Mindfulness Meditation for the Treatment of Tobacco Use

A Systematic Review

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Preface

The Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury is interested in determining the efficacy and comparative effectiveness of integrative medicine approaches for psychological health conditions. Accordingly, the RAND Corporation was asked to develop a series of systematic reviews on interventions for such conditions as substance abuse, major depressive disorder, and posttraumatic stress disorder. These reviews may be used by committees charged with updating U.S. Department of Veterans Affairs and Department of Defense treatment guidelines, and may be of interest to military health policymakers and practitioners, civilian health care providers, and policymakers, payers, and patients.

This systematic review assesses the effectiveness of mindfulness meditation as an intervention for tobacco use cessation. The work was performed during year two of this two-year project on integrative medicine approaches for psychological health conditions.

None of the authors has any conflicts of interest to declare.

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Abstract

This systematic review synthesized evidence on mindfulness meditation interventions for the treatment of tobacco use (PROSPERO 2015: CRD42015025053).

We searched five electronic databases from inception to July 2015, as well as bibliographies of existing systematic reviews, to identify English-language randomized controlled trials (RCTs) evaluating the efficacy and safety of mindfulness meditation interventions that had goals of smoking cessation or reduction or of a decrease in nicotine cravings. Two independent reviewers screened identified literature using predetermined eligibility criteria, abstracted study-level information, and assessed the quality of included studies. Meta-analyses used the Hartung-Knapp-Sidik-Jonkman method for random-effects models. The quality of evidence was assessed using the GRADE approach.

Nine RCTs of mindfulness meditation interventions for tobacco use met inclusion criteria. Intervention duration and intensity varied considerably. No RCT was rated as good quality or reported power calculations indicating sufficient statistical power. Most did not report the randomization method, the allocation concealment, or whether outcome assessors were blinded. Effects on smoking cessation (abstinence) favored meditation but were not statistically different from comparator interventions (OR 3.46; CI 0.74, 16.13; 5 RCTs; I² 58%; very low quality of evidence). Studies compared such interventions as mindfulness training for smokers (MTS), mindfulness training, and a mindfulness-based smoking cessation program with American Lung Association’s Freedom from Smoking (FFS) program, quitline counseling, interactive learning, or treatment as usual (TAU). The number of cigarettes smoked per day at follow-up was also not statistically different between mindfulness training approaches and the comparators FFS, cue exposure with no instructions, sham meditation, or TAU (WMD 1.52; CI −1.03, 4.07; 4 RCTs, I² 16%; very low quality of evidence). A meta-regression suggested differences in effects associated with the type of intervention (p=0.01). The largest group of interventions, MTS, showed effects not statistically significantly differently from FFS, quitline counseling, or interactive learning (OR 1.44; CI 0.38, 5.45; 3 RCTs; I² 21%; very low quality of evidence). Due to the small number of studies and heterogeneity in interventions, comparators, and outcomes, we were unable to detect reliable systematic differences between adjunctive versus monotherapy interventions or effects of the duration and frequency of meditation. Only three RCTs reported on adverse events; they stated that there were no reportable medication reactions associated with the adjunctive nicotine replacement treatment or that no serious adverse events occurred.

In sum, the effects of mindfulness meditation on tobacco use did not differ significantly from comparator interventions. Quality of evidence is very low, as only a small number of RCTs of mindfulness meditation interventions have been published and the interventions, comparators, and outcomes vary considerably. Important aspects of methodology were often unreported in the
journal articles describing these RCTs. Additional, high-quality RCTs with samples large enough to detect statistical differences between competing interventions should be conducted. These RCTs should have sufficient duration to assess long-term effects on tobacco use and confirm smoking cessation through biochemical means.
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Summary

Introduction

The U.S. Department of Defense (DoD) faces a significant public health problem as a result of tobacco use among members of the U.S. military. Estimates suggest a greater prevalence of cigarette smoking among U.S. military members and veterans relative to the general U.S. adult population (Brown, 2010; U.S. Department of Defense, 2013). Additionally, research shows that military deployment may lead to higher rates of initiation and relapse, as well as more overall tobacco use (Boyko et al., 2015; Harte, Proctor, and Vasterling, 2014). Consequently, DoD spends $1.6 billion annually on tobacco-related health care costs and lost productivity (Institute of Medicine, 2009). According to 2008 Public Health Service guidelines recommended by DoD, treatments for tobacco use disorder include counseling and medications, such as nicotine replacement. However, civilian settings are more frequently including complementary and alternative medicine in smoking cessation programs (Carim-Todd, Mitchell, and Oken, 2013).

Based on ancient Eastern meditation practices, mindfulness meditation is a form of meditation that facilitates a stance of detached observation as part of the meditation process. This review aims to synthesize data from existing randomized controlled trials (RCTs) on the efficacy and safety of mindfulness meditation interventions for tobacco use (PROSPERO 2015: CRD42015025053). The review may be used by committees charged with updating U.S. Department of Veterans Affairs and DoD treatment guidelines.

Key Questions

This review was guided by the following key questions (KQs):

- KQ 1: What are the efficacy and safety of mindfulness meditation interventions, as an adjunctive or monotherapy, for smoking cessation or reduction compared with treatment as usual, waitlists, no treatment, or other active treatments?
  - KQ 1a: Does the effect vary by the type of mindfulness meditation intervention?
  - KQ 1b: Does the effect differ when the intervention is offered as an adjunctive therapy rather than as a monotherapy?
  - KQ 1c: Does the effect vary depending on the duration and frequency of mindfulness meditation (i.e., dose effect)?

Methods

To answer our key questions, we searched five electronic databases—PubMed, CINAHL (Cumulative Index to Nursing and Allied Health Literature), PsycINFO, AMED (Allied and
Complementary Medicine Database), and CENTRAL (Cochrane Central Register of Controlled Trials)—from inception to July 2015, as well as bibliographies of existing systematic reviews and included studies, to identify reports of English-language RCTs evaluating the efficacy and safety of mindfulness meditation used adjunctively or as monotherapy to treat adults who wish to reduce tobacco use or quit altogether.

Two teams of two independent reviewers screened identified literature using predetermined eligibility criteria, abstracted pre-specified study-level information, and assessed the quality of included studies. The primary outcome of interest was smoking/tobacco cessation. Other outcomes of interest included reduction in use, decrease in cravings, health-related quality of life, and adverse events.

Meta-analyses for efficacy outcomes were conducted using the Hartung-Knapp-Sidik-Jonkman method for random-effects models when sufficient data were available and clinical heterogeneity was acceptable. We abstracted any adverse events reported, but too few were reported to include in quantitative analyses. The quality of evidence was assessed using the Grades of Recommendation, Assessment, Development, and Evaluation (or GRADE) approach.

**Results**

Nine RCTs of mindfulness meditation intervention for treatment of tobacco use met our inclusion criteria. The studies assessed a wide variety of interventions and comparators, including mindfulness training for smokers (MTS) and brief mindfulness training. Intervention duration and intensity varied considerably.

**Key Question 1**

Two studies compared mindfulness meditation with the American Lung Association’s Freedom from Smoking (FFS) program, which is considered the standard of care for smoking cessation. Four RCTs compared mindfulness meditation with an active intervention, including telephone counseling (in addition to nicotine replacement), interactive learning for smokers, relaxation training, and suppression strategies. Two studies utilized comparators that did not offer a therapeutic intervention; comparators were sham meditation and cue exposure with no instruction. Finally, one study compared mindfulness meditation with treatment as usual (TAU), which could include counseling or nicotine replacement. No RCT used a waitlist comparator.

No RCT was rated as good quality. None of the studies reported an *a priori* power calculation with targeted sample size achieved. Most did not report the randomization method, the allocation concealment, or whether outcome assessors were blinded. Reported outcome measures varied across studies, and in several cases, the size of the effect could not be computed.

*Cessation.* Five RCTs reported the number of participants that had achieved smoking cessation. We conducted three meta-analyses by follow-up time: longest follow-up, two to four weeks, and 17 to 24 weeks. Effects on smoking cessation (abstinence) favored meditation but
were not statistically different from comparator interventions (odds ratio [OR] 3.46; 95% confidence interval [CI] 0.74, 16.13; 5 RCTs; $I^2$ 58%; very low quality of evidence) comparing MTS, mindfulness training, and a mindfulness-based smoking cessation program to the FFS program, quitline counseling, interactive learning, or TAU at the longest reported follow-up. The pooled odds ratio for trials reporting cessation at two to four weeks was 1.68 (CI 0.67, 4.20; 4 RCTs; $I^2$ 26%; low quality of evidence). The odds ratios resulting from the meta-analyses of longer follow-up times had very large confidence intervals; for example, the pooled odds ratio for the four trials reporting cessation past four weeks (range 17 to 24 weeks) was 3.32 (CI 0.37, 29.52; 4 RCTs; $I^2$ 66%; very low quality of evidence). Due to the small number of studies, diversity of interventions and comparators, and imprecision of results, quality of evidence is rated low for short-term (four weeks or less) cessation and very low for long-term cessation.

Reduction in tobacco use. Results of four RCTs reporting the number of cigarettes per day at both baseline and follow-up were pooled. Two studies were poor quality and two were fair quality. Pooled results favored mindfulness meditation; however, the effect was not statistically significantly different between mindfulness training approaches and the comparators FFS, cue exposure with no instructions, sham meditation, or TAU (weighted mean difference [WMD] 1.52; CI −1.03, 4.07; 4 RCTs; $I^2$ 16%; very low quality of evidence). In addition, the weighted mean difference of 1.5 cigarettes per day is not clinically meaningful. Due to the low number of RCTs and inconsistency of results, there is very low quality evidence that reduction in smoking does not differ between participants in mindfulness interventions and the comparator interventions.

Cravings. Five RCTs measured nicotine craving at baseline and follow-up, using a variety of instruments. Meta-analysis was not possible due to heterogeneity of outcomes reported. Four of the five studies were of poor quality. Only one reported a significant difference between the mindfulness meditation group and the comparator group at follow-up. That study did not describe how craving was measured, and stated only that the mean decrease in craving from baseline to two-week follow-up was statistically significant in the mindfulness intervention group but not in the comparator group (relaxation training). Thus, there is very low quality evidence that decrease in nicotine craving does not differ between participants in mindfulness interventions and the various other comparator interventions.

Health-related quality of life. No studies reported quality of life measures.

Adverse events. Two studies utilized mindfulness meditation interventions plus nicotine replacement and solely expressed that there were “no reportable medication reactions” among nicotine replacement users. Another study that reported on adverse events related to the mindfulness intervention stated that “no serious adverse events were reported in either treatment group.” In sum, it appears that in the nine included studies, there were no adverse events due to mindfulness meditation interventions. However, the quality of evidence is very low, given that two-thirds of the studies did not mention tracking adverse events.
**Key Question 1a**

Regarding type of mindfulness intervention, a meta-regression indicated that the size of the treatment effect is associated with the type of intervention \( p=0.01 \). However, the analysis could only compare MTS with other approaches; other interventions were tested in only one RCT each or reported on different outcomes across studies. A subgroup analysis pooling the three studies of MTS showed that the odds ratio for cessation favored MTS but was not statistically significantly different from FFS, quitline counseling, or interactive learning \( \text{OR} 1.44; \text{CI} 0.38, 5.45; 3 \text{ RCTs}; I^2 21\%; \text{low quality of evidence} \).

**Key Question 1b**

Due to the diversity in reported outcome measures, we could not perform meta-regressions to determine whether the effect of mindfulness meditation on tobacco use varies systematically between adjunctive or monotherapy. Results for both the five monotherapy studies and the two studies of adjunct therapy with nicotine replacement were inconsistent. Two other studies that allowed nicotine replacement at the participant’s discretion reported significant smoking cessation results favoring the mindfulness intervention. Due to the small number of studies, lack of precision, and heterogeneity of outcomes reported, quality of evidence for the subgroups was determined to be very low.

**Key Question 1c**

Meta-regression for the outcome number of cigarettes did not detect a statistically significant association with the length of the intervention \( p=0.849 \), but the number of included studies in the subgroups was small. Due to the diversity in reported outcome measures, we could not perform a meta-regression across studies to determine whether the treatment effect is systematically associated with the frequency of the intervention. A subgroup analysis that included only the highest-frequency interventions (requiring more than four hours per week of participation in sessions, homework, and meditation) found smoking cessation results not statistically different from comparator interventions \( \text{OR} 2.84; \text{CI} 0.35, 22.70; 4 \text{ RCTs}; I^2 58\%; \text{very low quality of evidence} \). The quality of evidence for the subgroups was very low due to the small number of studies and inconsistent results within subgroups.

