Protocol

Mindfulness Meditation for Tobacco Use Cessation

A Systematic Review Protocol

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Preface

The Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE) is interested in determining the efficacy and comparative effectiveness of integrative medicine approaches for psychological health conditions. This document is a systematic review protocol for a review to be performed during year two of this two-year project. The review will be of interest to military health policymakers and practitioners, civilian health care providers and policymakers, payers, and patients.

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

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Acknowledgments

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Abstract

The high prevalence of tobacco use among active and retired service members leads to a significant burden of morbidity, mortality, and economic costs. In recent years, many civilian tobacco cessation programs have incorporated mindfulness meditation. The purpose of this systematic review is to synthesize the evidence from randomized controlled trials (RCTs) of mindfulness meditation to provide estimates of its effectiveness for treatment of tobacco use (TU).

We will search electronic databases (PubMed, CINAHL, PsycINFO, AMED, CENTRAL), as well as bibliographies of existing systematic reviews and included studies, to identify English-language reports of RCTs that evaluate the efficacy and safety of mindfulness meditation—used adjunctively or as mono-therapy—to treat adults with nicotine dependence or tobacco use disorder (TUD). Two reviewers will independently screen literature identified by the searches using predetermined eligibility criteria, abstract information and outcome data from those studies that meet the inclusion criteria, and also assess their methodological quality. Outcomes of interest include cessation of tobacco use, reduction in tobacco use, and adverse events of mindfulness meditation. If we identify sufficient numbers of homogeneous studies, we will synthesize data via meta-analysis, and conduct pre-planned subgroup and sensitivity analyses as data allow. Lastly, the reviewers will assess the quality of evidence for each outcome using the GRADE approach. The review will be registered in PROSPERO.

The methods, literature search results, findings, conclusions, and quality of the evidence will be reported in a comprehensive report, and all studies will be described in evidence tables. The results of this review will help to inform the Department of Veterans Affairs/Department of Defense (VA/DoD) clinical decision-making regarding mindfulness meditation used adjunctively or as mono-therapy in treating tobacco use.

Introduction

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 US military was estimated at 24.5%, compared with the US adult population prevalence of 19.0% (U.S. Department of Defense, 2013). The US military 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%) of Operation Iraqi Freedom-deployed Army and National Guard soldiers smoked cigarettes at two time points surveyed. Age-adjusted smoking prevalence is also higher among US veterans (27%) than in civilians (21%) according to data from the 2003–2007 Behavioral Risk Factor Surveillance System (BRFSS) (Brown, 2010). Thus, it is not surprising that the Institute of Medicine estimates that the Department of Defense spends over 1.6 billion a year on tobacco related health-care costs and lost productivity (Institute of Medicine: Combating Tobacco Use in Military and Veteran Populations, 2009).

The DoD currently recommends that health care providers follow the 2008 Public Health Service (PHS) guidelines for treating tobacco use and dependence; counseling and medications, including nicotine replacement, are the primary focus (U.S. Department of Health and Human Services, May 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, or the intentional self-regulation of attention from moment to moment (Goleman and Schwartz, 1976). Mindfulness meditation is a Western, non-sectarian form of meditation derived from a 2,500 year old Buddhist practice. Mindfulness facilitates an attentional stance of detached observation. It is characterized by paying attention to the present moment with openness, curiosity, and acceptance. It can be trained systematically to be used in daily life by people of any background (UCLA Mindfulness Awareness Research Center (MARC), 2015).

Our proposed review aims to synthesize data from existing randomized controlled trials (RCTs) in order to provide reliable estimates of the effectiveness and safety of mindfulness meditation interventions for tobacco use.

Key Questions

The following questions and sub-questions will guide this systematic review:

1. What are the efficacy and safety of mindfulness meditation interventions, as an adjunctive or mono-therapy, for smoking cessation or reduction, compared to treatment as usual,

wait-lists, no-treatment, or other active treatments?

a. Does the effect vary by the type of mindfulness meditation intervention?
b. Does the effect differ when the intervention is offered as an adjunctive therapy rather than as a mono-therapy?
c. Does the effect vary depending on the duration and frequency of mindfulness meditation (i.e., dose effect)?

