selectivity¹⁵⁸; provider burnout¹⁰⁵; self-compassion¹⁵⁹; experimentally induced stress¹⁰³; distressed personality traits¹⁰²; caregiver support^{96,160}; blood pressure¹⁶¹; distress in breast-feeding mothers¹⁰¹; emotion regulation processes¹⁶²; experimentally induced neurogenic inflammation¹⁰⁰; trait mindfulness¹⁶³; stress in the workplace^{99,164}; stress in medical students¹⁶⁵; childbirth and labor¹⁶⁶; and physician wellbeing.¹²⁷ The largest trial (1,222 healthy nulliparous women) identified in the scoping search found no between-group differences in use of epidural analgesia, self-reported pain measures duration of childbirth, and other birth outcomes comparing self-hypnosis, relaxation and mindfulness training, and usual care.¹⁶⁶

FUTURE RESEARCH

Systematic reviews in patients' experiences, sleep disturbance, hot flashes, eating disorders, and intellectual disability specifically searched for mindfulness intervention studies, but no RCTs (*ie*, high level of evidence research studies) were identified. Most evidence is available for comparisons of mindfulness interventions and passive comparators; information on comparisons to active control groups and comparative effectiveness research is currently very limited. The evidence map has identified a number of areas with unclear evidence. Future systematic reviews may provide more definitive answers. In some cases, the scope of the review might have to be reduced to concentrate on specific outcomes or clinical indications, and the effect of MBSR, MBCT, and other mindfulness-based interventions may need to be evaluated individually.

Ongoing Research

A protocol for a Cochrane review on mindfulness-based 'third wave' cognitive and behavioral therapies (including MBCT, Acceptance and Commitment Therapy, Compassionate Mind Training, and Dialectical Behavior Therapy) for depression was published in 2010 and was updated in 2012.¹⁶⁷ Unpublished systematic reviews registered in PROSPERO that specifically target mindfulness-based intervention studies address MBSR in breast cancer care (CRD42014009409), mindfulness-based approaches to treat pathological gambling (CRD42014010748), mindfulness meditation for overeating and weight loss (CRD42013004293), mindfulness in primary care (CRD42013004133), and MBCT and MBSR for depression and vascular disease (CRD42013003852).

SUMMARY AND LIMITATIONS

Most research is available for general overviews on health benefits or psychological wellbeing, and in the more specific areas chronic illness, depression, substance use, somatization disorders, distress, and mental illness. Reviews suggest differential effects of MBSR, MBCT, and other mindfulness-based interventions, and definitions of “mindfulness-based” varied. The most consistent effect was reported for depression, but published meta-analyses also indicated positive effects of MBSR on overall health, chronic illness, and psychological variables, positive effects of MBCT in mental illness, and positive effects of mindfulness interventions for somatization disorders, compared to passive control groups. Limited evidence, judging from existing systematic reviews reporting pooled treatment effects, is also available for mindfulness interventions for pain, anxiety, and psychosis, compared to passive control groups.

The evidence map is not designed to provide detailed and definitive information on the effectiveness of interventions and mindfulness interventions represent a large spectrum of interventions. Furthermore, the implementation of the reviewed interventions in practice will require additional steps (*eg*, identifying the optimal intervention format, validation of facilitators). Evidence maps are a very broad overview of the evidence base, indicating areas in which research has been conducted, to help stakeholders interpret the state of the evidence to inform policy and clinical decision making.