**Conclusions**

Only a small number of RCTs of mindfulness meditation interventions for treatment of tobacco use have been published, and the interventions, comparators, and outcomes vary considerably. Important aspects of methodology were often unreported in the journal articles describing these RCTs. The results of several meta-analyses indicate no difference in tobacco use outcomes between mindfulness interventions and comparator interventions; however, five studies were “pilot” studies that noted insufficient power, and the remaining four studies did not
report any information about a power calculation. The quality of evidence for mindfulness meditation for smoking cessation in the short term (two to four weeks) is low, while the quality of evidence for reduction in tobacco use, reduction in nicotine cravings, and long-term cessation is very low; lack of significant results may be due to the small number of studies and lack of statistical power. Additional high-quality RCTs with samples large enough to detect statistical differences in outcomes should be conducted. These RCTs should have sufficient duration to assess long-term effects on tobacco use, track the adherence to mindfulness and any co-interventions, and confirm smoking cessation through biochemical means. The CONSORT (CONsolidated Standards of Reporting Trials) statement on reporting standards should be followed when publishing future RCTs on mindfulness meditation and tobacco use.
Acknowledgments

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Abbreviations

AMED  Allied and Complementary Health Database
CENTRAL  Cochrane Central Register of Controlled Trials
CI  confidence interval
CINAHL  Cumulative Index to Nursing and Allied Health Literature
CO  carbon monoxide
DoD  U.S. Department of Defense
EPC  Evidence-based Practice Center
FFS  Freedom from Smoking
GRADE  Grades of Recommendation, Assessment, Development and Evaluation
ITT  intention-to-treat
MD  mean difference
MTS  mindfulness training for smokers
OR  odds ratio
RCT  randomized controlled trial
SD  standard deviation
SE  standard error
TAU  treatment as usual
USPSTF  United States Preventive Services Task Force
WMD  weighted mean difference
Chapter One: Introduction

Background and Objective

Use of tobacco products, including cigarette smoking and tobacco chewing, presents a significant public health problem for the US Department of Defense (DoD). In 2011, the prevalence of smoking within the past 30 days among members of the U.S. military was estimated at 24.5 percent, compared with 19.0 percent for the U.S. adult population (U.S. Department of Defense, 2013). The Millennium Cohort Study found that deployment with combat experience predicted higher initiation rate and relapse rate (Boyko et al., 2015). According to Harte and colleagues (Harte, Proctor, and Vasterling, 2014), almost half (48.9 percent) of Army and National Guard soldiers deployed to Operation Iraqi Freedom smoked cigarettes at two time points surveyed. Age-adjusted smoking prevalence is also higher among U.S. veterans (27 percent) than civilians (21 percent), according to data from the 2003–2007 Behavioral Risk Factor Surveillance System (Brown, 2010). Thus, it is not surprising that the Institute of Medicine estimates that DoD spends more than $1.6 billion a year on tobacco-related health care costs and lost productivity (Institute of Medicine, 2009).

DoD currently recommends that health care providers follow the 2008 Public Health Service guidelines in treating tobacco use disorder; counseling and medications, including nicotine replacement, are the primary focus (U.S. Department of Health and Human Services, 2008). Individual, group, and telephone counseling are all effective, with effectiveness increasing with intensity. Nicotine replacement, bupropion SR (sustained release), and varenicline are recommended as first-line medications. Each of these interventions has consistently been found effective in many high-quality randomized controlled trials (RCTs), resulting in the highest rating for strength of evidence (U.S. Department of Health and Human Services, 2008).

In civilian settings, complementary and alternative medicine has been increasingly used in smoking cessation programs (Carim-Todd, Mitchell, and Oken, 2013). One such modality is mindfulness meditation, derived from a 2,500-year-old Buddhist practice called Vipassana, or insight meditation. Jon Kabat-Zinn, a pioneer in modern use of mindfulness meditation, defines mindfulness as “paying attention on purpose, in the present moment, and non-judgmentally, to the unfolding of experience moment to moment” (Kabat-Zinn, 1990). The practice can be trained systematically to be used in daily life by people of any background (Mindfulness Awareness Research Center, undated). Clinical uses of mindfulness include applications in substance abuse (Chiesa and Serretti, 2014), stress reduction (Goyal et al., 2014), and treatment of chronic pain (Cramer et al., 2012; Kozasa et al., 2012; Reiner, Tibi, and Lipsitz, 2013). The most commonly used mindfulness meditation interventions are described in Table 1.1 (Mindfulness Awareness Research Center, undated).
Table 1.1. Interventions Based on Mindfulness Meditation

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mindfulness-based stress reduction</td>
<td>In addition to mindfulness meditation, mindfulness-based stress reduction involves teaching of body scan or yoga to encourage open, nonjudgmental observation and acceptance of painful or unpleasant sensation, negative thoughts, or emotions instead of cognitively appraising them, and increasing anticipatory anxiety, avoidance, or other maladaptive patterns.</td>
</tr>
<tr>
<td>Mindfulness-based cognitive therapy</td>
<td>In addition to mindfulness meditation, mindfulness-based cognitive therapy encourages acceptant, nonjudgmental observation of negative thoughts and emotions instead of their cognitive appraisal triggering ruminative negative thoughts and habitual emotional reactivity.</td>
</tr>
<tr>
<td>Mindfulness-based relapse prevention</td>
<td>In addition to mindfulness meditation, mindfulness-based relapse prevention teaches relapse prevention skills, and nonjudgmental, open, and acceptant observation of cravings. It aims to decouple (1) the negative thoughts and emotions that are associated with cravings and (2) relapse.</td>
</tr>
<tr>
<td>Mindfulness training for smokers (MTS)</td>
<td>In addition to mindfulness meditation, MTS provides targeted training in how to apply mindfulness to smoking relapse determinants, such as smoking triggers, strong emotions, addictive thoughts, urges, and withdrawal symptoms.</td>
</tr>
<tr>
<td>Mind-body bridging and mindfulness-based therapy for insomnia</td>
<td>In addition to mindfulness meditation, mind-body bridging and mindfulness-based therapy for insomnia use behavioral strategies to reduce night wakefulness.</td>
</tr>
<tr>
<td>Mindfulness-oriented recovery enhancement</td>
<td>In addition to mindfulness meditation, mindfulness-oriented recovery enhancement teaches neutral, open, and acceptant observation of painful sensations. It also incorporates positive psychology and behavioral techniques directed toward neuroscientific underpinnings of addiction.</td>
</tr>
</tbody>
</table>

This review aims to synthesize data from existing RCTs on the efficacy and safety of mindfulness meditation interventions for tobacco use. The project was funded by the U.S. Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury, which commissioned the RAND Corporation to develop a series of systematic reviews on complementary and alternative medicine interventions for such conditions as substance abuse, major depressive disorder, and posttraumatic stress disorder. These reviews may be used by committees charged with updating U.S. Department of Veterans Affairs and DoD guidelines for treatment of these conditions.

Key Questions

We conducted a systematic review to identify RCTs testing the efficacy and safety of mindfulness meditation in tobacco users (PROSPERO Number: CRD42015025053). Specifically, this systematic review aimed to answer the following key questions (KQs):

- KQ 1: What are the efficacy and safety of mindfulness meditation interventions, as an adjunctive or monotherapy, for smoking cessation or reduction compared with treatment as usual, waitlists, no treatment, or other active treatments?
  - KQ 1a: Does the effect vary by the type of mindfulness meditation intervention?
– KQ 1b: Does the effect differ when the intervention is offered as an adjunctive therapy rather than as a monotherapy?
– KQ 1c: Does the effect vary depending on the duration and frequency of mindfulness meditation (i.e., dose effect)?
Chapter Two: Methods

Search Strategy

We searched the electronic databases PubMed, CINAHL (Cumulative Index to Nursing and Allied Health Literature), PsycINFO, AMED (Allied and Complementary Health Database), and CENTRAL (Cochrane Central Register of Controlled Trials) for English-language RCTs. In addition to this search and the reference-mining of all included studies identified through it, we screened existing systematic reviews on the topic to ensure that all studies that met our inclusion criteria (see below) were identified.

The search strategy was developed by the chief reference librarian for RAND’s Knowledge Services, informed by search results of an environmental scan of the literature at the initiation of this study (as part of unpublished RAND research by Melony Sorbero, Sean Grant, and Susanne Hempel) and existing reviews. The search was conducted in July 2015 and covered each database from its inception. The search strategy is presented in Appendix A.

Eligibility Criteria

The inclusion and exclusion criteria for this review were developed using the framework of participants, interventions, comparators, outcomes, timing, settings, and study design, or PICOTSS:

- **Participants**: Studies were limited to adults, male and female, 18 years of age and over, who use tobacco products. Studies were included regardless of whether a diagnosis of tobacco use disorder was required for enrollment.
- **Interventions**: Studies involving mindfulness meditation, either as an adjunctive or monotherapy, were included—for example, mindfulness-based stress reduction, MTS, mindfulness-based cognitive therapy, brief mindfulness training, Vipassana, Zazen, Zen, or Shambhala interventions. Studies evaluating other meditation interventions, such as yoga, tai chi, qigong, and transcendental meditation techniques, without reference to mindfulness meditation were excluded.
- **Comparator**: Studies were not limited by comparator. We included studies with treatment as usual (TAU) or “standard care,” waitlist control, no treatment, or other active treatments as comparators. Studies that compared mindfulness meditation offered as adjunctive therapy versus monotherapy were included as well.
- **Outcomes**: Studies were required to report tobacco use cessation, attempts to quit, or reduction in use. Biological confirmation of cessation was not required for study inclusion. Studies that reported only intention or “motivation and readiness” to quit were excluded.
- **Timing**: Studies were included with any treatment duration and any follow-up period.
- **Setting**: Studies were not limited by setting (e.g., country, physical location of treatment).
• **Study design:** Included studies were limited to parallel group, individually-randomized, or cluster-randomized controlled trials.

**Inclusion Screening**

Two reviewers (the project lead, who is an experienced systematic reviewer and former Associate Director of the Southern California Evidence-based Practice Center [EPC], and a RAND research assistant with experience in systematic reviews) independently screened titles and abstracts of retrieved citations following a pilot session to ensure similar interpretation of the inclusion and exclusion criteria.

Citations judged as potentially eligible by one or both reviewers were obtained as full text. Each full-text publication was then screened against the specified inclusion criteria by two independent literature reviewers; for expediency, two teams of two trained reviewers participated. Any disagreements were resolved through discussion within the review team. The flow of citations throughout this process was documented in an electronic database, and reasons for exclusion of full-text publications were recorded.

Studies on the same participants were counted as one study regardless of the number of publications the results were presented in. If multiple publications on the same study were identified, all publications on studies meeting inclusion criteria were reviewed for data abstraction.

**Data Extraction**

Two of the aforementioned reviewers each independently abstracted study-level data in an electronic database. Data collection forms were designed by the project lead, with input from the project team. Reviewers pilot-tested the data collection forms on a few randomly selected studies, modified the forms as necessary, and performed a final pilot of the forms on a random selection of three included studies to ensure agreement of interpretation. EPC biostatisticians abstracted all outcome data to ensure accuracy.

Study-level data were abstracted for the following information:

- **Participants:** gender, age, baseline tobacco use, comorbid psychological or behavioral health conditions, comorbid medical conditions
- **Interventions:** content of mindfulness meditation sessions, dosage (duration of intervention, intensity, frequency), and any co-intervention(s)
- **Comparators:** type of comparator (e.g., counseling, nicotine replacement, other medication, other complementary and alternative medicine intervention, waitlist), dosage (intensity, frequency, duration)
- **Outcomes:** primary endpoint; longest follow-up; measures of tobacco abstinence, reduction in use, cravings, health-related quality of life, and adverse events for each time point of measurement; domain; method of measurement; metric of data expression (e.g., means, proportions); and corresponding results (e.g., effect estimate, precision)
• **Timing**: time points of outcome assessment, timing of intervention
• **Setting**: geographic region, setting, interventionist training
• **Study design**: aim of study, inclusion and exclusion criteria, sample size, reported power calculations, items relevant to risk of bias and quality ratings.

We relied on published data; we did not include conference abstracts and dissertations. No inquiries were made to authors or sponsors. Outcome data were based on intention-to-treat (ITT) analyses reported in the included studies. In the absence of ITT data, we used the number randomized as the denominator; in the absence of the number randomized, we used the number of participants at follow-up.

**Risk of Bias and Study Quality**

The two reviewers assessed the risk of bias of included studies using the Cochrane Risk of Bias tool (Higgins et al., 2011) and quality criteria used by the U.S. Preventative Services Task Force (USPSTF) (U.S. Preventive Services Task Force, 2008). Specifically, the reviewers assessed risks of bias related to the following domains: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and providers (performance bias), blinding of outcome assessors (detection bias), completeness of reporting outcome data (attrition bias), and selective outcome reporting (reporting bias).

Other biases related to USPSTF’s criteria for internal validity of included studies were also assessed, namely those related to equal distribution among groups of potential confounders at baseline; crossovers or contamination between groups; equal, reliable, and valid outcome measurement; clear definitions of interventions; and ITT analysis. These criteria were used to rate the quality of individual included studies using the following guidelines (Schulz et al., 2010; U.S. Preventive Services Task Force, 2008):

- **Good**: Comparable groups are initially assembled and maintained throughout the study with at least 80-percent follow-up; reliable, valid measurement is used and applied equally to all groups; interventions are clearly described; all important outcomes are considered; appropriate attention is given to confounders in analysis; ITT analysis is used.
- **Fair**: One or more of the following issues is found in the study: some though not major differences between groups exist at follow-up; measurement instruments are acceptable but not ideal, though are generally applied equally; some but not all important outcomes are considered; some but not all potential confounders are accounted for in analyses. ITT analysis must be done.
- **Poor**: One or more of the following “fatal flaws” is found in the study: initially assembled groups are not comparable or maintained throughout the study; unreliable or invalid measurements are used or applied unequally across groups; key confounders are given little to no attention in analyses; ITT analysis is not used.
Data Synthesis

The primary aim of this systematic review was to identify whether mindfulness meditation as an intervention for tobacco use cessation is effective and safe. Smoking or tobacco cessation was the primary outcome; commonly used cessation measures include seven-day abstinence.