Methods

We will perform a systematic review to identify RCTs that evaluate the efficacy and safety of mindfulness meditation for tobacco use cessation. The results of electronic searches will be documented in a literature flow diagram (see Figure 1), and identified literature will be mapped onto the Key Questions as per previous evidence synthesis reports for VA/DoD clinical practice guidelines (The Lewin Group and ECRI Institute, 2014) (see Table 1). The systematic review will be registered in PROSPERO, an international registry for systematic reviews.

Sources

We will search PubMed, CINAHL, PsycINFO, AMED, and Cochrane CENTRAL for English-language RCTs. In addition to this search and the reference mining of all included studies identified through it, we will also screen studies included in prior systematic reviews related to this topic.

Search strategy

The search strategy is being developed by the Chief Reference Librarian for RAND's Knowledge Services, informed by search results of the prior environmental scan (Sorbero, Grant and Hempel, October 2014) and existing reviews. The draft PubMed search string is described in the Appendix.

Eligibility criteria

The inclusion and exclusion criteria we will apply to the retrieved publications can be summarized in the following "PICOTSS" framework of participants, interventions, comparators, outcomes, timing, settings, and study design.

PICOTSS

- Participants: Studies of male and female participants, 18 years of age or older, who use tobacco products will be included. Studies will be included regardless of whether TUD diagnosis was required for enrollment.
- Interventions: Studies involving mindfulness meditation, either as an adjunctive or mono-therapy, will be included—e.g., mindfulness-based stress reduction (MBSR), mindfulness-based cognitive therapy (MBCT), 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 will be excluded.
- Comparators: Studies will not be limited by comparator. We will include studies that include treatment as usual (TAU) or "standard care," wait-list control, no-treatment, or other active treatments./ Studies that compare mindfulness meditation offered adjunctive versus mono-therapy will be included.
- Outcomes: Studies must report tobacco use cessation, attempts to quit, reduction in use, relapse rate, or change in craving. Biological confirmation of cessation will not be required for study inclusion. Studies that report only intention or "motivation and readiness" to quit will be excluded.
- Timing: Studies may involve any treatment duration and any follow-up time period.
- Setting: Studies will not be limited by setting.
- Study Design: Included studies will be limited to parallel group, individually- or cluster-RCTs.

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) will independently screen 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 will be obtained as full text. The full text publications will then be screened against the specified inclusion criteria by two independent literature reviewers; any disagreements will be resolved through discussion within the review team. The flow of citations throughout this process will be documented in an electronic database, and reasons for exclusion of full-text publications will be recorded.

Data extraction

The two aforementioned reviewers each will independently abstract study-level data in an electronic database. Data collection forms will be designed by the project lead, with input from the project team. These two reviewers will then pilot test the data collection forms on a few randomly selected studies, modify the forms, and perform a final pilot of the forms on a random selection of three included studies to ensure agreement of interpretation. EPC biostatisticians will abstract all outcome data to ensure accuracy.

Study-level data will be abstracted for the following information:

- Participants: gender, age, race/ethnicity, baseline tobacco use, comorbid psychological / behavioral health conditions, comorbid medical conditions
- Interventions: content of mindfulness meditation sessions, dosage (intensity, frequency, duration), and any co-intervention(s)
- Comparators: type of comparator (e.g., brief advice, counseling, nicotine replacement, other medication, wait list), dosage (intensity, frequency, duration)
- Outcomes: primary endpoint; longest follow-up; measures of tobacco abstinence, number of quit attempts, reduction in use, relapse rate, change in cravings, health-related quality of life, 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, clinical 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

If different reports appear to be from the same study, descriptions of participants will be compared to ensure that data from the same study populations enter the analysis only once. For each included study, findings will be reported in an Evidence Table that will include details about the intervention, specific comparison(s), and outcome(s) measured (see Table 2).

Risk of bias and study quality

The two reviewers will assess the risk of bias of the included studies using the Cochrane Risk of Bias tool (Higgins and Green, 2011). Specifically, the following criteria/biases will be assessed: 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). Involvement of the intervention developers in evaluation of its efficacy will be noted as a potential source of bias.