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APPENDIX: PEER REVIEW COMMENTS/AUTHOR RESPONSES

Comment	Response
Line 38 reads “patient sands” instead of “patients and”	Corrected
The use of MBSR and meditation more broadly is of great interest in the management of PTSD. While the map is unclear of the benefit, some of the conditions associated with PTSD such as depression and pain did show potential benefit. Is there any evidence to suggest that symptom improvement in conditions associated with PTSD amongst PTSD patients may be improved?	We have checked the patient population in studies included in the evidence map reviews: 5 RCTs in included reviews were in cancer survivors, one in hurricane survivors, but only one was described in the context of PTSD; that one is included in the identified PTSD review ¹¹
Highlighting the fact that in most cases there was not much difference with other active treatments would be helpful as this would help both in showing that multiple approaches that can be used to deal with these conditions as well as highlighting that these may be adjunctive rather than replacement interventions.	To address this point we have added more detail to the results of the 5 comparative effectiveness results, see in particular the VA priority area depression section. Effects varied by comparator and the statistical power to show a difference between groups was often unclear
This project is very well defined and described.	Appreciated
It is clearly stated that this is a review of other reviews and systematic reviews of RCT's. It would seem equally beneficial to differentiate which of those reviews focused on “passive” controls versus “active” control groups. Such information, in my opinion, strengthens the evidence. Having a “wait-list” control where one group receives the mindfulness intervention and the other group receives nothing, seems less compelling than having an active control group. However, given the state of the science on mindfulness research, there is likely to be more RCT's without active control groups.	Passive comparators were the most common comparators but we have expanded the description of comparisons to control groups matched in time and attention and comparative effectiveness results as outlined above
Could the final discussion on results separate those studies or systematic reviews that focused only on passive controls, and then compare findings with systematic reviews using active controls?	We have added more detail to individual sections as outlined above; however, there are too few comparisons and no consistent effect to warrant a separate evidence statement; we have added this point to the future research section
After thoroughly reviewing the article twice, I do not have any edits to suggest. This is a very well written report.	Appreciated
I am not sure that Transcendental Meditation (TM) or relaxation response (RR) fits in this review, although both require concentration, which I view as a form of mindfulness. Although there has been some controversy regarding the history and rigor of TM research, I am aware of some studies now being conducted in active military and veterans groups using both TM and RR.	We acknowledge that there is not a universal agreement on what interventions should be considered "mindfulness." With input from our partners and TEP, we have included only reviews (and RCTs for priority areas) that specifically refer to “mindfulness” and mantra-based interventions without reference to mindfulness were not eligible for inclusion
The definition of mindfulness using only 2 references and citing Jon Kabat-Zinn (1990) as the source for the Sanskrit definition seems biased to me (as noted on page 1, lines 21-22: “Mindfulness, often translated from Sanskrit to mean “awareness,” is an ancient Buddhist concept whose	We have revised the paragraph accordingly

practice entails the "...non-judgmental awareness of the present moment experience." ¹	
"For the VA priority areas, recent RCTs using a mindfulness intervention, reporting patient outcomes, and not yet included in existing reviews were also reviewed." There were studies missing that had "mindfulness" as keyword, even though the term had not been used in the title.	We have restructured the method section and state more clearly now that interventions had to explicitly refer to "mindfulness" in the title to be included. We acknowledge that there is limited agreement on the definition of "mindfulness interventions" and we have added this as a limitation
Before implementation, there needs to be validation of expert facilitators.	We have added a sentence on implementation steps to the limitation section
DBT included in some of the studies which is conceptually problematic. Inclusion of ACT and DBT have been largely accepted in review papers as mindfulness based interventions but I argue the mindfulness component of these interventions, particularly DBT, is secondary and is a potential confound. In DBT, for example, mindfulness is just one quarter of the skills building portion of the intervention which is in turn just a part of the treatment. This is admittedly a minority view.	To address this comment, we have revised the intervention overview and individual sections to avoid confusion and conflation of results; while several reviews included a variety of interventions, only a small number did not differentiate Acceptance and Commitment Therapy and Dialectical Behavior Therapy results from other mindfulness intervention results
Suicidal ideation is not addressed. This is due of course to the typical approach of excluding patients with SI from study participation. While not an RCT, a recent project at the VA (Serpa, Taylor & Tillisch, in press) took all comers and one quarter of MBSR participants reported SI. Class appears to be effective at reducing SI, a particular concern for VA care.	We did not identify a summary estimate on the outcome suicidal ideation. One review ⁶ addressed suicidality but results were based on an individual case study, not the included RCTs; we have added a description to the VA priority section on depression
In 43 "medication" is meditation	Corrected
This report does not address the specific training requirements for the delivery of mindfulness-based interventions. This is clearly outside the scope of an evidence map yet particularly relevant given the specific skills needed to teach an effective mindfulness course. Many of the studies cited include a description of the interventionist's skill such as "class was provided by a psychologist certified to teach MBSR with experience teaching more than 10 cohorts." Skill sufficient to teach MBSR is a 2-3 year development process and a life-long learning approach, not a weekend training course. Yet this is an implementation rather than an evidence-based issue. This is a highly effective and easily used evidence map. It is very well executed.	To address this comment we have added information on the intervention, including the training of the interventionist, to the VA priority areas. However, the available information is very limited and we have added this point as a limitation
The review's scope and objectives are clear and well thought out. The method, consisting of using systematic reviews to identify evidentiary data, is problematic despite the attempt to identify differences in approach (<i>ie</i> , MBSR, MBCT, other mindfulness approaches?), since it's unclear (it may be unavoidable given the nature of the reviews) across studies what the key feature of the "mindfulness" training being investigated was. It would have been helpful to have a bit more description of key components of mindfulness including the intensity/length of training, attentional focus, insight, moment-to-moment awareness,	To the extent possible we have added more information on the mindfulness intervention of successful programs in the VA priority areas. However, we acknowledge that this broad overview does not address pertinent intervention details specific to individual research studies