When sufficient data were available and clinical heterogeneity was acceptable, we conducted meta-analysis to pool results across included studies for the outcomes of interest. Heterogeneity was expressed as I-squared ($I^2$). We used the Hartung-Knapp-Sidik-Jonkman method for our random-effects meta-analysis (Hartung, 1999; Hartung and Knapp, 2001; Sidik and Jonkman, 2006). This approach may be preferred when the number of studies pooled is small and when there is evidence of heterogeneity (IntHout, Ioannidis, and Borm, 2014). It has been shown that the error rates are more robust than the previously used DerSimonian and Laird method (Sánchez-Meca and Marín-Martínez, 2008). Categorical variables were summarized as odd ratios (ORs), together with their 95% confidence intervals (CIs). The number of cigarettes smoked was summarized as weighted mean differences (WMDs). Adverse events were abstracted; however, there were too few to conduct quantitative analysis.

Quality of Evidence

The quality of evidence was assessed for major outcomes using the Grades of Recommendation, Assessment, Development, and Evaluation (or GRADE) approach (Balshem et al., 2011). Namely, the body of evidence was assessed based on the following dimensions: study limitations (low, medium, or high), consistency (consistent, inconsistent, or unknown), directness (direct or indirect), and precision (precise or imprecise) (Egger et al., 1997). The quality of the body of evidence was downgraded when results were primarily based on studies with substantial limitations; when results were inconsistent across individual studies, in the presence of substantial heterogeneity in pooled analyses; when the result was based on only a single study without replication in an independent research study; when conclusions were based on indirect evidence (e.g., effects based on subgroup analyses or meta-regressions in the absence of head-to-head comparisons); and when pooled results were imprecise estimates of the treatment effect with wide confidence intervals spanning effect sizes with different clinical conclusions.

The quality of evidence was graded on a four-item scale:

- **High** indicates that the review authors are very confident that the effect estimate lies close to the true effect for a given outcome, as the body of evidence has few or no deficiencies. As such, the reviewers believe the findings are stable. That is, further research is very unlikely to change confidence in the effect estimate.

- **Moderate** indicates that the review authors are moderately confident that the effect estimate lies close to the true effect for a given outcome, as the body of evidence has some deficiencies. As such, the reviewers believe that the findings are likely to be stable,
but further research may change confidence in the effect estimate and may even change the estimate.

- *Low* indicates that the review authors have limited confidence that the effect estimate lies close to the true effect for a given outcome, as the body of evidence has major or numerous (or both) deficiencies. As such, the reviewers believe that additional evidence is needed before concluding either that the findings are stable or that the effect estimate lies close to the true effect.

- *Very low* indicates that the review authors have very little confidence that the effect estimate lies close to the true effect for a given outcome, as the body of evidence has very major deficiencies. As such, the true effect is likely to be substantially different from the estimated effect; thus, any estimate of effect is very uncertain.
Results of the Search

We identified 157 citations through the electronic database search and reference-mining of included studies and previous systematic reviews related to tobacco use (see Figure 3.1).

![Flow Diagram](image)

**Figure 3.1. Flow Diagram**

- **Titles identified from RAND library searches**
  - n=139

- **Relevant citations identified from previous systematic reviews**
  - n=18

**Total number of abstracts identified for dual review**
- n=157

**Abstracts rejected**
- n=128
  - Off-topic: n=45
  - Intervention (not mindfulness meditation): n=37
  - Design (not RCT): n=17
  - Background (nonsystematic review, history, etc.): n=14
  - Outcome (not tobacco use): n=7
  - No comparator: n=3
  - Participants (not adults): n=2
  - Duplicate: n=2
  - Systematic review/meta-analysis: n=1

**Total articles identified for full text review**
- n=29

**Full-text articles rejected**
- n=20
  - Duplicate publication of included study: n=6
  - Design (not RCT): n=6
  - Off topic (not tobacco use): n=3
  - Intervention (not mindfulness meditation): n=2
  - Conference abstract: n=2
  - No relevant outcomes: n=1

**Total articles contributing to the data synthesis**
- n=9
Full texts were obtained for 29 citations identified as potentially eligible by two independent reviewers. In total, 20 articles were excluded at the full-text stage because they did not meet eligibility criteria. Three of these did not report tobacco use outcomes. Two others employed an intervention that did not meet our definition of mindfulness meditation. Six of the excluded studies were not RCTs. Two of the studies were conference abstracts, and six were duplicate publications of included studies. One of the studies was excluded for having no relevant outcomes (only reported craving and intention to quit). Appendix B lists excluded publications with reasons for exclusion. Nine RCTs met inclusion criteria; details of these studies are displayed in Table 3.1.

### Table 3.1. Evidence Base for Key Questions

<table>
<thead>
<tr>
<th>KQ Question</th>
<th>Number of RCTs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> What are the efficacy and safety of mindfulness meditation interventions, as an adjunctive or monotherapy, for smoking cessation or reduction compared with treatment as usual, waitlists, no treatment, or other active treatments?</td>
<td>9 RCTs with these comparators:  • 2 American Lung Association Freedom from Smoking program  • 1 cue exposure with no instruction  • 1 cue exposure with urge suppression  • 1 telephone quitline  • 1 interactive learning for smokers  • 1 sham meditation  • 1 relaxation training  • 1 assorted TAU</td>
</tr>
<tr>
<td><strong>1a</strong> Does the effect vary by the type of mindfulness meditation intervention?</td>
<td>3 MTS 2 brief mindfulness interventions 4 other mindfulness</td>
</tr>
<tr>
<td><strong>1b</strong> Does the effect differ when the intervention is offered as an adjunctive therapy rather than as a monotherapy?</td>
<td>2 adjunct with nicotine replacement 5 monotherapy 2 unclear</td>
</tr>
<tr>
<td><strong>1c</strong> Does the effect vary depending on the duration and frequency of mindfulness meditation (i.e., dose effect)?</td>
<td>9 RCTs, ranging 1 day to 8 weeks 1 low frequency (&lt;1 hour per week) 4 medium (1–4 hours per week) 4 high (&gt;4 hours per week)</td>
</tr>
</tbody>
</table>

### Description of Included Studies

**Design**

All RCTs randomized individual participants, rather than clusters of participants. Overall, studies assigned 780 participants; sample size ranged from 27 to 196 participants. None of the studies reported an *a priori* power calculation with targeted sample size achieved; four studies did not report any information about a power calculation, while five studies were “pilot” studies that noted insufficient power.
Setting

All of the studies were conducted in North America. The mindfulness intervention was delivered remotely, via personal digital assistant, in one of the studies (Ruscio et al., 2015). Four of the studies delivered the mindfulness intervention in an outpatient setting (Davis, Mills, et al., 2013; Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b; Tang, Tang, and Posner, 2013). In four of the studies, it was unclear where the intervention was delivered (Bowen and Marlatt, 2009; Brewer et al., 2011; Rogojanski, Vettese, and Antony, 2011a; Singh et al., 2014).

Participants

The mean age of participants ranged from 21.46 (standard deviation [SD] 3.08) to 45.9 (SD 10.2) years. All of the studies included both male and female participants. The proportion of males ranged from 50 to 80 percent. Only two of the studies reported comorbid medical conditions or special populations. One of these was a study of young binge drinkers (Davis, Mills, et al., 2013). In the other study, the participants had mild intellectual disability (Singh et al., 2014).

Interventions

The total length of treatment with a mindfulness intervention ranged from one day to eight weeks. The interventions included three studies utilizing MTS (Davis, Mills, et al., 2013; Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b). Two of the studies had brief mindfulness interventions (Bowen and Marlatt, 2009; Ruscio et al., 2015), described as brief mindfulness practice and brief mindfulness-based instructions, respectively. One of the studies utilized integrative body-mind training (Tang, Tang, and Posner, 2013). Three of the studies described their interventions as mindfulness training, mindfulness meditation, and mindfulness-based smoking cessation program (Brewer et al., 2011; Rogojanski, Vettese, and Antony, 2011a; Singh et al., 2014).

Five RCTs provided the mindfulness intervention as monotherapy (Bowen and Marlatt, 2009; Davis, Mills, et al., 2013; Ruscio et al., 2015; Singh et al., 2014; Tang, Tang, and Posner, 2013). Two RCTs utilized a mindfulness intervention as adjunctive therapy, specifying that all participants received this in addition to nicotine replacement (Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b). Two of the studies were unclear in whether the mindfulness intervention was monotherapy or adjunctive therapy (Brewer et al., 2011; Singh et al., 2014).

Comparators

Two RCTs compared a mindfulness intervention with the American Lung Association’s Freedom from Smoking (FFS) program (Brewer et al., 2011; Davis, Manley, et al., 2014b). In one of these, both mindfulness and FFS groups were provided with nicotine replacement (Davis, Manley, et al., 2014b). Four RCTs compared mindfulness meditation with an alternative
intervention, including telephone counseling (in addition to nicotine replacement), interactive learning for smokers, relaxation training, and suppression strategies (Davis, Mills, et al., 2013; Davis, Goldberg, et al., 2014a; Rogojanski, Vettese, and Antony, 2011a; Tang, Tang, and Posner, 2013). Three of the studies utilized comparators that did not offer a therapeutic intervention, including sham meditation, passive (no instruction), and TAU, which varied among participants and could include counseling or nicotine replacement (Bowen and Marlatt, 2009; Ruscio et al., 2015; Singh et al., 2014).

Risk of Bias and Study Quality for Individual Included Studies

The risk of bias and study quality for each of the included studies can be found in Table 3.2. None of the studies obtained a “good” quality rating. Four studies were judged to be fair quality, primarily due to lack of participant blinding and being unclear about concealment of allocation (Brewer et al., 2011) and blindness of outcome assessment (Brewer et al., 2011; Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b; Singh et al., 2014). The five other studies were judged as poor quality. One study had less than 80-percent follow-up (Davis, Mills, et al., 2013). Four studies were judged poor primarily due to possible selective reporting of outcomes (Bowen and Marlatt, 2009; Rogojanski, Vettese, and Antony, 2011a; Ruscio et al., 2015; Tang, Tang, and Posner, 2013) in addition to unclear methodology.

Random sequence generation. Five studies had unclear selection bias because they did not report their random sequence generation method; four other studies reported adequate random sequence generation methods (e.g., computerized random generator).

Allocation concealment. No studies reported an allocation concealment method.

Blinding of participants and providers. Participant blinding of behavioral interventions is extremely difficult. Eight of the studies were considered high risk because of lack of blinding of participants. One study had low risk of bias, as participants in both groups reported not knowing whether they were in the control or intervention group at follow-up. This study used an active control (suppression therapy).

Blinding of outcome assessors. Eight studies had unclear risk of detection bias because they did not report whether outcome assessors were blind to participant intervention conditions. One study had low risk of bias, as the authors explicitly indicated that the outcome assessors were blind to intervention assignment.

Outcome data. Six studies had low risk of attrition bias, one had high risk, and two were unclear.

Selective outcome reporting. Four studies had low risk of reporting bias. One study had unclear risk of bias. Four studies were determined to be at high risk of reporting bias, as cessation was not reported, although one of these explicitly stated that cessation was not the goal.

Other. Three studies reported an unequal distribution among groups of potential confounders at baseline, while six of the studies had equal distribution. There were no crossover studies; in
one study, it was possible that cross-contamination between treatments could have occurred. All of the studies utilized validated outcome measurements. One study had issues with clear definitions of the interventions. One study was identified as having problems with appropriate ITT analysis for outcomes with missing data, and two studies were unclear about ITT analysis.
### Table 3.2. Study Quality/Risk of Bias for Individual Included Studies

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Random Sequence Generation (selection bias)</th>
<th>Allocation Concealment (selection bias)</th>
<th>Blinding of Participants and Personnel (performance bias)</th>
<th>Blinding of Outcome Assessors (detection bias)</th>
<th>Completeness of Reporting Outcome Data (attrition bias)</th>
<th>Selective Outcome Reporting (reporting bias)</th>
<th>Other Biases</th>
<th>USPSTF Quality Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowen and Marlatt, 2009</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>High</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Brewer et al., 2011</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Davis, Mills, et al., 2013</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>High</td>
<td>Low</td>
<td>No</td>
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</tr>
<tr>
<td>Davis, Goldberg, et al., 2014a</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
<td>No</td>
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<tr>
<td>Davis, Manley, et al., 2014b</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
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<tr>
<td>Rogojanski, Vettese, and Antony, 2011a</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Ruscio et al., 2015</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Low</td>
<td>Unclear</td>
<td>Low</td>
<td>High</td>
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<td>No</td>
</tr>
<tr>
<td>Singh et al., 2014</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
<td>Unclear</td>
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<tr>
<td>Tang, Tang, and Posner, 2013</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
<td>High</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
KQ 1: What Are the Efficacy and Safety of Mindfulness Meditation Interventions, as an Adjunctive or Monotherapy, for Smoking Cessation or Reduction Compared with Treatment as Usual, Waitlists, No Treatment, or Other Active Treatments?

**Smoking Cessation**

Five of the nine included RCTs reported smoking cessation outcomes. Four of these reported seven-day point prevalence of abstinence from tobacco use in each study arm, as verified by carbon monoxide measurement (Brewer et al., 2011; Davis, Mills, et al., 2013; Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b). The other (Singh et al., 2014) relied on self-report. Three of the RCTs studied MTS (Davis, Mills, et al., 2013; Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b), one studied mindfulness training adapted from a manual on mindfulness meditation for substance abuse (Brewer et al., 2011), and one studied a program based on intention, mindful observation of thoughts, and meditation on the soles of the feet (Singh et al., 2014). Comparators were FFS (Brewer et al., 2011; Davis, Manley, et al., 2014b), quitline counseling (Davis, Goldberg, et al., 2014a), interactive learning for smokers (Davis, Mills, et al., 2013), and TAU (Singh et al., 2014). Follow-up times ranged from two to 40 weeks. Although two studies found that participants in mindfulness interventions had a significantly higher abstinence rate at follow-up than those in the comparator groups, the others did not report a statistically significant effect, and confidence intervals varied widely among studies (see Figure 3.2).