Other biases related to the US Preventive Services Task Force's (USPSTF) criteria for internal validity of included studies will also be assessed, namely those related to: equal distribution amongst groups of potential confounders at baseline; cross-overs or contamination between groups; equal, reliable, and valid outcome measurement; clear definitions of interventions; and intention to treat analysis (US Preventive Services Task Force, 2008; The Lewin Group and ECRI Institute, 2014). These criteria will be used to rate the quality of evidence of individual included studies using the following guidelines:

- **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; intention-to-treat

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 account for in analyses. Intention-to-treat 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; intention-to-treat analysis is not used.

Planned synthesis

The primary aim of this systematic review is to identify whether mindfulness meditation for tobacco use cessation is effective and safe. Smoking/tobacco cessation will be the primary outcome; commonly used cessation measures include 7 day abstinence, 30 day abstinence, and 6 month abstinence.

When sufficient data are available and statistical heterogeneity is below agreed thresholds (Higgins and Green, 2011), we will perform meta-analysis to pool effectiveness results across included studies for each of the outcomes of interest, and present forest plots for these meta-analyses. For efficacy outcomes we will use the Hartung-Knapp-Sidik-Jonkman method for 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 using this method are more robust than the previously used DerSimonian and Laird method (Sánchez-Meca and Marín-Martínez, 2008). Adverse events will be classified and grouped according to the Common Terminology Criteria for Adverse Events (CTCAE) system. For specific adverse events, many of which may be very rare, we will use exact conditional methods to estimate odd ratios (OR) and 95 percent confidence intervals (CI) if a sufficient number of studies report specific adverse events.

In addition, when sufficient data are available, we will describe results of head-to-head comparisons and conduct subgroup analyses and meta-regressions to address the sub-questions of this systematic review. Specifically, we will examine whether there are differences in effect sizes between different mindfulness meditation interventions; different comparison groups; and by mindfulness meditation intervention as mono-therapy versus an adjunctive therapy. Given the complexity of the topic, subgroup and sensitivity analyses will only be performed for those outcomes with sufficient data. If heterogeneity precludes meta-analysis, differences between studies will be narratively described. For meta-analysis of data with clear outliers, sensitivity

analysis may be conducted (excluding the outliers), if appropriate (Hamling et al., 2008). If sufficient data are available, we will conduct sensitivity analyses omitting the lower quality studies for major comparisons.

Quality of evidence

The quality of the body of evidence will be assessed for major outcomes using the GRADE approach (Balshem et al., 2011; The Lewin Group and ECRI Institute, 2014) in which the body of evidence is assessed based on the following dimensions: study limitations, directness, consistency, precision, and reporting bias (Egger et al., 1997).

The quality of evidence is graded on a 4-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: i.e., 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.

The data sources, basic study characteristics, and each quality-of-evidence domain rating will be summarized in a Quality of Evidence table detailing our reasoning for arriving at the overall rating (see Table 4).

Summary of findings

Review findings will be summarized in a table and organized by outcomes that reflect the key questions for this systematic review. This table will list the intervention and comparators evaluated and the outcomes assessed for each type of comparison; the number of studies and number of participants included for each outcome assessment, the direction and magnitude of the effect for each outcome, and the quality of the evidence for each outcome (see Table 4). For each outcome, results of pooled analyses will be described first, followed by narrative descriptions of

individual studies not included in the pooled analyses (if any). Findings will first be reported for the broad comparison of mindfulness meditation compared with any comparison group. Findings will then be reported separately by: intervention (e.g. MBSR), type of comparator (e.g., brief advice, counseling, nicotine replacement, wait list), and therapy characteristic (i.e. mono-therapy, adjunctive therapy). All study level and synthesis information will be shown in concise tables to allow a transparent overview and results will be described in more detail in the text.