the degree of home practice, resources provided to intervention subjects.	
In terms of stress/distress, it was reported that there was low evidence of improved stress/distress in mindfulness meditation programs but from the studies cited, it was difficult to conclude on the true effectiveness or lack thereof of mindfulness since there was no clear information on stress-specific behavioral or psycho-physiologic responses which might alter as a result of specific mindfulness interventions.	We have revised the AHRQ report summary to avoid confusion ("low" refers to the strength of evidence)
Provide more specifics on the nature of the interventions reviewed, populations studied, more clarity on outcome measures.	See comment above. We have also added more study-level detail on populations and outcome measures, where reported in included reviews; but the information is limited
Toneatto, T. & Nguyen, L. Does mindfulness meditation improve anxiety and mood symptoms? A review of the controlled research. <i>Canadian Journal of Psychiatry</i> ; 2007; 52:260-266.	We have added this review (it was not indexed as a systematic review for multiple reasons) but met inclusion criteria
Hofmann SG, Sawyer AT, Witt AA, Oh D. The effect of mindfulness-based therapy on anxiety and depression: a meta-analytic review. <i>J Consult Clin Psychol</i> 2010;78:169–183.	The review is included in the evidence map (ref 42)
Orme-Johnson DW & Barnes VA. Effects of the transcendental meditation technique on trait-anxiety: a meta-analysis of randomized controlled trials. <i>J Alt & Comp Med</i> 2014;(20)5: 330-341.	See above. Meditation approaches without reference to mindfulness were not eligible for inclusion
Bormann JE, Thorp S, Wetherell JL, Golshan S, & Lang AJ. Meditation-based mantram intervention for veterans with posttraumatic stress disorder: a randomized trial. <i>Psychological Trauma: Theory, Research, Practice, and Policy</i> ; 2013;(5)3:259-267.	The study was part of the review on mind-body practices for PTSD; ¹¹ we have added more detail to the VA priority area section on PTSD
Bormann JE, Thorp S, Wetherell JL, Golshan, S. A spiritually based group intervention for combat veterans with PTSD: Feasibility study. <i>Journal of Holistic Nursing</i> , 2008;26(2), 109-116.	See above. We had to restrict this review to studies explicitly referring to mindfulness, hence this was outside the scope of the overview
There are several published studies on Mindfulness and ADHD in adults and children which were omitted. See chapter by Zylowska, L, Smalley, S. and Schwartz, J. in <i>Handbook for Mindfulness</i> , e. Fabrizio Didona, New York,: Springer-Verlag, 2008.	We did not identify systematic reviews on mindfulness and ADHD. A RCT in adults with ADHD reporting on the outcome depression ¹³³ is included (see priority section) but studies in children were outside the scope of the review
Bajjal, S. & Gupta, R., "Meditation Based Training: A Possible Intervention for Attention Deficit Hyperactivity Disorder .: <i>Psychiatry</i> 5, no. 4 (April, 2008): 48-55.	The review was assessed but did not meet inclusion criteria for a systematic review
Our current study addresses the use MBCT in suicidal veterans.	The study will be of great interest to the VA; however, this evidence map displays the published literature
There is a study by Williams, J. M.G.& Swales, M. The Use of Mindfulness-Based Approaches for Suicidal Patients. <i>Archives of Suicide Research</i> , 8:315-329, 2004 in this emerging area.	We assessed the review but it did not meet inclusion criteria for a systematic review

Note: we omitted comments specific to the dissemination within the VA