Pooled analysis indicates that the difference in cessation rates was not statistically significant, although the direction favored mindfulness meditation over the comparators (OR 3.64; CI 0.74, 16.13; 5 RCTs; I² 58%). The analysis detected moderate heterogeneity. We conducted a sensitivity analysis excluding Singh et al. (2014), as the study participants had mild intellectual disabilities. Results also showed no significant difference in cessation rates (OR 2.12; CI 0.37, 12.19; 4 RCTs; I² 39%), with more-precise confidence intervals, smaller effect, and less heterogeneity.
To determine the difference between the short- and long-term effects of mindfulness meditation, we pooled outcomes at the follow-up times closest to four weeks and then at long-term (>four weeks) follow-up. Three RCTs of MTS conducted by the same research group (Davis, Mills, et al., 2013; Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b) measured seven-day point prevalence of abstinence at four-week follow-up, and one RCT of training adapted from a manual on mindfulness meditation for substance abuse measured the same at two weeks (Brewer et al., 2011). All four studies verified cessation biologically. Comparators were the FFS program (Brewer et al., 2011; Davis, Manley, et al., 2014b), quitline counseling (Davis, Goldberg, et al., 2014a), and interactive learning for smokers (Davis, Mills, et al., 2013). Figure 3.3 displays the results; the pooled analysis showed that the difference in cessation rates between participants in mindfulness meditation and participants in the comparison groups was not statistically significant (OR 1.68; CI 0.67, 4.20; 4 RCTs; $I^2$ 26%). Little heterogeneity was detected.

**Smoking Cessation: Short-Term**

To determine the difference between the short- and long-term effects of mindfulness meditation, we pooled outcomes at the follow-up times closest to four weeks and then at long-term (>four weeks) follow-up. Three RCTs of MTS conducted by the same research group (Davis, Mills, et al., 2013; Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b) measured seven-day point prevalence of abstinence at four-week follow-up, and one RCT of training adapted from a manual on mindfulness meditation for substance abuse measured the same at two weeks (Brewer et al., 2011). All four studies verified cessation biologically. Comparators were the FFS program (Brewer et al., 2011; Davis, Manley, et al., 2014b), quitline counseling (Davis, Goldberg, et al., 2014a), and interactive learning for smokers (Davis, Mills, et al., 2013). Figure 3.3 displays the results; the pooled analysis showed that the difference in cessation rates between participants in mindfulness meditation and participants in the comparison groups was not statistically significant (OR 1.68; CI 0.67, 4.20; 4 RCTs; $I^2$ 26%). Little heterogeneity was detected.
Four RCTs that reported smoking cessation followed study participants for more than four weeks (Brewer et al., 2011; Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b; Singh et al., 2014); comparators were FFS (Brewer et al., 2011; Davis, Manley, et al., 2014b), quitline counseling (Davis, Goldberg, et al., 2014a), and TAU (Singh et al., 2014). Two RCTs studied MTS (Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b), one studied training adapted from a manual on mindfulness meditation for substance abuse (Brewer et al., 2011), and one studied a program based on intention, mindful observation of thoughts, and meditation on the soles of the feet (Singh et al., 2014). Figure 3.4 presents data from the longest follow-up (range: 17–40 weeks). In two studies, the mindfulness meditation groups had significantly higher cessation rates than the comparison groups; however, confidence intervals were very wide. In pooled analysis, differences in cessation rates between mindfulness intervention groups and comparison groups were not statistically significant (OR 3.32; CI 0.37, 29.52; 4 RCTs; I² 66%). Substantial heterogeneity was detected. When Singh et al. (2014) was excluded due to heterogeneity of population (mild intellectual disability), results were also statistically insignificant (OR 2.29; CI 0.74, 7.07; 3 RCTs; I² 29%); heterogeneity decreased considerably.
**Reduction in Use: Number of Cigarettes Smoked Per Day**

Four RCTs reported reduction in tobacco use measured by number of cigarettes smoked per day (Bowen and Marlatt, 2009; Brewer et al., 2011; Ruscio et al., 2015; Singh et al., 2014). Interventions included brief mindfulness instruction (Bowen and Marlatt, 2009), training adapted from a manual on mindfulness meditation for substance abuse (Brewer et al., 2011), brief mindfulness practice (Ruscio et al., 2015), and a program based on intention, mindful observation of thoughts, and meditation on the soles of the feet (Singh et al., 2014). Comparators were FFS (Brewer et al., 2011), cue exposure with no instruction (Bowen and Marlatt, 2009), sham meditation (Ruscio et al., 2015), and TAU (Singh et al., 2014). Overall, the difference in the number of cigarettes smoked per day between mindfulness participants and comparison group participants was not statistically significant (WMD 1.52; CI –1.03, 4.07; 4 RCTs, $I^2$ 16%), as displayed in Figure 3.5. Little heterogeneity was detected. Excluding Singh et al. (2014) resulted in more precise confidence intervals, and a smaller, still statistically insignificant effect (WMD 0.11; CI -0.14, 0.37; 3 RCTs, $I^2$ 0%).
Figure 3.5. Number of Cigarettes Smoked Per Day

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Cigarettes Smoked</th>
<th>WMD [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowen, 2009</td>
<td></td>
<td>0.80 [-1.02, 2.62]</td>
</tr>
<tr>
<td>Brewer, 2011</td>
<td></td>
<td>1.00 [-3.02, 5.02]</td>
</tr>
<tr>
<td>Ruscio, 2015</td>
<td></td>
<td>-0.50 [-6.05, 5.05]</td>
</tr>
<tr>
<td>Singh, 2014</td>
<td></td>
<td>3.70 [0.95, 6.44]</td>
</tr>
<tr>
<td>RE Model</td>
<td></td>
<td>1.52 [-1.03, 4.07]</td>
</tr>
</tbody>
</table>

- Total N = 332

Mean Days Abstinence

One study reported a continuous measure of smoking abstinence by collecting data on the number of days smoked in the first two weeks, as the authors stated that this has been shown to correlate well with six-month smoking cessation outcomes (Davis, Mills, et al., 2013). Smokers aged 18–29 years with regular episodes of binge drinking were randomized to either MTS or interactive learning for smokers. Independent t-tests showed that MTS participants had a significantly greater number of days of smoking abstinence in the first two weeks compared with participants in interactive learning for smokers in both ITT analysis (MTS 5.10 [SD 6.00]; interactive learning for smokers 2.04 [SD 3.98]; p=0.03) and analysis of completers (MTS 10.20 [SD 4.36]; interactive learning for smokers 5.10 [SD 5.00]; p=0.01).

Fagerstrom Test of Nicotine Dependence

Only one study reported the Fagerstrom score at both baseline and follow-up (Rogojanski, Vettese, and Antony, 2011a). Participants were randomly assigned to a brief suppression-based versus mindfulness-based strategy to help them manage cravings during an experimental cue
exposure to cigarettes. Nicotine dependence was measured using the Fagerstrom Test of Nicotine Dependence, which is a brief, six-item scale asking individuals to respond to multiple-choice questions. Higher scores indicate higher levels of dependence. Post hoc paired-sample t-tests indicated that participants’ Fagerstrom nicotine dependence scores were significantly reduced from baseline to one-week follow-up in the mindfulness condition (4.74 [SD 1.15] at baseline; 4.25 [SD 1.48] at follow-up; p=0.04) but not in the suppression condition (4.43 [SD1.50] at baseline; 4.61 [SD 1.59] at follow-up; p=0.55). However, the difference in mean Fagerstrom score between the mindfulness group and the suppression group at follow-up was not statistically significant (mean difference [MD] 0.23; CI −0.34, 0.80).

**Craving**

Due to the low number of studies and heterogeneity of outcome measures, a meta-analysis on nicotine craving could not be performed. Two studies (Davis, Manley, et al., 2014b; Ruscio et al., 2015) provided results that allowed the calculation of an effect. One of these (Ruscio et al., 2015) randomized 44 participants to either a brief mindfulness practice intervention or sham meditation, and then asked participants to rate the statement “I have strong urges to smoke” on a scale from 1-disagree to 7-strongly agree at one-week and two-week follow-up. Differences between groups were not statistically significant at either follow-up; MD was 0.22 (CI −0.47, 0.92) at one week and 0.66 (CI −0.06, 1.37) at two weeks, favoring the mindfulness group. The other study (Davis, Manley, et al., 2014b) randomized 175 participants to either mindfulness training or FFS and asked, “over the past 24 hours, how strong have your urges to smoke been on a scale of 0–10?” At follow-up (24 weeks), differences between the groups were not statistically significant (MD 0.41; CI 0.07, 0.75).

There were three additional studies that reported craving outcomes (Bowen and Marlatt, 2009; Rogojanski, Vettese, and Antony, 2011a; Tang, Tang, and Posner, 2013). The first of these studies (Tang, Tang and Posner, 2013) randomized 27 smokers to either integrative body-mind training or relaxation training. There was a significant decrease in craving in the mindfulness group (p<0.01) but not the relaxation group (p>0.05) at two-week follow-up. This study did not state how craving was measured or report the actual craving data. The second study (Bowen and Marlatt, 2009) randomized 123 undergraduate smokers to either brief mindfulness-based instructions or no instruction. There were no significant differences in responses to the ten-item short form of the Questionnaire of Smoking Urges over the four in-session time points (F(1,117)=2.21, p=0.140). The third of these studies (Rogojanski, Vettese, and Antony, 2011a) randomized 61 participants to either a mindfulness-based or a suppression-based strategy for coping with cigarette cravings. Neither the mindfulness nor the suppression groups experienced significant reduction in cravings, as measured on a 0 to 100 visual analog scale, at one-week follow-up.
Quit Attempts

No studies reported the number of quit attempts.

Health-Related Quality of Life

No studies reported quality of life measures.

Adverse Events

Three of the nine studies reported on adverse events. Two of these studies utilized mindfulness meditation interventions plus nicotine replacement and solely expressed that there were “no reportable medication reactions” among nicotine replacement users (Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b). Another study reported on adverse events related to the mindfulness intervention, stating that “no serious adverse events were reported in either treatment group” (Brewer et al., 2011).

Study Characteristic Moderators and Risk of Bias

Due to the small number of studies and heterogeneity of outcomes reported, we could not conduct a sensitivity analysis or meta-regression by study quality (risk of bias). The subquestions below attempt to assess the effect of intervention characteristics.

KQ 1a: Does the Effect Vary by the Type of Mindfulness Meditation Intervention?

The nine included studies varied in the types of interventions used, as described above. We did not identify any direct comparisons between different mindfulness interventions. Due to the small number of studies per intervention type and heterogeneity of outcome measures, we were able to perform quantitative analysis for only one intervention type (MTS) across studies. A meta-regression comparing the smoking cessation results of the three MTS studies with two non-MTS studies (Brewer et al., 2011; Singh et al., 2014) indicated a statistically significant effect of the intervention on treatment effect estimates (p=0.01).

Four studies described the interventions as mindfulness training (Brewer et al., 2011; Davis, Mills, et al., 2013; Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b). Three of these RCTs studied MTS; all were conducted by the same research group. Comparators were FFS (Davis, Manley, et al., 2014b), quitline counseling (Davis, Goldberg, et al., 2014a), and interactive learning for smokers (Davis, Mills, et al., 2013). The RCTs of MTS versus FFS and quitline counseling provided nicotine replacement to all participants, regardless of group assignment. We conducted a subgroup analysis to assess the effect of MTS on smoking cessation. Results are displayed in Figure 3.6.
Figure 3.6. Mindfulness Training for Smokers

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Quitter, MTS</th>
<th>OR [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davis, 2014b</td>
<td></td>
<td>1.04 [ 0.51 , 2.12 ]</td>
</tr>
<tr>
<td>Davis ITT, 2014a</td>
<td></td>
<td>1.62 [ 0.81 , 3.25 ]</td>
</tr>
<tr>
<td>Davis ITT, 2013</td>
<td></td>
<td>6.00 [ 0.67 , 53.68 ]</td>
</tr>
<tr>
<td>RE Model</td>
<td></td>
<td>1.44 [ 0.38 , 5.45 ]</td>
</tr>
<tr>
<td>I-squared=20.9%</td>
<td></td>
<td>Total N = 386</td>
</tr>
</tbody>
</table>

The odds ratio for cessation favored MTS but was not statistically significant (OR 1.44; CI 0.38, 5.45; 3 RCTs; I² 21%). Little heterogeneity was detected.

Another “training” study randomized 88 participants to either mindfulness training or FFS. Participants in the treatment group showed a greater rate of reduction in cigarette use during the treatment and maintained these gains during follow-up (p=0.001), with a trend toward greater point prevalence abstinence rates at the end of treatment (p=0.063), which was significant at the 17-week follow-up (p=0.012) (Brewer et al., 2011).

Three studies described their mindfulness interventions as brief; these reported on craving and/or cigarette quantity (Bowen and Marlatt, 2009; Ruscio et al., 2015). A brief mindfulness practice study randomized 44 smokers to either brief mindfulness practice or sham meditation and reported no significant difference in craving at either one-week or two-week follow-up. The authors of the study followed up on tobacco use daily. For quantity of cigarettes smoked, they found a significant effect of “day” for the treatment group, indicating that smoking declined over time, whereas in the control group, there was no effect of day (Ruscio et al., 2015). The study of brief mindfulness-based instructions randomized 123 undergraduate smokers to either this intervention or no instruction. There were no differences between groups in urges to smoke over
the four in-session time points. Regarding number of cigarettes smoked, there was a significant difference between rates of smoking at baseline and day seven for the mindfulness group, but not the control group ( Bowen and Marlatt, 2009). The final brief intervention study randomized 27 smokers to either brief integrative body-mind training or relaxation training. There was significant smoking reduction in the body-mind training group (p<0.01), but no significant reduction in the relaxation group; there was a significant decrease in craving in the mind-body group (p<0.01) but not the relaxation group; outcome data were not reported ( Tang, Tang, and Posner, 2013).