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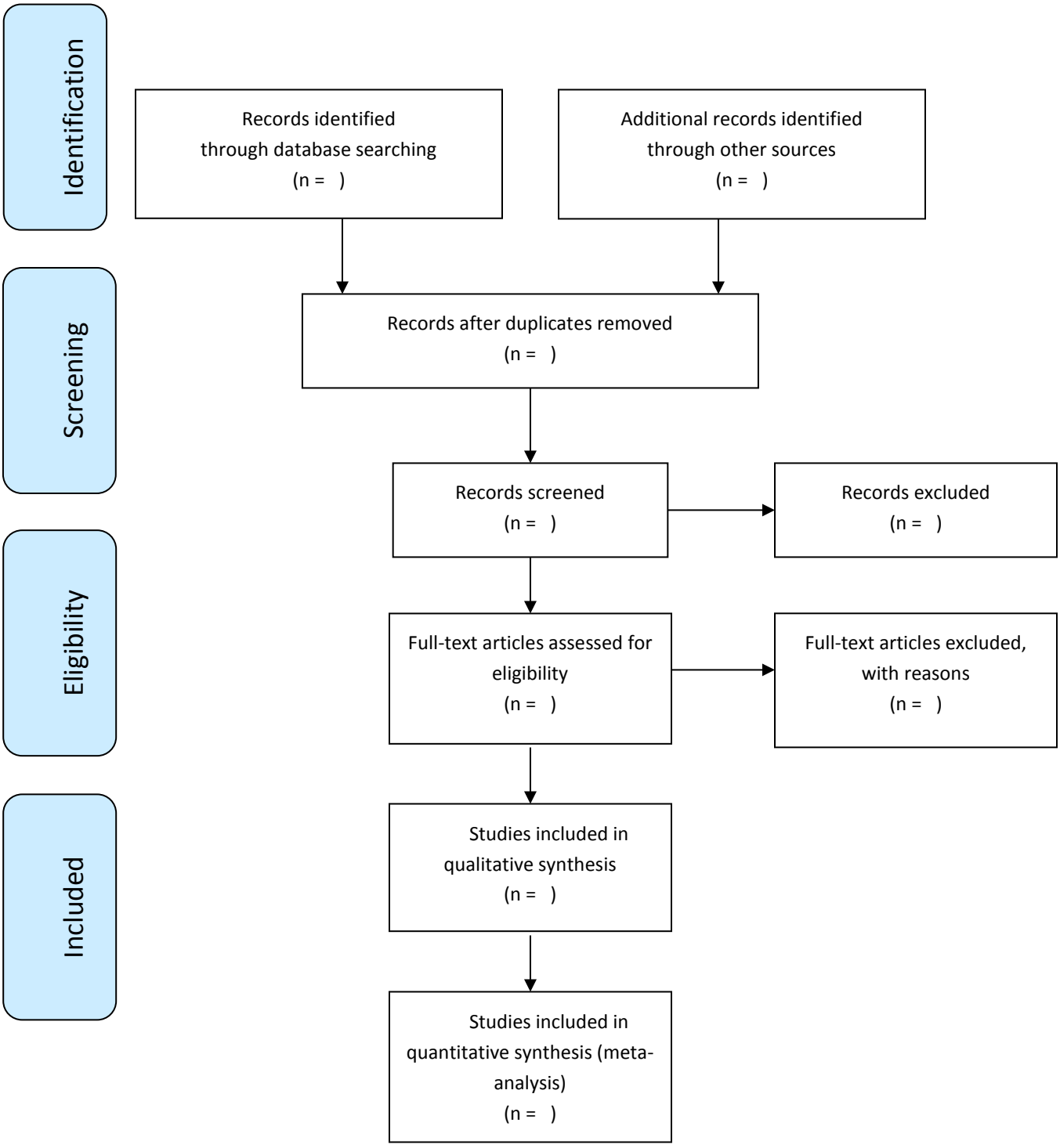
Figures

Figure 1: Draft Flow Diagram



Tables

Table 1: Draft Table—Evidence Base for Key Questions

Number of Question	Question	Number of RCTs
1	What is the efficacy and safety of mindfulness meditation interventions, as an adjunctive or mono-therapy, for TUD compared to treatment as usual, wait-lists, no-treatment, or other active treatments?	# RCTs with efficacy data: # RCTs with safety data:
1a	Does the effect vary by the type of mindfulness meditation intervention?	# MBSR RCTs: # MBCT RCTs: # Mindfulness training RCTs:
1b	Does the effect differ when the interventions is offered as an adjunctive therapy rather than as a mono-therapy?	# adjunctive therapy: # mono-therapy:
1c	Does the effect vary depending on the duration and frequency of mindfulness meditation (i.e., dose effect)?	# RCTs addressing dose

Table 2: Draft Evidence Table

Study Details	Participants	Intervention/Treatment	Outcomes/Results
Reference:	**Number of patients:**	**Content of intervention:**	**Abstinence rate:**
Country:	**Baseline tobacco use:**	**Setting:**	**Quantity / frequency of use:**
Purpose:	**Comorbid conditions:**	**Dosage:**	**Attempts to quit:**
	Age (years):	**Co-interventions:**	**Relapse:**
Quality rating:	**Gender:**	**Comparator:**	**Craving:**
	Race / Ethnicity:	**Primary endpoint:**	**Health-related QoL:**
	Inclusion criteria:	**Power calculation:**	**Adverse events:**
	Exclusion criteria:	**Follow-up:**	

Note: For each outcome reported, we will collect the following information when available: domain, method of measurement (e.g., questionnaire, observation), data metric (e.g., mean score, proportion with outcome), time(s) of follow-up (e.g., 3 and 6 months after baseline), and corresponding results (effect estimate, measure of dispersion). QoL Quality of Life

Table 3: Draft Table for Study Quality/Risk of Bias for Individual Included Studies

Study ID	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)	Selective outcome reporting (reporting bias)	Involvement of intervention developer in trial (independent replication)	Other biases (balance of confounders, cross-overs/ contamination, measurement, intervention definition, ITT)	USPSTF Quality rating (Good, Fair, Poor)

Note: See Methods section of this document for USPSTF Quality rating criteria.

Table 4: Draft Quality of Evidence and Summary of Findings Table

Outcome	Number of RCTs and Participants	Findings: Direction/ Magnitude of Effect	Study Limitations (Study Quality; RoB)	Inconsistency	Indirectness	Imprecision	GRADE of Evidence for Outcome
KQ 1 Comparison: any mindfulness meditation intervention vs any comparator							
7 day abstinence							
30 day abstinence							
6 month abstinence							
Number of quit attempts							
Relapse rate							
Change in cravings							
Frequency in use							
Health-related QoL							
Adverse event 1							
Adverse event 2							
KQ1 Comparison: mindfulness meditation interventions vs passive comparator (e.g., waitlist, no treatment)							
Analyzed outcomes depend on available evidence							
KQ1 Comparison: mindfulness meditation interventions vs active comparator (e.g., counseling, nicotine replacement)							
Analyzed outcomes depend on available evidence							
KQ1a: If meta-regression indicates a difference in intervention subgroups: MBSR vs any comparator							
Analyzed outcomes depend on							

available evidence							
KQ1a: If meta-regression indicates a difference in intervention subgroups: e.g., MBCT vs any comparator							
Analyzed outcomes depend on available evidence							
KQ1a: If meta-regression indicates a difference in intervention subgroups: e.g., MBRP vs any comparator							
Analyzed outcomes depend on available evidence							
KQ1a: If meta-regression indicates a difference in intervention subgroups: Other mindfulness meditation approaches vs any comparator							
Analyzed outcomes depend on available evidence							
KQ 1b. If meta-regression indicates a difference: Comparison: mindfulness meditation as mono-therapy vs any comparator							
Analyzed outcomes depend on available evidence							
KQ 1b. If meta-regression indicates a difference: Comparison: mindfulness meditation as adjunctive therapy vs any comparator							
Analyzed outcomes depend on available evidence							
KQ1c. Does the effect vary depending on the duration							

and frequency of mindfulness meditation (i.e., dose effect)?							
Analyzed outcomes depend on available evidence							

Appendix

Draft Search Strategy

DATABASES:
PubMed, PsycINFO, AMED, CINAHL, Cochrane CENTRAL

TIME PERIOD COVERED:
Since inception to June 2015

PubMed
SEARCH STRATEGY:
"Mindfulness"[Mesh]) OR "Meditation"[Mesh] OR mindfulness* or mindfulness-based or mbsr or mbct OR m-bct OR meditat* OR Vipassana OR satipaṭṭhāna OR anapanasati OR Zen OR Sudarshan OR zazen OR shambhala OR buddhis*
AND
“Tobacco Use"[Mesh] OR "Tobacco"[Mesh] OR "Tobacco Products"[Mesh] OR tobacco[tiab] OR cigarette*[tiab] OR smoking[tiab] OR smoker*[tiab]
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*

LANGUAGE:
English

After importing all results into Endnote, duplicates and animal-only studies will be deleted.