Finally, the intervention in one study was described as mindfulness-based therapy ( Singh et al., 2014) and in another as mindfulness meditation ( Rogojanski, Vettese, and Antony, 2011a). In the first ( Singh et al., 2014), 51 participants with mild intellectual disabilities were randomized to either the mindfulness meditation or TAU group. Among the participants who remained in the study until smoking cessation was successful or for the full 40 weeks, 100 percent of the treatment completers in the experimental condition reached full smoking cessation, whereas only 38.9 percent of treatment completers in the TAU condition reached full smoking cessation. According to ITT analysis, the difference between numbers of cigarettes smoked at the conclusion of the treatment phase between the experimental condition and TAU was significant. In the other study ( Rogojanski, Vettese and Antony, 2011a), 61 participants were randomized to either mindfulness-based strategy or suppression for coping with cigarette cravings. Neither the mindfulness nor the suppression groups experienced significant reduction in cravings. Although all participants reported smoking an average of 3.4 fewer cigarettes at the follow-up compared with baseline, there was no significant difference between study groups in amount of smoking at follow-up.

KQ 1b: Does the Effect Differ When the Intervention Is Offered as an Adjunctive Therapy Rather Than as a Monotherapy?

We did not identify any head-to-head comparisons between mindfulness interventions offered as adjunctive therapy versus monotherapy. Due to the small number of studies and heterogeneity of outcomes, meta-analysis could not be performed to address this question.

Two RCTs of mindfulness meditation provided nicotine replacement; these reported mixed results. Another two studies allowed nicotine replacement, but this was not part of the treatment protocol; these reported significant positive results in favor of mindfulness meditation. Finally, five RCTs of monotherapy reported mixed results. The results are described below.

Two studies provided nicotine replacement along with the mindfulness intervention ( Davis, Goldberg, et al., 2014a; Davis, Manley, et al., 2014b). One randomized 196 smokers with low socioeconomic status to mindfulness training plus nicotine replacement or to counseling plus nicotine replacement ( Davis, Goldberg, et al., 2014a). There was a significant difference between groups in six-month abstinence rates among those who completed follow-up, favoring the
mindfulness group (38.7 percent versus 20.6 percent, p=0.05); however, ITT analysis showed no significant difference between the biochemically confirmed seven-day point prevalence abstinence rates. The second study randomized 175 participants to mindfulness training plus nicotine replacement or to FFS plus nicotine replacement (Davis, Manley, et al., 2014b). There was no significant difference between interventions on six-month smoking abstinence rates or cravings.

Two studies allowed nicotine replacement therapy, but this was not part of the treatment protocol (Brewer et al., 2011; Singh et al., 2014). In one, 88 participants were randomized to either mindfulness training or FFS and were neither encouraged nor discouraged from using nicotine replacement during active treatment or in the posttreatment follow-up phase (Brewer et al., 2011). Participants in the mindfulness group showed a greater rate of reduction in cigarette use during the intervention and maintained these gains with a trend toward greater point prevalence abstinence rates at the end of intervention (36 percent versus 15 percent, p=0.063), which was significant at the 17-week follow-up (31 percent versus 6 percent, p=0.012). The other study randomized 51 participants with mild intellectual disabilities to either mindfulness meditation or TAU, and stated that TAU could include nicotine replacement therapy (used by four of 26 randomized to TAU) or behavior therapy plus nicotine replacement therapy (used by one participant in TAU group) (Singh et al., 2014). Use of nicotine replacement by those in the mindfulness intervention group was not described. Among the participants who remained in the study until smoking cessation was successful or for the full 40 weeks, 100 percent of the treatment completers in the experimental condition reached full smoking cessation, whereas only 38.9 percent of treatment completers in the TAU group reached full smoking cessation. According to ITT analysis, there was a significant difference between numbers of cigarettes smoked at the conclusion of the treatment phase between the mindfulness group (MD 12.40 [SD 34.50]) and the TAU group (MD 40.62, [SD 40.27]; p<.05).

In the remaining five studies, the mindfulness meditation interventions were conducted as monotherapy (Bowen and Marlatt, 2009; Davis, Mills, et al., 2013; Rogojanski, Vettese, and Antony, 2011a; Ruscio et al., 2015; Tang, Tang, and Posner, 2013). One study randomized 44 smokers to either brief mindfulness practice or sham meditation (Ruscio et al., 2015); there was no significant effect of the intervention on craving at either one-week (MD 0.22; CI −0.47, 0.92) or two-week follow-up (MD 0.66; CI −0.06, 1.37). For quantity of cigarettes smoked, they found a significant effect of “day” for the treatment group (F(1,19)=18.0; parameter estimate −0.37; standard error 0.09; p=0.0004), indicating that smoking declined over time, whereas in the control group, there was no effect of day (F(1, 15)=1.15; parameter estimate −0.09; standard error 0.08; p=0.30. Another study randomized 55 smokers aged 18–29 years with regular episodes of binge drinking to either mindfulness training for smokers or interactive learning for smokers (Davis, Mills, et al., 2013). ITT analysis showed no significant difference between the biochemically confirmed seven-day point prevalence abstinence rates at two weeks post-quit for MTS (20.0 percent) and interactive learning for smokers (4.0 percent; p=0.08). Another study
randomized 27 smokers to either integrative body-mind training or relaxation training (Tang, Tang, and Posner, 2013). There was significant smoking reduction in the mindfulness group (p<0.01) but no significant reduction in the relaxation group (p>0.05), and a significant decrease in craving in the mindfulness group (p<0.01) but not the relaxation group (p>0.05). Another study randomized 123 undergraduate smokers to either brief mindfulness-based instructions or no instruction (Bowen and Marlatt, 2009). There were no significant effects of mindfulness instruction on urges to smoke over the four in-session time points. Both groups decreased the number of cigarettes smoked per day; difference between groups was not significant. Finally, 61 participants were randomized to either mindfulness-based strategy or suppression for coping with cigarette cravings; neither group experienced significant reduction in cravings (Rogojanski, Vettese and Antony, 2011a).

KQ 1c: Does the Effect Vary Depending on the Duration and Frequency of Mindfulness Meditation (i.e., Dose Effect)?

We did not identify any direct comparisons. The duration and frequency in the included studies varied widely.

The length of interventions ranged from one day to eight weeks in the nine included RCTs. A meta-regression did not detect a systematic effect of the length of intervention on the study outcome, but the number of studies was small, included studies had a limited range in duration varying only from one day to four weeks, and the analysis could be performed only for the outcome number of cigarettes smoked (p=0.849). The equivalent analysis for the outcome smoking cessation would include the same studies shown in KQ 1a, which compares the MTS studies with two other, short-term interventions.

We categorized the frequency according to number of hours per week that participants were expected to spend in session, homework, and other practice. Interventions requiring less than one hour per week were categorized as low, those requiring one to four hours per week were categorized as medium, and those requiring more than four hours were categorized as high.

Two RCTs reported on a one-time training (Bowen and Marlatt, 2009; Rogojanski, Vettese, and Antony, 2011a). In the first of these, 123 undergraduate smokers were randomized to either brief mindfulness-based instructions or no instruction, and participants spent one to four hours in session, homework, and other practice each week (Bowen and Marlatt, 2009). There were no significant differences between groups in urges to smoke over the four in-session time points. Regarding number of cigarettes smoked, there was a significant difference between rates of smoking at baseline and day seven for the mindfulness group (p=0.000) but not for the control group (p=0.436). The second one-time training study randomized 61 participants to either mindfulness-based strategy or suppression for coping with cigarette cravings (Rogojanski, Vettese, and Antony, 2011a). The frequency was low, as less than one hour was spent in mindfulness practice each week. Neither the mindfulness nor the suppression groups experienced
significant reduction in cravings, and there were no significant differences between study groups in amount of smoking at follow-up.

Regarding frequency, MTS was categorized as a high-frequency intervention, as was the study of mindfulness meditation conducted by Singh et al. (2014). A subgroup analysis that included only the RCTs of high-frequency interventions found smoking cessation results not statistically different from comparator interventions (OR 2.84; CI 0.35, 22.70; 4 RCTs; I²=58%). As only one other RCT reported smoking cessation, meta-regression could not be conducted.
Chapter Four: Discussion

Summary of Findings

In this chapter, we first summarize the findings in response to each key question, along with the quality of the evidence. We briefly discuss the findings in the context of prior systematic reviews. We then describe the limitations of both our methods and the body of literature and provide suggestions for further research.

Nine RCTs of mindfulness meditation intervention for tobacco use met inclusion criteria. The studies used a wide variety of interventions and comparators. Studies compared mindfulness meditation with FFS (considered standard of care for smoking cessation), telephone counseling (in addition to nicotine replacement), interactive learning for smokers, relaxation training, suppression strategies, sham meditation, cue exposure with no instruction, or TAU, which could include counseling or nicotine replacement. Intervention duration and intensity varied considerably, as did outcome measures reported. Important aspects of methodology, such as randomization sequence generation, allocation concealment, and whether outcome assessors were blinded, were often unreported. No RCTs were rated as good quality, and results were mixed. Effects on smoking cessation (abstinence) were not statistically different from comparator interventions (OR 3.46; CI 0.74, 16.13; 5 RCTs; I² 58%). The number of cigarettes per day was not statistically different between meditation and comparator interventions (WMD 1.52; CI −1.03, 4.07; 4 RCTs; I² 16%). The quality of evidence for efficacy of mindfulness meditation for tobacco use cessation in the short term (two to four weeks) is low. The quality of evidence for reduction in tobacco use (long-term cessation) and reduction in cravings is very low.

Details are described below and displayed in Table 4.1, along with the quality of evidence rating for the main key question and its subquestions. For each, the table displays the number of RCTs and their quality ratings, total sample size, overall results, and whether the study results are inconsistent, indirect, or imprecise. Consistency refers to consistency of direction (positive or negative) of the studies; it is not possible to judge consistency if only one study exists. Precision refers to the width of confidence intervals; results are imprecise if the confidence intervals span effect sizes with possible different clinical conclusions. Directness reflects how well various aspects of studies (e.g., population, intervention, comparator) address the question. Important reasons for downgrading the quality of evidence ratings are indicated with asterisks.
KQ 1: What Are the Efficacy and Safety of Mindfulness Meditation Interventions, as an Adjunctive or Monotherapy, for Smoking Cessation or Reduction Compared with Treatment as Usual, Waitlists, No Treatment, or Other Active Treatments?

Five RCTs reported smoking cessation, which allowed the conduct of three meta-analyses by follow-up time: longest follow-up, two to four weeks, and 17 to 24 weeks. Pooled results for each of these meta-analyses found that although odds ratios favored the mindfulness intervention, differences in abstinence rates between the mindfulness meditation groups and the comparators were not statistically significant. The odds ratios resulting from the meta-analyses of longer follow-up times had very wide confidence intervals. As displayed in Table 4.1, due to the small number of studies, diversity of interventions and comparators, and imprecision of results, quality of evidence is rated low for short-term (four weeks or less) cessation and very low for long-term cessation.

Results of four RCTs reporting the number of cigarettes per day at both baseline and follow-up were pooled. Results (displayed in Table 4.1) favored mindfulness meditation; however, the difference was not statistically significant. In addition, the weighted mean difference of 1.5 cigarettes per day is not clinically meaningful. Due to the low number of RCTs and inconsistency of results, there is very low quality evidence that reduction in smoking does not differ between participants in mindfulness interventions and the comparator interventions.

Five RCTs measured nicotine craving at baseline and follow-up; only one reported a significant difference between the mindfulness meditation group and the comparator group at follow-up. Thus, as displayed in Table 4.1, quality of evidence for this outcome is rated very low.

No studies reported quality of life measures.

Two studies utilized mindfulness meditation interventions plus nicotine replacement and solely expressed that there were “no reportable medication reactions” among nicotine replacement users, while another study that reported on adverse events related to the mindfulness intervention stated that “no serious adverse events were reported in either treatment group.” In sum, it appears that in the nine included studies, there were no adverse events resulting from mindfulness meditation interventions. However, quality of evidence is very low, given that two-thirds of the studies did not mention tracking adverse events.

KQ 1a: Does the Effect Vary by the Type of Mindfulness Meditation Intervention?

There were no head-to-head trials of different mindfulness interventions for tobacco use. The interventions studied in the nine RCTs varied widely. A meta-analysis including only the three RCTs of MTS favored MTS, but this was not statistically significant. A meta-regression comparing the smoking cessation results of these three MTS studies with the two non-MTS studies that reported this outcome had statistically significant results, indicating that the treatment effect was associated with the intervention. Three other RCTs studied interventions
described as “brief” by the authors; these reported results for craving and/or reduction in tobacco use. Results were mixed, as were the results of the other three RCTs. In sum, quality of evidence for MTS is low, while quality is very low for the other intervention types.

**KQ 1b: Does the Effect Differ When the Intervention Is Offered as an Adjunctive Therapy Rather Than as a Monotherapy?**

Due to heterogeneity of outcome measures, it was not possible to conduct a subgroup analysis or meta-regression to address this subquestion. Results for the monotherapy and adjunct therapy studies were inconsistent. Two other studies that allowed nicotine replacement at the participant’s discretion (rather than by study protocol) reported significant smoking cessation results favoring the mindfulness interventions. As displayed in Table 4.1, due to the small number of studies, lack of precision, and heterogeneity of outcomes reported, quality of evidence for this question is very low.

**KQ 1c: Does the Effect Vary Depending on the Duration and Frequency of Mindfulness Meditation (i.e., Dose Effect)?**

Meta-regression analyses found no significant effect of length of intervention on reduction in number of cigarettes smoked per day. A subgroup analysis that included only the highest-frequency interventions (requiring more than four hours per week participation in sessions, homework, and meditation) found smoking cessation results not statistically different from comparator interventions. Quality of evidence that effects differ by length or frequency of intervention is very low, as displayed in Table 4.1.
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Study Design (number of RCTs and participants)</th>
<th>Findings (direction and magnitude of effect)</th>
<th>Study Limitations (study quality; risk of bias)</th>
<th>GRADE of Evidence for Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>KQ 1 Smoking cessation, longest follow-up</strong></td>
<td>5 RCTs, 524 participants</td>
<td>OR 3.46 (CI 0.74, 16.13), n.s.</td>
<td>4 fair quality, 1 poor*</td>
<td>Consistent; moderate heterogeneity*</td>
</tr>
<tr>
<td><strong>Smoking cessation, 2 to 4 weeks follow-up</strong></td>
<td>4 RCTs, 473 participants</td>
<td>OR 1.68 (CI 0.67, 4.20), n.s.</td>
<td>3 fair quality, 1 poor*</td>
<td>Consistent; low heterogeneity</td>
</tr>
<tr>
<td><strong>Smoking cessation, &gt;4 weeks follow-up</strong></td>
<td>4 RCTs, 469 participants</td>
<td>OR 3.32 (CI 0.37, 29.52), n.s.</td>
<td>4 fair quality*</td>
<td>Consistent; substantial heterogeneity*</td>
</tr>
<tr>
<td><strong>Number of cigarettes per day</strong></td>
<td>4 RCTs, 332 participants</td>
<td>WMD 1.52 (CI −1.03, 4.07), n.s.</td>
<td>2 fair quality, 2 poor*</td>
<td>Inconsistent*; low heterogeneity</td>
</tr>
<tr>
<td><strong>Cravings</strong></td>
<td>5 RCTs, 389 participants</td>
<td>Pooling not possible, 1 RCT with positive significant results</td>
<td>1 fair quality, 4 poor*</td>
<td>Inconsistent*</td>
</tr>
<tr>
<td><strong>Health-related quality of life</strong></td>
<td>Not reported in any studies</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Mindfulness meditation vs. FFS</strong></td>
<td>2 RCTs, 223 participants</td>
<td>Both favor mindfulness, differences in cessation significant in 1 RCT</td>
<td>2 fair quality*</td>
<td>Consistent</td>
</tr>
<tr>
<td><strong>Mindfulness meditation vs. cue exposure with no instruction</strong></td>
<td>1 RCT, 123 participants</td>
<td>Number of cigarettes per day, MD 0.80 (CI −1.02, 2.62), n.s.</td>
<td>1 poor quality</td>
<td>No replication**</td>
</tr>
<tr>
<td><strong>Mindfulness meditation vs. cue exposure with urge suppression</strong></td>
<td>1 RCT, 61 participants</td>
<td>Fagerstrom Test for Nicotine Dependence, MD 0.23 (CI −0.34, 0.80), n.s.</td>
<td>1 poor quality</td>
<td>No replication**</td>
</tr>
<tr>
<td><strong>Mindfulness meditation vs. quitline counseling</strong></td>
<td>1 RCT, 196 participants</td>
<td>ITT, cessation verified by carbon monoxide (CO); OR 1.78 (CI 0.85, 3.74), n.s.</td>
<td>1 fair quality</td>
<td>No replication**</td>
</tr>
<tr>
<td><strong>Mindfulness meditation vs. sham meditation</strong></td>
<td>1 RCT, 44 participants</td>
<td>Number of cigarettes per day, MD −0.50 (CI −6.05, 5.05), n.s.</td>
<td>1 poor quality</td>
<td>No replication**</td>
</tr>
<tr>
<td>Outcome</td>
<td>Study Design (number of RCTs and participants)</td>
<td>Findings (direction and magnitude of effect)</td>
<td>Study Limitations (study quality; risk of bias)</td>
<td>GRADE of Evidence for Outcome</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Mindfulness meditation vs. relaxation training</td>
<td>1 RCT, 27 participants</td>
<td>“Significant smoking reduction in the intervention group (p&lt;0.01) but no significant reduction in the relaxation training group and a significant decrease in craving in the intervention (p&lt;0.01) but not the relaxation group;” exact results not reported</td>
<td>1 poor quality No replication** Direct Not reported</td>
<td>Very low</td>
</tr>
<tr>
<td>Mindfulness meditation vs. TAU</td>
<td>1 RCT, 51 participants</td>
<td>Cessation, nonverified, non-ITT, OR 71.67 (CI 3.76, 1,364.30)</td>
<td>1 fair quality No replication** Direct Imprecise*</td>
<td>Very low</td>
</tr>
<tr>
<td>Mindfulness meditation vs. interactive learning</td>
<td>1 RCT, 55 participants</td>
<td>Cessation, verified by CO, OR 6.00 (CI 0.67, 53.68), n.s.</td>
<td>1 poor quality No replication** Direct Imprecise*</td>
<td>Very low</td>
</tr>
<tr>
<td><strong>KQ 1a</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTS</td>
<td>3 RCTs, 386 participants</td>
<td>Cessation OR 1.44 (CI 0.38, 5.45), n.s.</td>
<td>2 fair quality, 1 poor*, all RCTs by same author Consistent Direct Precise</td>
<td>Low</td>
</tr>
<tr>
<td>Brief mindfulness training</td>
<td>3 RCTs, 194 participants</td>
<td>Mixed results</td>
<td>3 poor quality* Inconsistent* Direct Imprecise*</td>
<td>Very low</td>
</tr>
<tr>
<td>Meta-regression cessation: MTS vs. non-MTS</td>
<td>5 RCTs, 524 participants</td>
<td>The meta-regression suggested an effect of the type of intervention (p=0.01)</td>
<td>4 fair quality, 1 poor*, few non-MTS studies that could be analyzed* NA Indirect** Precise</td>
<td>Very low</td>
</tr>
<tr>
<td><strong>KQ 1b</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monotherapy</td>
<td>5 RCTs, 310 participants</td>
<td>Very few significant differences between groups in craving or tobacco use</td>
<td>5 poor quality* Inconsistent* Direct Imprecise*</td>
<td>Very low</td>
</tr>
<tr>
<td>Adjunct to nicotine replacement</td>
<td>2 RCTs*, 139 participants</td>
<td>Both favor mindfulness, but differences in cessation n.s. per ITT analyses</td>
<td>2 fair quality* Consistent Direct Imprecise*</td>
<td>Very low</td>
</tr>
<tr>
<td>Unclear; nicotine replacement allowed, but not provided by study</td>
<td>2 RCTs*, 129 participants</td>
<td>Both report significant difference in long-term cessation favoring mindfulness</td>
<td>2 fair quality* Consistent Direct Imprecise*</td>
<td>Very low</td>
</tr>
<tr>
<td>Outcome</td>
<td>Study Design (number of RCTs and participants)</td>
<td>Findings (direction and magnitude of effect)</td>
<td>Study Limitations (study quality; risk of bias)</td>
<td>Inconsistency</td>
</tr>
<tr>
<td>---------</td>
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<tr>
<td>KQ 1c</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency: Low (&lt;1 hour per week)</td>
<td>1 RCT, 123 participants</td>
<td>No significant reduction in cravings in either group; difference in number of cigarettes smoked vs. comparator n.s.</td>
<td>1 poor quality*</td>
<td>No replication**</td>
</tr>
<tr>
<td>Frequency: Medium (1–4 hours per week)</td>
<td>4 RCTs, 282 participants</td>
<td>Mixed results, significant difference in cessation in 1 RCT</td>
<td>1 fair quality, 3 poor*</td>
<td>Inconsistent*</td>
</tr>
<tr>
<td>Frequency: High (&gt;4 hours per week)</td>
<td>4 RCTs, 437 participants</td>
<td>Smoking cessation OR 2.84 (CI 0.35, 22.70), n.s.</td>
<td>3 fair quality, 1 poor*</td>
<td>Consistent; considerable heterogeneity*</td>
</tr>
<tr>
<td>Meta-regression length of intervention and number of cigarettes smoked</td>
<td>4 RCTs, 332 participants</td>
<td>The meta-regression did not suggest a systematic effect (p=0.849)</td>
<td>2 fair quality, 2 poor*</td>
<td>NA</td>
</tr>
</tbody>
</table>

NOTE: * = downgraded by one level; ** = downgraded by two levels. MM = mindfulness meditation; NA = not applicable; n.s. = not statistically significant.
Other Reviews in this Area

The results of this review are comparable to those reported in previous reviews that found inconclusive evidence on mindfulness meditation for smoking cessation. A 2013 systematic review that examined both yoga and meditation as mind-body practices for smoking cessation (Carim-Todd, Mitchell, and Oken, 2013) included 14 studies; three were RCTs of mindfulness-based interventions that were also included in our review (Bowen and Marlatt, 2009; Brewer et al., 2011; Rogojanski, Vettese, and Antony, 2011a). Two of these found significant differences favoring the mindfulness interventions (Bowen and Marlatt, 2009; (Rogojanski, Vettese, and Antony, 2011a). Heterogeneity prevented performing a meta-analysis.

A more recent systematic review found that mindfulness-based interventions yielded mixed results (de Souza et al., 2015). Outcomes reported included smoking cessation, number of cigarettes smoked, moderation of the strength of the relationship between craving and smoking, and the development of coping strategies to deal with triggers to smoke. Substantial heterogeneity between studies compromised the authors’ ability to perform a meta-analysis. That recent review included 13 articles on RCTs; our systematic review included six of these (Bowen and Marlatt, 2009; Brewer et al., 2011; Davis, Mills, et al., 2013; Davis, Goldberg, et al., 2014a; Rogojanski, Vettese, and Antony, 2011a; Singh et al., 2014). Another RCT included in the de Souza et al. (2015) review was an unpublished manuscript by Davis and colleagues; we believe this was later published as Davis, Manley, et al. (2014b), which we also included. An unpublished abstract by Schuman-Olivier was excluded as a secondary analysis of Brewer et al. (2011). One study was excluded because participants were not randomized (Altner, 2002). Two RCTs by the same authors (Ussher, West, et al., 2006; Ussher, Cropley, et al., 2009) were excluded because the intervention did not meet our definition of mindfulness meditation (these studies compared the effect of isometric exercise and body scan with passive sitting). Another RCT was excluded because it did not report cessation, attempts to quit, or reduction in use (Adams et al., 2013). Finally, an RCT was included twice in the de Souza review due to duplicate publication in different journals (Rogojanski, Vettese, and Antony, 2011a; Rogojanski, Vettese, and Antony, 2011b).

Strengths and Limitations

This review has several strengths: an a priori research design, duplicate study selection and data abstraction of study information, a comprehensive search of electronic databases, risk of bias assessments, and comprehensive quality of evidence assessments used to formulate review conclusions. However, some limitations are worth noting. First, only a small number of studies met our inclusion criteria, which limited our ability to conduct meta-analyses across intervention types, comparators, and length of intervention, including whether treatment was adjunctive or monotherapy. Furthermore, the study quality of those articles included in our review ranged from
fair to poor, primarily due an inability to blind participants and personnel, possible reporting bias, and unclear or inappropriate ITT analyses. In addition, five of the nine included RCTs did not report on randomization sequence generation, none reported on allocation concealment, and eight did not report whether outcome assessors were blinded. We did not contact individual study authors; results and quality ratings reported in the review are based on published data. (Suggestions for improvements in reporting are noted in the section below.) Importantly, none of the included studies noted a priori power calculation with sufficient power to detect small differences between study groups. Finally, only three studies reported any details on the absence or existence of adverse events, limiting our ability to assess the safety of mindfulness meditation.

Implications for Future Research and Practice

Similar to previous reviews in this area, we conclude that the weaknesses in the body of evidence prevent any strong conclusions about mindfulness meditation for tobacco use. Few studies were available for specific forms of mindfulness mediation other than MTS. Only one-third of the studies collected information on adverse events. Several studies were “pilots” that did not report smoking cessation outcomes. Importantly, none of the studies reported an a priori power calculation with targeted sample size achieved. Other important aspects of methodology were unreported in most of the included RCTs.

In sum, more well-designed, rigorous, and large RCTs are needed in order to develop an evidence base that can more decisively provide estimates of the effectiveness of mindfulness mediation for tobacco use. Future studies should measure smoking cessation and achieve a sample size large enough to detect statistical differences in this outcome. Although expensive, chemical confirmation of cessation is encouraged for scientific validity. Studies should follow up with participants for six to 12 months in order to assess the effects of meditation on long-term cessation; adherence to mindfulness practice, co-interventions, comparator interventions, and simultaneous use of other therapies should be monitored frequently.

Future publications on RCTs of mindfulness meditation should adhere to CONSORT (CONsolidated Standards of Reporting Trials) standards (Schulz et al., 2010). The CONSORT statement was developed by researchers, guideline developers, and journal editors to improve the reporting of RCTs, enabling readers to understand a study’s methodology. According to CONSORT, this can be achieved only through complete adherence and transparency by authors. CONSORT requires reporting of randomization sequence generation, concealment of allocation, blinding of outcomes assessors, and many other aspects of methodology. As of December 2015, 585 journals have endorsed the CONSORT statement, including top journals such as the *British Medical Journal*, *Journal of the American Medical Association* (JAMA), *PLoS One*, *American Journal of Public Health*, and complementary and alternative medicine journals, such as *Complementary Therapies in Clinical Practice*. 

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Finally, no included studies focused on active military or veteran populations. Future RCTs incorporating military-related eligibility criteria could provide evidence more applicable to pain resulting from military service and evidence for use by decisionmakers in military and veteran health systems.
Appendix A: Search Strategy

PubMed

**TIME PERIOD COVERED:**
Inception to 7/10/2015

**LANGUAGE:**
English

**SEARCH STRATEGY:**
Mindfulness”[Mesh]) OR “Meditation”[Mesh] OR mindfulness* or mindfulness-based or mbsr or mbct OR m-bct OR meditation OR meditat* OR Vipassana OR satipaṭṭhāna OR anapanasati OR Zen OR Sudarshan OR zazen OR shambhala OR buddhis*
AND
AND
systematic[sb] OR systematic review* OR random* OR rct* OR randomized controlled trial*[pt]
OR “Randomized Controlled Trial” [Publication Type] OR “Randomized Controlled Trials as Topic”[Mesh] OR meta-analy* OR metaanaly* OR meta analy*

====================================================================

PsycINFO

**TIME PERIOD COVERED:**
Inception to 7/10/2015

**LANGUAGE:**
English

**SEARCH STRATEGY:**
TI (mindfulness* or mindfulness-based or mbsr or mbct or m-bct or meditation or meditat* OR Vipassana OR Zen OR Sudarshan OR zazen OR shambhala OR buddhis* OR satipatthana OR anapanasati ) OR AB (mindfulness* or mindfulness-based or mbsr or mbct or m-bct or meditation or meditat* OR Vipassana OR Zen OR Sudarshan OR zazen OR shambhala OR buddhis* OR satipatthana OR anapanasati ) OR SU ( (“Mindfulness” OR “Meditation”) )
AND
TI (tobacco OR cigarette* OR smoking OR smoker* ) OR AB (tobacco OR cigarette* OR smoking OR smoker* ) OR SU ( “Smoking Cessation” OR “tobacco smoking” )
AND
[FILTER:
Narrow by Methodology: - meta analysis

39
Narrow by Methodology: - systematic review
Narrow by Methodology: - treatment outcome/clinical trial
Narrow by Methodology: - quantitative study
Narrow by Methodology: - empirical study
Search modes - Find all search terms

OR
TI (“systematic review” OR random* OR meta-analy* OR metaanaly* OR meta analy* ) OR SU
( “systematic review” OR random* OR meta-analy* OR metaanaly* OR meta analy* ) OR AB
( “systematic review” OR random* OR meta-analy* OR metaanaly* OR meta analy* )

=====================================================================  

CINAHL (Cumulative Index to Nursing and Allied Health Literature)

TIME PERIOD COVERED:
Inception to 7/20/2015

LANGUAGE:
English

SEARCH STRATEGY:
TI ( mindfulness* or mindfulness-based or mbsr or mbct OR m-bct OR meditation OR meditat* OR Vipassana OR satipaṭṭhāna OR anapanasati OR Zen OR Sudarshan OR zazen OR shambhala OR buddhis* ) OR AB ( mindfulness* or mindfulness-based or mbsr or mbct OR m-bct OR meditation OR meditat* OR Vipassana OR satipaṭṭhāna OR anapanasati OR Zen OR Sudarshan OR zazen OR shambhala OR buddhis* ) OR SU ( mindfulness* or mindfulness-based or mbsr or mbct OR m-bct OR meditation OR meditat* OR Vipassana OR satipaṭṭhāna OR anapanasati OR Zen OR Sudarshan OR zazen OR shambhala OR buddhis* )
AND
TI ( tobacco OR cigarette* OR smoking OR smoker* ) OR AB ( tobacco OR cigarette* OR smoking OR smoker* ) OR SU ( tobacco OR cigarette* OR smoking OR smoker* )
AND
TI ( “systematic review” OR random* OR meta-analy* OR metaanaly* OR meta analy* ) OR AB ( “systematic review” OR random* OR meta-analy* OR metaanaly* OR meta analy* ) OR SU ( “systematic review” OR random* OR meta-analy* OR metaanaly* OR meta analy* )

=====================================================================  

CENTRAL (Cochrane Central Register of Controlled Trials)

TIME PERIOD COVERED:
Inception to 7/20/2015

LANGUAGE:
English
SEARCH STRATEGY:
mindfulness* or mindfulness-based or mbsr or mbct or m-bct or meditation or meditat* or Vipassana or satipaṭṭhāna or anapanasati or Zen or Sudarshan or zazen or shambhala or buddhis*:ti,ab,kw (Word variations have been searched)
AND
racco or cigarette* or smoking or smoker*:ti,ab,kw (Word variations have been searched)

-----------------------------------------------

AMED (Allied and Complementary Medicine Database)

TIME PERIOD COVERED:
Inception to 7/21/2015

LANGUAGE:
English

SEARCH STRATEGY:
mindfulness* or mindfulness-based or mbsr or mbct or m-bct or meditation or meditat* or Vipassana or satipaṭṭhāna or anapanasati or Zen or Sudarshan or zazen or shambhala or buddhis*
AND
racco or cigarette* or smoking or smoker*
Appendix B: Excluded Full-Text Articles

Reason Excluded: Conference Abstract


Reason Excluded: Design (Not RCT)


Reason Excluded: Off-Topic (Not Mindfulness Meditation or Tobacco Use)


Reason Excluded: No Relevant Outcomes


Appendix C: Evidence Table of Included Studies

<table>
<thead>
<tr>
<th>Study Details</th>
<th>Participants</th>
<th>Invention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference: Bowen and Marlatt, 2009</td>
<td>Number of Patients: 123 randomized</td>
<td>Content of Intervention: Participants in the mindfulness group received instructions to accept feelings, sensations, or thoughts in a mindful, nonjudgmental fashion, based on techniques described by Marlatt (Marlatt and Gordon, 1985) and on those used in similar research (e.g., Hayes, et al. 1999). They were given “urge-surfing” instructions in which one “rides” the urge through the fluctuations in its intensity. The cue exposure trial was delivered in four stages, each stage lasting approximately 4–6 minutes, and each with increasing levels of intensity.</td>
<td>Abstinence Rate: Not Reported</td>
</tr>
<tr>
<td>Country: United States or Canada</td>
<td>Baseline Tobacco Use: ≤10 cigarettes per day</td>
<td>Setting: Unclear</td>
<td>Reduction:</td>
</tr>
<tr>
<td>Purpose: To investigate effects of a brief mindfulness-based instruction set, based on Marlatt’s “urge-surfing” technique, on smoking-related urges and behavior</td>
<td>Comorbid Conditions: Not Reported</td>
<td>Dosage: Medium (1–4 hours spent in session, homework, and other each week)</td>
<td>• 1-week follow-up, Number of cigarettes per day: MD 0.80 (CI −1.02, 2.62)</td>
</tr>
<tr>
<td>Quality Rating: Poor</td>
<td>Mean Age: 20.33 (SD 3.34)</td>
<td>Co-interventions: None</td>
<td>Adverse Events: No mention</td>
</tr>
<tr>
<td></td>
<td>Gender (% Male): 73.2%</td>
<td>Comparator: Cue exposure with no instructions for coping</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inclusion Criteria: At least 18 years old, current cigarette smoker, and have some interest in cutting down or quitting.</td>
<td>Primary Endpoints: Number of cigarettes per day, cravings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria: Currently involved in a smoking cessation program.</td>
<td>Power Calculation: No</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Follow-Up Time: 1 week</td>
<td></td>
</tr>
</tbody>
</table>
Reference: Brewer et al., 2011  
Country: United States or Canada  
Purpose: To assess the efficacy of mindfulness training versus FFS using 1-week point prevalence abstinence and number of cigarettes smoked per day as primary endpoints at treatment completion and a 17-week follow-up. The secondary objective was to assess correlations between the amount of completed home practice in both treatment arms and smoking outcomes.  
Quality Rating: Fair

<table>
<thead>
<tr>
<th>Study Details</th>
<th>Participants</th>
<th>Invention</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Reference: Brewer et al., 2011 | Number of Patients: 88 randomized, 87 analyzed | Content of Intervention: Mindfulness training was adapted for active smoking cessation from a previous mindfulness training manual for drug relapse prevention. The overarching theme of momentary awareness and acceptance of cravings and affect was introduced and reinforced in complementary ways. | Abstinence Rate:  
- 4-week follow-up: Treatment: 36%, Control: 15%  
- 17-week follow-up: Treatment: 31%, Control: 6%  
7-day point prevalence abstinence (verified by CO<7ppm):  
- 4-week follow-up: OR 3.05 (CI 0.99, 9.38)  
- 17-week follow-up: OR 7.83 (CI 1.57, 38.99)  
Reduction:  
- 4-week follow-up, Number of cigarettes per day: MD 1.00 (CI −3.02, 5.02)  
Adverse Events: “No serious adverse events were reported in either treatment group” |
| Country: United States or Canada | Baseline Tobacco Use: 11–20 cigarettes per day | Setting: Unclear |  
| Purpose: To assess the efficacy of mindfulness training versus FFS using 1-week point prevalence abstinence and number of cigarettes smoked per day as primary endpoints at treatment completion and a 17-week follow-up. The secondary objective was to assess correlations between the amount of completed home practice in both treatment arms and smoking outcomes. | Comorbid Conditions: Not Reported | Dosage: Medium (1–4 hours spent in session, homework, and other each week) |  
| Quality Rating: Fair | Mean Age: 45.9 (SD 10.2) | Co-interventions: Not Reported |  
| Inclusion Criteria: 18–60 years of age, smoked 10+ cigarettes per day, had fewer than 3 months of abstinence in the past year, and reported interest in quitting smoking. | Gender (% Male): 62.1% | Comparator: FFS program |  
| Exclusion Criteria: Currently used psychoactive medications, had a serious or unstable medical condition in the past 6 months, or met DSM-IV criteria for other substance dependence in the past year. | Inclusion Criteria: 18–60 years of age, smoked 10+ cigarettes per day, had fewer than 3 months of abstinence in the past year, and reported interest in quitting smoking. | Primary Endpoints: 7-day abstinence, number of cigarettes per day |  
| Exclusion Criteria: Currently used psychoactive medications, had a serious or unstable medical condition in the past 6 months, or met DSM-IV criteria for other substance dependence in the past year. | | Power Calculation: No |  
| Follow-Up Time: 17 weeks | | |  

<table>
<thead>
<tr>
<th>Study Details</th>
<th>Participants</th>
<th>Invention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference: Davis, Mills, et al., 2013</td>
<td>Number of Patients: 55</td>
<td>Content of Intervention: MTS was designed to be intensive enough to activate core mindfulness insights of a mindfulness-based stress reduction–style course, but also include training on how to use mindfulness to more skillfully manage relapse challenges related to smoking triggers, social situations, strong emotions, stressful situations, relapse-related thoughts, urges, and withdrawal symptoms. Each class included instruction, group discussion, and meditation or silent, non-directed walking.</td>
<td>Abstinence Rate:</td>
</tr>
<tr>
<td>Country: United States or Canada</td>
<td>Baseline Tobacco Use: 11–20 cigarettes per day</td>
<td>Setting: Other outpatient</td>
<td></td>
</tr>
<tr>
<td>Purpose: To test a pilot study designed for novel smoking cessation intervention, MTS, in smokers age 18–29 years with regular episodes of binge drinking</td>
<td>Comorbid Conditions: Binge drinkers</td>
<td>Dosage: High: (&gt;4 hours spent in session, homework, and other each week)</td>
<td></td>
</tr>
<tr>
<td>Quality Rating: Poor</td>
<td>Mean Age: 21.9 (SD 2.53)</td>
<td>Co-interventions: None</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gender (% Male): 70.9%</td>
<td>Comparator: Interactive learning for smokers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inclusion Criteria: 18–29 years old, smoke 10 or more cigarettes per day, and report 5 or more alcohol “binges” per month.</td>
<td>Primary Endpoint: 7-day abstinence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria: Drinking 4 or more drinks on 6 or more nights per week, self-reported diagnosis of schizophrenia, bipolar or delusional disorder, CO level of 10 ppm or less at orientation.</td>
<td>Power Calculation: Power insufficient</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Follow-Up Time: 2 weeks</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Adverse Events: No mention</td>
<td></td>
</tr>
</tbody>
</table>

Abstinence Rate:
- 2-week follow-up, self-report, ITT: Treatment: 20%, Control: 4%
- 2-weeks follow-up, self-report, non-ITT: Treatment: 40%, Control: 10%

7-day point prevalence abstinence (verified by CO<7ppm):
- 2-week follow-up: OR 6.00 (CI 0.67, 53.68)
<table>
<thead>
<tr>
<th>Study Details</th>
<th>Participants</th>
<th>Invention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference: Davis, Goldberg, et al., 2014a</td>
<td>Number of Patients: 135 enrolled and analyzed</td>
<td>Content of Intervention: During each class, instructors would play approximately 20 minutes of the MTS instructional video, which provided instruction in mindfulness meditation, walking, smoking, eating, and mindful management of smoking triggers, urges, addictive thoughts, and emotions. After playing the video, instructors would lead exercises and provide more-nuanced and -individualized instruction. The final hour of class was a &quot;meditation group,&quot; consisting of guided meditation and group-support practice called &quot;mindful talking and listening.&quot; On the Quit Day Retreat, smokers attempted smoking cessation and initiated a 2-week course of nicotine patches.</td>
<td>Abstinence Rate:</td>
</tr>
<tr>
<td>Country: United States or Canada</td>
<td>Baseline Tobacco Use: 11–20 cigarettes per day</td>
<td>Setting: Other outpatient</td>
<td>4-week follow-up: Treatment: 35.3%, Control: 34.3%</td>
</tr>
<tr>
<td>Purpose: To compare mindfulness training for smokers to enhanced FFS on measures of class attendance, attrition, practice compliance, smoking abstinence, urge intensity, mindfulness acquisition, and psychological outcomes</td>
<td>Comorbid Conditions: Not Reported</td>
<td>Dosage: High: (&gt;4 hours spent in session, homework, and other each week)</td>
<td>24-week follow-up: Treatment: 25%, Control: 17.9%</td>
</tr>
<tr>
<td>Quality Rating: Fair</td>
<td>Mean Age: 44.50 (SD 12.73)</td>
<td>Co-interventions: Nicotine replacement</td>
<td>7-day point prevalence abstinence (verified by CO&lt;7ppm):</td>
</tr>
<tr>
<td></td>
<td>Gender (% Male): 53.3%</td>
<td>Comparator: FFS program</td>
<td>• 4-week follow-up, OR 1.04 (CI 0.51, 2.12)</td>
</tr>
<tr>
<td></td>
<td>Inclusion Criteria: At least 18 years of age, smoke 5 or more cigarettes per day, claim high motivation to quit.</td>
<td>Primary Endpoint: 7-day abstinence</td>
<td>• 24-week follow-up: OR 1.53 (CI 0.67, 3.51)</td>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria: Use of other tobacco products, consume more than 4 alcoholic drinks per day on more than 4 days per week.</td>
<td>Power Calculation: Power insufficient</td>
<td>Craving:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Follow-Up Time: 24 weeks</td>
<td>• 24-week follow-up, Craving – Over the past 24 hours, how strong have your urges to smoke been on a scale of 0-10?: MD 0.41 (CI 0.07, 0.75)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Adverse Events: Authors reported “no reportable medication reactions” among nicotine replacement users</td>
</tr>
<tr>
<td>Study Details</td>
<td>Participants</td>
<td>Invention</td>
<td>Outcomes</td>
</tr>
<tr>
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</tr>
<tr>
<td>Reference: Davis, Manley, et al., 2014b</td>
<td>Number of Patients: 196</td>
<td>Content of Intervention: MTS provides instruction in general mindfulness practices, such as meditation, mindful walking, and mindful eating, and provides targeted training in how to apply mindfulness to smoking relapse determinants, such as smoking triggers, strong emotions, addictive thoughts, urges, and withdrawal symptoms.</td>
<td>Abstinence Rate:</td>
</tr>
<tr>
<td>Country: United States or Canada</td>
<td>Baseline Tobacco Use: 11–20 cigarettes per day</td>
<td>Setting: Other outpatient</td>
<td>• ITT analysis, 4-week follow-up: Treatment: 25.7%, Control: 17.6%</td>
</tr>
<tr>
<td>Purpose: To test the treatment acceptability of MTS in smokers with low socioeconomic status on class attendance and meditation time, measured via Time-Line Follow-Back; to compare MTS with usual care treatment on rates of smoking cessation, measured by 7-day point prevalence abstinence and Time-Line Follow-Back at 4 and 24 weeks post-quit attempt; and to explore possible mediators of effect in the mindfulness intervention via self-report measures</td>
<td>Comorbid Conditions: Not reported</td>
<td>Dosage: High: (&gt;4 hours spent in session, homework, and other each week)</td>
<td>• ITT, 24-week follow-up: Treatment: 22.7%, Control: 14.5%</td>
</tr>
<tr>
<td>Quality Rating: Fair</td>
<td>Mean Age: 41.65 (SD 13.29)</td>
<td>Co-interventions: Nicotine replacement</td>
<td>• Non-ITT, 4-week follow-up: Treatment: 45.8%, Control: 25.4%</td>
</tr>
<tr>
<td></td>
<td>Gender (% Male): 50%</td>
<td>Comparator: Quitline plus nicotine replacement</td>
<td>• Non-ITT, 24-week follow-up: Treatment: 38.7%, Control: 20.6%</td>
</tr>
<tr>
<td></td>
<td>Inclusion Criteria: 18 or more years of age, smoke 5 or more cigarettes per day, claim “high motivation to quit,” and state “a willingness to attend 10 meetings over a 2-month period.”</td>
<td>Primary Endpoint: 7-day abstinence</td>
<td>7-day point prevalence abstinence (verified by CO&lt;7ppm):</td>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria: Use of other tobacco products, consume 4 or more alcoholic drinks on 4 or more nights per week.</td>
<td>Power Calculation: Power insufficient</td>
<td>• ITT, 4-week follow-up: OR 1.62 (CI 0.81, 3.25)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Follow-Up Time: 24 weeks</td>
<td>• ITT, 24-week follow-up: OR 1.78 (CI 0.85, 3.74)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Non-ITT, 4-week follow-up: OR 2.48 (CI 1.14, 5.39)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Non-ITT, 24-week follow-up: OR 2.50 (CI 1.10, 5.69)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Adverse Events: Authors reported “no reportable medication reactions” among nicotine replacement users</td>
</tr>
<tr>
<td>Study Details</td>
<td>Participants</td>
<td>Invention</td>
<td>Outcomes</td>
</tr>
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</tr>
<tr>
<td>Reference: Rogojanski, Vettese, and Antony, 2011</td>
<td>Number of Patients: Mindfulness: 31, Control: 30</td>
<td>Content of Intervention: During the study session, participants engaged in a 20-minute smoking cue exposure while simultaneously receiving mindfulness instructions (to accept the thoughts and feelings that arise in a mindful way).</td>
<td>Abstinence Rate: Not Reported</td>
</tr>
<tr>
<td>Country: United States or Canada</td>
<td>Baseline Tobacco Use: 11–20 cigarettes per day</td>
<td>Setting: Unclear</td>
<td>1-week follow-up, Fagerstrom Test for Nicotine Dependence: MD 0.23 (CI -0.34, 0.80)</td>
</tr>
<tr>
<td>Purpose: To investigate the effectiveness of a brief suppression versus mindfulness-based strategy for coping with cigarette cravings</td>
<td>Comorbid Conditions: Not reported</td>
<td>Dosage: Low: (1-hour or less spent in session, homework, and other each week)</td>
<td>Adverse Events: No mention</td>
</tr>
<tr>
<td>Quality Rating: Poor</td>
<td>Mean Age: 40.34 (SD 12.42)</td>
<td>Co-interventions: None</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gender (% Male): 59%</td>
<td>Comparator: Cue exposure with urge suppression instruction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inclusion Criteria: Having smoked an average of 10 or more cigarettes per day over the past month, age greater than 18, having thought about cutting back on smoking or tried to quit smoking in the past.</td>
<td>Primary Endpoints: Craving, Fagerstrom Test for Nicotine Dependence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria: Difficulty reading, speaking, or writing in English; significant difficulty using a computer to respond to questionnaires.</td>
<td>Power Calculation: Power insufficient</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Follow-Up Time: 1 week</td>
<td></td>
</tr>
<tr>
<td>Study Details</td>
<td>Participants</td>
<td>Invention</td>
<td>Outcomes</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------</td>
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<td>----------</td>
</tr>
<tr>
<td>Reference: Ruscio et al., 2015</td>
<td>Number of Patients: 44 enrolled</td>
<td>Content of Intervention: Five guided meditations pre-loaded on a personal digital assistant. The first guided meditation consisted of an “urge-surfing” technique developed to teach smokers mindfulness of urges and cravings during a progressive cue-exposure exercise. The four other meditations were on mindfulness of the breath, mindfulness of the body, mindfulness of thoughts, and mindfulness of emotions.</td>
<td>Abstinence Rate: Not Reported</td>
</tr>
<tr>
<td>Country: United States or Canada</td>
<td>Baseline Tobacco Use: 11–20 cigarettes per day</td>
<td>Setting: Remote (e.g., telephone Internet app)</td>
<td>Number of cigarettes per day:</td>
</tr>
<tr>
<td>Purpose: To test a pilot trial of a brief mindfulness practice intervention on self-reported smoking behavior delivered to smokers on a personal digital assistant in the field</td>
<td>Comorbid Conditions: Not reported</td>
<td>Dosage: Medium (1–4 hours spent in session, homework, and other each week)</td>
<td>- 1-week follow-up: MD −4.30 (CI −9.43, 0.83)</td>
</tr>
<tr>
<td>Quality Rating: Poor</td>
<td>Age Range: 18–65</td>
<td>Co-interventions: None</td>
<td>- 2-week follow-up: MD −0.50 (CI −6.05, 5.05)</td>
</tr>
<tr>
<td></td>
<td>Gender (% Male): 50%</td>
<td>Comparator: Sham meditation</td>
<td>Craving:</td>
</tr>
<tr>
<td></td>
<td>Inclusion Criteria: Smokers were accepted regardless of their intentions to quit or cut down on smoking. Participants were included if they were 18–65 years of age and had a history of smoking 10 or more cigarettes per day for at least 2 years.</td>
<td>Primary Endpoints: Craving, number of cigarettes per day</td>
<td>- 1-week follow-up, Craving – I have strong urges to smoke, 1-disagree to 7-strongly agree: MD 0.22 (CI −0.47, 0.92)</td>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria: Impaired hearing, expired breath CO levels lower than 10 ppm, tobacco use other than cigarettes, and current smoking cessation treatment (counseling or medication).</td>
<td>Power Calculation: Power insufficient</td>
<td>- 2-week follow-up, Craving – I have strong urges to smoke, 1-disagree to 7-strongly agree: MD 0.66 (CI −0.06, 1.37)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Follow-Up Time: 2 weeks</td>
<td>Adverse Events: No mention</td>
</tr>
</tbody>
</table>
## Study Details

Reference: Singh et al., 2014

Country: United States or Canada

Purpose: To extend the current literature on the use of mindfulness-based interventions for smoking cessation in this population (individuals with mild intellectual disabilities)

Quality Rating: Fair

## Participants

Number of Patients: 51 enrolled

Baseline Tobacco Use: 11–20 cigarettes per day

Comorbid Conditions: Mild intellectual disability

Mean Age: Treatment: 32.56 (SD 10.29), Control: 34.40 (SD 10.46)

Gender (% Male): 80%

Inclusion Criteria: Adult with mild intellectual disability, ability to give own informed consent, willingness to enter a smoking cessation study, approval by their primary care physician to engage in this smoking cessation program, willingness to engage in mindfulness training.

Exclusion Criteria: Axis I psychiatric diagnosis.

## Invention

Content of Intervention: Sessions replicated the three mindfulness-based procedures used by Singh et al. (2011; 2013): Intention, mindful observation of thoughts, and meditation on the soles of the feet.

Setting: Unclear

Dosage: High

Co-interventions: Not reported

Comparator: TAU—Motivational therapies (n=9), behavior therapies (n=7), nicotine replacement therapy (n=4), non-nicotine medicines (n=4), behavior therapy and nicotine replacement therapy (n=1), and behavior therapy and motivational therapy (n=1)

Primary Endpoints: Abstinence, number of cigarettes per day

Power Calculation: No

Follow-Up Time: 40 weeks

## Outcomes

Abstinence Rate:
- 40-week follow-up, Treatment: 100%, Control: 38.89%
- 40-week follow-up, Smoking cessation: OR 71.67 (CI 3.76, 1,364.4)

Various follow-up times, Number of cigarettes per day: MD 3.70 (CI 0.95, 6.44)

Adverse Events: No mention
<table>
<thead>
<tr>
<th><strong>Study Details</strong></th>
<th><strong>Participants</strong></th>
<th><strong>Invention</strong></th>
<th><strong>Outcomes</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference: Tang, Tang, and Posner, 2013</td>
<td>Number of Patients: 27 smokers randomized, 26 analyzed</td>
<td>Content of Intervention: Integrative body-mind training is a form of mindfulness meditation that involves body relaxation, mental imagery, and mindfulness training accompanied by selected music background. The trainees concentrated on achieving a balanced state of body and mind, guided by an integrative body-mind training coach and a compact disc.</td>
<td>Abstinence Rate: Not Reported</td>
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<tr>
<td>Country: United States or Canada</td>
<td>Baseline Tobacco Use: ≤10 cigarettes per day</td>
<td>Setting: Other outpatient</td>
<td>Reduction: Significant smoking reduction in the integrative body-mind training group (p&lt;0.01) but no significant reduction in the relaxation group (p&gt;0.05)</td>
</tr>
<tr>
<td>Purpose: To test whether improved self-control through short-term integrative body-mind training would reduce craving and smoking</td>
<td>Comorbid Conditions: Not reported</td>
<td>Dosage: Medium: (1–4 hours spent in session, homework, and other each week)</td>
<td>Craving: Significant decrease in craving in the mindfulness group (p&lt;0.01) but not the relaxation group (p&gt;0.05) at 2 weeks, data not reported</td>
</tr>
<tr>
<td>Quality Rating: Poor</td>
<td>Mean Age: 21.46 (SD 3.08)</td>
<td>Co-interventions: None</td>
<td>Adverse Events: No mention</td>
</tr>
<tr>
<td></td>
<td>Gender (% Male): 70%</td>
<td>Comparator: Relaxation training</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inclusion Criteria: Healthy college students</td>
<td>Primary Endpoint: Not reported</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria: Participants with the goal of quitting smoking</td>
<td>Power Calculation: No</td>
<td></td>
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<tr>
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<td>Follow-Up Time: 2 weeks</td>
<td></td>
</tr>
</tbody>
</table>
References


As of February 5, 2016:


