BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-062516
Article Type:	Protocol
Date Submitted by the Author:	02-Mar-2022
Complete List of Authors:	Kuribayashi, Kazuto; Tokyo Medical and Dental University Graduate School of Health Care Sciences, Department of Mental Health and Psychiatric Nursing Takano, Ayumi; Tokyo Medical and Dental University Graduate School of Health Care Sciences, Department of Mental Health and Psychiatric Nursing Inagaki, Akiko; Tokyo Healthcare University, Faculty of Healthcare, Division of Nursing Imamura, Kotaro; The University of Tokyo, Graduate School of Medicine, Department of Mental Health Kawakami, Norito; The University of Tokyo, Graduate School of Medicine, Department of Mental Health
Keywords:	MENTAL HEALTH, OCCUPATIONAL & INDUSTRIAL MEDICINE, Depression & mood disorders < PSYCHIATRY

March 1, 2022

The effect of stress management based on cognitive behavioral therapy on nurses as a universal prevention in the workplace: a systematic review and meta-analysis protocol

Authors
Kazuto Kuribayashi[1]
E-mail: kkuribayashi-jans@umin.ac.jp
Ayumi Takano[1]
E-mail: ayumi-takano@umin.ac.jp
Akiko Inagaki[2]
akikok-tky@umin.ac.jp
Kotaro Imamura[3]
E-mail: kouima-tky@umin.ac.jp
Norito Kawakami[3]
E-mail: norito@m.u-tokyo.ac.jp

Correspondence to: Kazuto Kuribayashi
Department of Mental Health and Psychiatric Nursing, Graduate School of Health Care Sciences, Tokyo Medical and Dental University,
1-5-45 Yushima, Bunkyo-ku, Tokyo 113-8510, JAPAN
Tel: +81-3-5803-5336
E-mail: kkuribayashi-jans@umin.ac.jp

Authors' information
[1]Department of Mental Health and Psychiatric Nursing, Graduate School of Health Care Sciences, Tokyo Medical and Dental University, 1-5-45 Yushima, Bunkyo-ku, Tokyo 113-8510, Japan.
[2]Division of Nursing, Faculty of Healthcare, Tokyo Healthcare University, 4-1-17 Higashigotanda, Shinagawa-ku, Tokyo 141-8648, Japan.
[3]Department of Mental Health, Graduate School of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan.

Keywords: Nurse, Cognitive behavioral therapy, Universal prevention, Systematic review, Meta-analysis

Word count: 2,752

ABSTRACT

Introduction

The mental health status of nurses affects not only their well-being but also the organizational outcomes and the quality of patient care. Hence, stress management strategies are critical as a universal prevention measure to maintain nurses' mental health in the workplace. No systematic review or meta-analysis has been conducted to evaluate the effect of cognitive behavioral therapy (CBT) that specifically focuses on universal prevention. Therefore, the aim of this study is to examine the effectiveness that is reported in published randomized controlled trial (RCT) studies.

Methods and analysis

This systematic review and meta-analysis will analyze published studies selected from electronic databases (i.e., Cochrane Central Register of Controlled Trials, PubMed, CINAHL, PsycINFO, PsycARTICLES, Web of Science, and the Japan Medical Abstracts Society). The inclusion criteria for studies are that they (1) were conducted to assess the effect of CBT on the mental health of nurses as a universal prevention, (2) used an RCT design, (3) provided sufficient results (sample sizes, means, and standard deviations) to estimate the pooled effect sizes with 95% confidence intervals, and (4) were published as original articles and written in English or Japanese. Studies will be excluded if they only targeted nurses who had been screened as being at high risk in terms of their mental health and indicated that they required the prevention. The study selection, data collection, quality assessment, and statistical syntheses will be conducted based on discussions among the authors.

Ethics and dissemination

Ethical approval is not required because this study is based on information obtained from previous studies. The results and findings of this study will be submitted for publication in a peer-reviewed international scientific journal. Results from this study will be helpful when implementing CBT strategies for nurses as a universal preventative measure in the workplace and for managing stress-related outcomes.

Strengths and limitations of this study

► This systematic review and meta-analysis will offer the strongest evidence about the effectiveness of CBT-based interventions on the mental health of nurses that can be applied as a universal prevention in the workplace.

► This study will not include RCT studies that targeted only nurses who were screened as being high risk in terms of their mental health.

► The findings from the study will be useful for conducting CBT-based stress management interventions for nurses in the workplace as a universal prevention and managing stress-related outcomes.

► This study is limited because the findings cannot be generalized to countries or groups that are not

included in the selected studies.

PROSPERO registration number CRD42020152837.

INTRODUCTION

Studies of stress in nursing workplaces have reported that nurses have a high prevalence of probable occupational stress.[1, 2] The main causes of the work-related stress among nurses are heavy workloads, interpersonal conflicts, the emotional impacts of care, lack of reward or control, and shift work.[3] Occupational stress is known to be a major risk factor for burnout, anxiety, and depression.[3] These mental health problems can lead to the worsening of the nurses' somatic symptoms[4] and the degradation of their quality of life[5] and their work engagement,[6] and it can have negative effects in the workplace (e.g., an increase in absenteeism[7] and the intention to leave employment[7]) and lead to a deterioration in the quality of care that the nurses provide.[8] As in nursing workplaces, there are seldom Employee Assistance Programs (EAP) that provide any formal stress management initiatives for employees to improve their mental health by learning coping mechanisms, due to lack of manpower, resources, and managers' awareness,[9] nurses can be vulnerable to depression due to the lack of stress management skills.[10] According to two surveys in the U.S., the prevalence of depression in nurses varies from 18% to 35%, which is higher than in the general population.[4, 5] Maintaining and improving nurses' mental health as a primary prevention is necessary not only for their well-being but also for improving their productivity, reducing the cost to their workplace, and guaranteeing the quality of care for the patients.[11] Therefore, stress management for nurses is needed in nursing workplaces.

Cognitive behavioral therapy (CBT) is one of the major stress management techniques for workers and it has been shown to have positive effects as a primary prevention. According to a meta-review[12] and several meta-analyses,[13, 14] it has been proved that CBT, as a stress management technique, significantly improves occupational stress, anxiety, and depression for workers in the workplace. These meta-analyses concluded that CBT was more effective than other interventions.[13, 14] In addition, in studies targeting nurses, a Cochrane review showed that CBT stress management interventions had significant positive effects on stress-related outcomes, including occupational stress and depressive symptoms, among nurses (standardized mean difference [SMD] = -0.34 at the six-month follow-up).[10] Thus, evidence about CBT-based stress management for nurses has accumulated.

Primary prevention strategies for mental health problems can be classified into three categories; 1) universal prevention which targets the general population and are not directed at a specific risk group, 2) selective prevention which targets individuals considered to be at potentially risk for mental illness as based on the presence of an identified risk factor such as parental mental illness, and 3) indicated prevention which targets individuals who are screened for already having early signs or symptoms of mental illness.[15–17] There are theoretical and practical reasons why universal prevention can be more appropriate for the workplace.[18] As universal prevention can reach more individuals, including

selected and indicated groups without the need for screening which is a costly process to implement,[15, 18, 19] and can reach individuals who might not want to seek treatment or disclose symptoms for fear of its perceived negative effects on work, the universal prevention of the nurses' mental health problems is a high-priority strategy for mental health management in nursing workplaces. Therefore, systematic reviews and meta-analyses are necessary to obtain a comprehensive understanding and conduct evidence-based interventions regarding the effect of CBT on nurses' mental health as a universal prevention in the workplace.

However, there has been no systematic review and/or meta-analysis that has specialized in the universal prevention effect of CBT on nurses' mental health. The abovementioned Cochrane review of stress management for nurses included studies of indicated prevention, which targeted only nurses at high risk who were sorted using a screening scale of mental health.[10] Other systematic reviews, as well, included studies that were not randomized or only for nurses who were screened as high-risk for their mental health.[1, 20–22] Therefore, the effect of CBT-based stress management interventions for universal prevention among nurses has not been clearly identified in a systematic review and/or a meta-analysis. Further, various provisional methods and formats have been developed for CBT in recent years as well as conventional face-to-face implementations of CBT. For example, iCBT (internet-based CBT), in which CBT is provided through an Internet-based platform is attracting attention, and studies that evaluate its effectiveness and social implementations are underway. However, the Cochrane review regarding nurse stress management[10] included studies up to 2013 and did not include new methods of implementation such as iCBT.

Therefore, the aim of this systematic review and meta-analysis is to evaluate the overall effectiveness of CBT-based interventions for stress management among nurses, including the recent studies, as a universal prevention in the workplace. We hypothesize that the CBT-based interventions will be effective for improving nurses' mental health as a universal prevention.

METHODS AND ANALYSIS

Study design

This study protocol for a systematic review and meta-analysis of intervention studies (randomized controlled trials; RCTs) follows the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) guideline.[23] Findings will be reported according to the PRISMA statement.[24] The study protocol was registered with PROSPERO (CRD42020152837).

Eligibility criteria

The participants, interventions, comparisons, and outcomes (PICO) of the studies included in this systematic review and meta-analysis will be defined as follows: (P) healthy nurses (not diagnosed as having a mental illness), (I) any type or mode of CBT-based intervention, (C) no intervention or not a

CBT-based intervention, and (O) mental health. We will include intervention studies (RCTs) conducted in the entire nurse population. Studies will be excluded if they correspond to selective or indicated prevention among primary prevention. We will exclude studies in which participants were practical nurses or nursing aides and those that involved other healthcare workers such as doctors in this systematic review and meta-analysis. There will be no exclusion criteria regarding participants' employment status or the healthcare settings in which they were employed. However, we will exclude studies that targeted individuals considered to be at potentially risk for mental illness according to an identified risk factor such as parental mental illness, or that exclusively targeted nurses who had been screened as being high risk in terms of their mental health. We will include studies with a CBT-based intervention that aimed to reduce burnout, anxiety, or depressive symptoms in the entire nursing population.

CBT is defined as an intervention that provides new ways to rationally think and/or behave in stressful situations, such as through cognitive restructuring, behavioral activation, problem solving, mindfulness-based cognitive therapy (MBCT), and acceptance and commitment therapy (ACT).[25, 26] The comparisons will be defined as no intervention; waiting-list control; treatment as usual, such as education or training (but not CBT) that is provided by the nursing association; or alternative (not CBT) interventions. Aspects of mental health (i.e., primary outcome) will include burnout, anxiety, or depression, which are the adverse effects of occupational stress.[3] These will be assessed using such self-reported measures as the Maslach Burnout Inventory,[27] the General Health Questionnaire,[28] and the Beck Depression Inventory,[29] as well as structured interviews, including the Hamilton Rating Scale for Depression.[30] As secondary outcomes, we will consider occupational outcomes, which can be the adverse effects of mental health problems. These will include absenteeism, intention to leave employment, work performance, or work engagement. Studies that did not conduct a statistical analysis to examine the intervention effects will be excluded.

Studies will be included in this systematic review and meta-analysis that (1) were conducted to evaluate the effect of CBT-based interventions on the mental health of nurses as a universal prevention, (2) used an RCT design, (3) did not exclusively target nurses who had been screened as being at high risk in terms of their mental health, (4) provide sufficient data (sample sizes, means, and standard deviations [*SDs*]) for calculating the effect sizes with 95% confidence intervals (CIs), (5) were published as original articles written in English or Japanese, and (6) were published up to 2022.

Information sources, search strategy, and data management

Systematic searches of published studies will be performed using the following electronic databases: Cochrane Central Register of Controlled Trials (CENTRAL), PubMed (MEDLINE), CINAHL, PsycINFO, PsycARTICLES, Web of Science, and the Japan Medical Abstracts Society. The search terms will include words related to the research PICO. The search strategy (i.e., the key terms) is listed

in the online Supplementary File 1. All identified studies will be managed using Microsoft Excel (Microsoft Corp., Redmond, WA, USA) files. Prior to the study selection process, duplicate citations in the Excel files will be excluded by KK who is a first author. Decisions about all of the studies will be recorded.

Study selection process

The study selection process will include two phases. The first is a sifting phase. According to the inclusion criteria, three review authors (KK, AT, and AI) will independently conduct the screening of the studies. The titles and abstracts will be screened according to the eligibility criteria created earlier in the sifting phase. The second is the full text review phase. The full text of all eligible studies will be obtained and reviewed using a standardized form (see the online Supplementary File 2) to assess their eligibility for inclusion in this review. Any discrepancies in the assessment will be recorded, and if they cannot be resolved, they will be settled by discussion among all of the authors until a consensus is reached. The reference lists from the studies will be carefully examined for any additional eligible studies. We will directly contact the corresponding authors of the eligible studies if (1) the results of the publication are unclear and/or may be related to multiple interpretations, or (2) the reported results did not show data relevant to our study analysis. A flow chart will be provided to show the entire review process.

Data extraction

The data will be independently extracted from the included studies by three review authors (KK, AT, and AI) using a standardized data extraction form. Any disagreement or inconsistencies will be recorded and solved by discussion among all of the authors until a consensus is reached. The extracted data will include the following: the year of publication, country where the study was conducted, number of participants included in the analysis, sampling framework, participants' demographic characteristics (i.e., mean age, sex proportions, years of nursing experience, and employment status), number of participants who were excluded or lost to follow-up, the contents of the intervention program, control condition (i.e., no intervention, waiting-list control, or other), outcome variables (i.e., stress-related outcomes such as burnout, anxiety, and depressive symptoms, or occupational outcomes such as absenteeism, intention to leave employment, work performance, or work engagement), length of follow-up, and sufficient data (i.e., the number of participants in each group (N), mean differences (MD) between groups, and SD for outcomes) for calculating the effect size with 95% CIs for determining the effect of CBT on the mental health of nurses for universal prevention. This extraction format is experimental and can be modified as needed. The relevant research teams of the studies will be contacted about the availability of unpublished or missing data.

Risk-of-bias assessment

Three review authors (KK, AT, and AI) will independently assess the methodological quality of the included studies using the Cochrane Collaboration's risk-of-bias tool.[31] The tool evaluates possible sources of bias in intervention studies based on seven main categories: (1) random sequence generation, (2) allocation concealment, (3) blinding of the participants and personnel, (4) blinding of the outcome assessment, (5) incomplete outcome data, (6) selective outcome reporting, and (7) other biases. Inconsistencies in the quality assessment of the methodology will be recorded and discussed by all of the authors until a consensus is reached. For the assessment of the meta-bias, the publication bias will be assessed using funnel plots for asymmetry and Egger's test.

Data synthesis and statistical methods

The included studies will be statistically synthesized by a meta-analysis to estimate the pooled effect (SMD) of CBT on the mental health of nurses as a universal prevention in the workplace. We will combine studies that we determine to be similar in terms of follow-up time. We will consider the effects over the following follow-up periods: (i) Up to one month, (ii) From one month to six months, or (iii) Over six months. Forest plots of the between-group and post-intervention effect sizes for mental health and the 95% CIs will be produced. The number of participants and the scores, such as the means and *SDs* for the intervention and the control group for the psychological outcomes, will be entered into Review Manager (RevMan).[32] The magnitude of the effect size will be interpreted as being small (0.2), medium (0.5), or large (0.8).[33]

The meta-analysis will be performed when at least three eligible studies can be collected. If it is not appropriate to perform a meta-analysis (i.e., no more than two studies are eligible and included), the results will be presented in a narrative form. The publication bias will be examined using a funnel plot and Egger's test. Statistical heterogeneity will be assessed using the chi-square (χ^2) test with Cochran's Q statistic and the I^2.[34] The I^2 values of 25%, 50%, and 75% indicate low, medium, and high heterogeneity, respectively.[35] An I^2 value of 50% or more will be deemed to indicate considerable heterogeneity. If there is little or no statistical heterogeneity (i.e., an I^2 value of less than 50%) in a comparison, we will pool the results using a fixed-effects model. If the I^2 statistic is more than 50%, we will use a random-effects model.[36]

Since the effect of the CBT may differ according to the specific population, subgroup analyses will be conducted to compare the results. The major possible grouping characteristics will include newly graduated nurses (i.e., less than 1 year of nursing experience) because they have been reported to have higher stress-related outcomes, including depressive symptoms, compared to veteran nurses. [11, 37–39] We will treat participants with more/less than 1 year of nursing experience as another stratification factor and conduct a subgroup analysis. In addition, the mode of CBT delivery (e.g., face-to-face vs computer-based CBT including iCBT) or outcome variables (i.e., burnout, anxiety, and depressive

symptoms) will be considered as possible grouping characteristics. Any subgroup differences will be reported, and our findings will be explained by considering these differences. To assess the effect of the risk of bias on the pooled results, a sensitivity analysis will be conducted of the included studies that are only classified as low risk according to the Cochrane Collaboration's risk-of-bias tool.[31] All of the extracted data and analyzed results will be deposited by the corresponding author and they will be available for external reviewers and readers upon request.

Patient and public involvement statement

This study will not involve any patients or participants because this study protocol is for a systematic review and meta-analysis.

Ethics and dissemination

As this systematic review and meta-analysis will be based on previously published studies, it does not require ethical approval. The results and findings of this study will be published in peer-reviewed international journals and be presented at related research conferences, academic symposiums, and seminars.

STRENGTHS AND LIMITATIONS

The greatest strength of this study is that, to the best of our knowledge, it will be the first systematic review and meta-analysis to offer evidence regarding the effect of CBT-based interventions on the mental health of nurses as a universal prevention in the workplace. Because the mental health status of nurses deleteriously affects not only the individuals but also the organizations and the quality of patient care,[8, 11] if the effect of the CBT provided in the workplace as a universal prevention is confirmed by this meta-analysis, it will be beneficial for the nurses', occupation's, and patients' health. The findings from this study will be helpful for conducting CBT-based stress management interventions for nurses as a universal prevention in the workplace and for managing stress-related outcomes.

However, this study has the limitation that the generalization of our study findings to countries or groups that are not included in the selected studies will be limited.

Acknowledgments

We would like to thank Editage [http://www.editage.com] for editing and reviewing this manuscript for English language.

Author Contributions

The study was conceived and designed by KK, KI, and NK. The initial draft of the manuscript was

written by KK, and all authors revised and contributed to the final manuscript. All authors read and approved the final manuscript. The entire study process (i.e., the data collection, assessment, and synthesis) will be conducted by all of the authors.

Funding statement

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Competing interests statement

The authors declare no conflict of interest.

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Supplementary File 1.

Search terms for PubMed

(nurse[tiab] OR nurses[tiab] OR nursing[tw] OR nursery[tw] OR "health personnel"[tw] OR "health care personnel"[tw] OR "healthcare personnel"[tw] OR "health care worker"[tw] OR "health care workers"[tw] OR "healthcare worker"[tw] OR "healthcare workers"[tw] OR "health worker"[tw] OR "health workers"[tw] OR "health professional"[tw] OR "health professionals"[tw] OR "health care professional"[tw] OR "health care professionals"[tw] OR "healthcare professional"[tw] OR "healthcare professionals"[tw] OR "medical care personnel"[tw] OR "health staff"[tw] OR "health staffs"[tw] OR "healthcare staff"[tw] OR "healthcare staffs"[tw] OR "health care staff"[tw] OR "health care staffs"[tw]) AND (cognitive[tw] OR behavio*[tw] OR mindfulness[tw] OR CBT[tw] OR ACT[tw]) AND (burnout[tw] OR anxiety[tw] OR anxious*[tw] OR depression[tw] OR depress*[tw] OR "mental health"[tw] OR stress*[tw] OR distress[tw]) AND ("randomized controlled trial"[pt] OR (randomized[tiab] AND controlled[tiab] AND trial[tiab]))

Supplementary File 2. Standardized form to assess eligibility for inclusion

ID	Database	No	Title	Author name	Source	Abstract	URL	reviewer 1	reviewer 2	Result_ screening 1	Result_ screening 2	Result_ discussion
1	PubMed	1	Mindfulness-based stress reduction training yields improvements in well-being and rates of perceived nursing errors among hospital nurses.	Daigle S, Talbot F, French DJ.	J Adv Nurs 2018; 74: 2427–2430. Date of Publication: 8 Jul 2018	INTRODUCTION: This pilot study aims to further document mindfulness-based stress reduction (MBSR)'s effect on well-being while exploring its impact on errors among hospital nurses. BACKGROUND: The concept of mindfulness has been found to be highly relevant to holistic nursing practices but remains understudied and underused. Preliminary evidence suggests that MBSR can reduce stress among nurses. As stress and mental processes such as inattention are potential sources of error, MBSR may also help to improve patient safety. Reducing errors is of significant relevance in healthcare settings. DESIGN: A randomized controlled trial with a matched pair design was conducted. METHODS: Seventy Registered Nurses and licensed practical nurses were randomized to MBSR (N = 37) or a waitlist control condition (N = 33). RESULTS: Intention-to-treat ANCOVAs revealed that MBSR produced significant improvements in distress. High levels of treatment satisfaction were reported by a majority of participants. Of the nurses who reported that errors had been a problem for them (28.6%), a perceived improvement was noticed by over a third (37.5%) at 3 months post-treatment. CONCLUSION: These initial findings suggest that the benefits of MBSR may extend to nursing errors.		KK	MS	○	×	×

Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	n/a

Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	PROSPERO registration number CRD42020152837
Authors			
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	10-11
Amendments			
	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a
Support			
Sources	#5a	Indicate sources of financial or other support for the review	11
Sponsor	#5b	Provide name for the review funder and / or sponsor	n/a

Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	n/a
Introduction			
Rationale	#6	Describe the rationale for the review in the context of what is already known	5-6
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
Methods			
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6-7
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	7-8
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	7-8

Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	7-8
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8
Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	8
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6-7
Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6-7
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or	8-9

		study level, or both; state how this information will be used in data synthesis	
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	9-10
Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	9-10
Data synthesis	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	9-10
Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	9
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	9
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	10

Notes:

- 2: PROSPERO registration number CRD42020152837 The PRISMA-P elaboration and explanation paper is distributed under the terms of the Creative Commons Attribution License CC-BY. This checklist was completed on 18. January 2022 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

BMJ Open

The effect of stress management based on cognitive behavioral therapy on nurses as a universal prevention in the workplace: a systematic review and meta-analysis protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-062516.R1
Article Type:	Protocol
Date Submitted by the Author:	08-Jun-2022
Complete List of Authors:	Kuribayashi, Kazuto; Tokyo Medical and Dental University Graduate School of Health Care Sciences, Department of Mental Health and Psychiatric Nursing Takano, Ayumi; Tokyo Medical and Dental University Graduate School of Health Care Sciences, Department of Mental Health and Psychiatric Nursing Inagaki, Akiko; Tokyo Healthcare University, Faculty of Healthcare, Division of Nursing Imamura, Kotaro; The University of Tokyo, Graduate School of Medicine, Department of Mental Health Kawakami, Norito; The University of Tokyo, Graduate School of Medicine, Department of Mental Health
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Nursing
Keywords:	MENTAL HEALTH, OCCUPATIONAL & INDUSTRIAL MEDICINE, Depression & mood disorders < PSYCHIATRY

June 3, 2022S

The effect of stress management based on cognitive behavioral therapy on nurses as a universal prevention in the workplace: a systematic review and meta-analysis protocol

Authors
Kazuto Kuribayashi[1]
E-mail: kkuribayashi-jans@umin.ac.jp
Ayumi Takano[1]
E-mail: ayumi-takano@umin.ac.jp
Akiko Inagaki[2]
akikok-tky@umin.ac.jp
Kotaro Imamura[3]
E-mail: kouima-tky@umin.ac.jp
Norito Kawakami[3]
E-mail: norito@m.u-tokyo.ac.jp

Correspondence to: Kazuto Kuribayashi
Department of Mental Health and Psychiatric Nursing, Graduate School of Health Care Sciences, Tokyo Medical and Dental University,
1-5-45 Yushima, Bunkyo-ku, Tokyo 113-8510, JAPAN
Tel: +81-3-5803-5336
E-mail: kkuribayashi-jans@umin.ac.jp

Authors' information
[1]Department of Mental Health and Psychiatric Nursing, Graduate School of Health Care Sciences, Tokyo Medical and Dental University, 1-5-45 Yushima, Bunkyo-ku, Tokyo 113-8510, Japan.
[2]Division of Nursing, Faculty of Healthcare, Tokyo Healthcare University, 4-1-17 Higashigotanda, Shinagawa-ku, Tokyo 141-8648, Japan.
[3]Department of Mental Health, Graduate School of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan.

Keywords: Nurse, Cognitive behavioral therapy, Universal prevention, Systematic review, Meta-analysis

Word count: 2,821

ABSTRACT

Introduction

The mental health status of nurses affects not only their well-being but also the organizational outcomes and the quality of patient care. Hence, stress management strategies are critical as a universal prevention measure that address an entire population and are not directed at a specific risk group to maintain nurses' mental health in the workplace. No systematic review or meta-analysis has been conducted to evaluate the effect of cognitive behavioral therapy (CBT) that specifically focuses on universal prevention. Therefore, the aim of this study is to examine the effectiveness that is reported in published randomized controlled trial (RCT) studies.

Methods and analysis

This systematic review and meta-analysis will analyze published studies selected from electronic databases (i.e., Cochrane Central Register of Controlled Trials, PubMed, CINAHL, PsycINFO, PsycARTICLES, Web of Science, and the Japan Medical Abstracts Society). The inclusion criteria for studies are that they (1) were conducted to assess the effect of CBT on the mental health of nurses as a universal prevention, (2) used an RCT design, and (3) provided sufficient results (sample sizes, means, and standard deviations) to estimate the pooled effect sizes with 95% confidence intervals. Studies will be excluded if they only targeted nurses who had been screened as being at high risk in terms of their mental health and indicated that they required the prevention. The methodological quality of the included studies will be assessed using the Cochrane Collaboration's risk-of-bias tool.

Ethics and dissemination

Ethical approval is not required because this study is based on information obtained from previous studies. The results and findings of this study will be submitted for publication in a peer-reviewed international scientific journal. Results from this study will be helpful when implementing CBT strategies for nurses as a universal preventative measure in the workplace and for managing stress-related outcomes.

Strengths and limitations of this study

► This systematic review and meta-analysis will offer the strongest evidence about the effectiveness of CBT-based interventions on the mental health of nurses that can be applied as a universal prevention in the workplace.

► This study will not include RCT studies that targeted only nurses who were screened as being high risk in terms of their mental health.

► The findings from the study will be useful for conducting CBT-based stress management interventions for nurses in the workplace as a universal prevention and managing stress-related outcomes.

► This study is limited because the findings cannot be generalized to countries or groups that are not

included in the selected studies.

PROSPERO registration number CRD42020152837.

INTRODUCTION

Studies of stress in nursing workplaces have reported that nurses have a high prevalence of probable occupational stress.[1,2] The main causes of the work-related stress among nurses are heavy workloads, interpersonal conflicts, the emotional impacts of care, lack of reward or control, and shift work.[3] Occupational stress is known to be a major risk factor for burnout, anxiety, and depression.[3] These mental health problems can lead to the worsening of the nurses' somatic symptoms or disorder,[4] insomnia,[5] the degradation of their quality of life,[6] and their work engagement,[7,8] and it can have adverse effects in the workplace (e.g., an increase in absenteeism [9] and the intention to leave employment[10]) and lead to a deterioration in the quality of care that the nurses provide.[2] As in nursing workplaces, there are seldom Employee Assistance Programs (EAP) that provide any formal stress management initiatives for employees to improve their mental health by learning coping mechanisms, due to lack of manpower, resources, and managers' awareness,[11] nurses can be vulnerable to depression due to the lack of stress management skills.[12] According to two surveys in the United States, the prevalence of depression in nurses varies from 18% to 35%, which is higher than in the general population.[4,13] Maintaining and improving nurses' mental health as a primary prevention (to prevent diseases before it occurs) is necessary not only for their well-being but also for improving their productivity, reducing workplace costs, and guaranteeing the quality of care for the patients.[14] Therefore, stress management for nurses is needed in nursing workplaces.

Cognitive behavioral therapy (CBT) is one of the major stress management techniques for workers and it has been shown to have positive effects as a primary prevention. According to a meta-review[15] and several meta-analyses,[16,17] it has been proved that CBT, as a stress management technique, significantly improves occupational stress, anxiety, and depression for workers in the workplace. These meta-analyses concluded that CBT was more effective than other interventions.[16,17] In addition, in studies targeting nurses, a Cochrane review showed that CBT stress management interventions had significant positive effects on stress-related outcomes, including occupational stress and depressive symptoms, among nurses (standardized mean difference [SMD] = -0.34 at the six-month follow-up).[12] Thus, evidence about CBT-based stress management for nurses has accumulated.

Primary prevention strategies for mental health problems can be classified into three categories; 1) universal prevention, which targets the general population and is not directed at a specific risk group, 2) selective prevention, which targets individuals considered to be at potential risk for mental illness as based on the presence of an identified risk factor such as parental mental illness, and 3) indicated prevention which targets individuals who are screened for already having early signs or subthreshold symptoms of mental illness.[18–21] There are theoretical and practical reasons why universal prevention can be more appropriate for the workplace.[22] As universal prevention can reach more

individuals, including selected and indicated groups without the need for screening which is a costly process to implement,[18,22,23] and can reach individuals who disclose symptoms for fear of its perceived negative effects on work, the universal prevention of the nurses' mental health problems is a high-priority strategy for mental health management in nursing workplaces. Therefore, systematic reviews and meta-analyses are necessary to obtain a comprehensive understanding and conduct evidence-based interventions regarding the effect of CBT on nurses' mental health as a universal prevention in the workplace.

However, there has been no systematic review and/or meta-analysis that has specialized in the universal prevention effect of CBT on nurses' mental health. The abovementioned Cochrane review of stress management for nurses included studies of indicated prevention, which targeted only nurses at high risk who were sorted using a screening scale of mental health.[12] Other systematic reviews, as well, included studies that were not randomized or only for nurses who were screened as high-risk for their mental health.[1,24–26] Therefore, the effect of CBT-based stress management interventions for universal prevention among nurses has not been clearly identified in a systematic review and/or a meta-analysis. Further, various provisional methods and formats have been developed for CBT in recent years as well as conventional face-to-face implementations of CBT. For example, iCBT (internet-based CBT), in which CBT is provided through an Internet-based platform is attracting attention, and studies that evaluate its effectiveness and social implementations are underway. However, the Cochrane review regarding nurse stress management[12] included studies up to 2013 and did not include new methods of implementation such as iCBT.

Therefore, the aim of this systematic review and meta-analysis is to evaluate the overall effectiveness of CBT-based interventions for stress management among nurses, including the recent studies, as a universal prevention in the workplace. We hypothesize that the CBT-based interventions will be effective for improving nurses' mental health as a universal prevention.

METHODS AND ANALYSIS

Study design

This study protocol for a systematic review and meta-analysis of intervention studies (randomized controlled trials; RCTs) follows the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) guideline.[27] Findings will be reported according to the PRISMA statement.[28] The study protocol was registered with PROSPERO (CRD42020152837).

Eligibility criteria

The participants, interventions, comparisons, and outcomes (PICO) of the studies included in this systematic review and meta-analysis will be defined as follows: (P) healthy nurses (not diagnosed as having a mental illness), (I) any type or mode of CBT-based intervention, (C) no intervention or not a

CBT-based intervention, and (O) mental health. We will include intervention studies (RCTs) conducted on the entire nurse population, including new graduate nurses (i.e., those with less than one year of nursing experience). Studies will be excluded if they correspond to selective or indicated prevention among primary prevention. This systematic review and meta-analysis focus on universal prevention as a primary strategy. Therefore, studies of selective or indicated prevention will be excluded from this review. In addition, we will exclude studies in which participants were practical nurses or nursing aides and those that involved other healthcare workers such as doctors in this systematic review and meta-analysis. There will be no exclusion criteria regarding participants' employment status or the healthcare settings in which they were employed. However, we will exclude studies that targeted individuals considered to be at potentially risk for mental illness according to an identified risk factor such as parental mental illness, or that exclusively targeted nurses who had been screened as being high risk in terms of their mental health. We will include studies with a CBT-based intervention that aimed to reduce burnout, anxiety, or depressive symptoms in the entire nursing population.

CBT is defined as an intervention that provides new ways to rationally think and/or behave in stressful situations, such as through cognitive restructuring, behavioral activation, problem solving, mindfulness-based cognitive therapy (MBCT), and acceptance and commitment therapy (ACT).[29,30] The comparisons will be defined as no intervention; waiting-list control; treatment as usual, such as education or training (but not CBT) that is provided by the nursing association; or alternative (not CBT) interventions. Aspects of mental health (i.e., primary outcome) will include burnout, anxiety, or depression, which are the adverse effects of occupational stress.[3] These will be assessed using such self-reported measures as the Maslach Burnout Inventory,[31] the General Health Questionnaire,[32] and the Beck Depression Inventory,[33] as well as structured interviews, including the Hamilton Rating Scale for Depression.[34] As secondary outcomes, we will consider occupational outcomes, which can be the adverse effects of mental health problems. These will include absenteeism, intention to leave current employment, degradation of care quality, work performance, or work engagement. Studies that did not conduct a statistical analysis to examine the intervention effects will be excluded.

Studies will be included in this systematic review and meta-analysis that (1) were conducted to evaluate the effect of CBT-based interventions on the mental health of nurses as a universal prevention, (2) used an RCT design, (3) did not exclusively target nurses who had been screened as being at high risk in terms of their mental health, (4) provide sufficient data (sample sizes, means, and standard deviations [*SDs*]) for calculating the effect sizes with 95% confidence intervals (CIs), (5) were published as original articles written in English or Japanese, and (6) were published up to 2022.

Information sources, search strategy, and data management

Systematic searches of published studies will be performed using the following electronic databases: Cochrane Central Register of Controlled Trials (CENTRAL), PubMed (MEDLINE), CINAHL, PsycINFO, PsycARTICLES, Web of Science, and the Japan Medical Abstracts Society. The search terms will include words related to the research PICO. The search strategy (i.e., the key terms) is listed in the online Supplementary File 1. Through systematic searches, we will also obtain information regarding studies that may have been completed but are not yet published. This search is essential to reduce publication bias in this systematic review. All identified studies will be managed using Microsoft Excel (Microsoft Corp., Redmond, WA, USA) files. Prior to the study selection process, duplicate citations in the Excel files will be excluded by KK who is a first author. Decisions about all of the studies will be recorded.

Study selection process

The study selection process will include two phases. The first is a sifting phase. According to the inclusion criteria, three review authors (KK, AT, and AI) will independently conduct the screening of the studies. The titles and abstracts will be screened according to the eligibility criteria created earlier in the sifting phase. The second is the full text review phase. The full text of all eligible studies will be obtained and reviewed using a standardized form (see the online Supplementary File 2) to assess their eligibility for inclusion in this review. Any discrepancies in the assessment will be recorded, and if they cannot be resolved, they will be settled by discussion among all of the authors until a consensus is reached. The reference lists from the studies will be carefully examined for any additional eligible studies. We will directly contact the corresponding authors of the eligible studies if (1) the results of the publication are unclear or may be related to multiple interpretations, (2) the reported results did not show data relevant to our study analysis, or (3) the study has been registered for clinical trials but are not yet published. If we contact those corresponding authors but do not receive a reply, we will not include their articles in the analysis. We will describe the process in the paper, including contact with the corresponding authors. A flow chart will be provided to show the entire review process.

Data extraction

The data will be independently extracted from the included studies by three review authors (KK, AT, and AI) using a standardized data extraction form (see the online Supplementary File 3). Any disagreement or inconsistencies will be recorded and solved by discussion among all of the authors until a consensus is reached. The extracted data will include the following: the year of publication, country where the study was conducted, number of participants included in the analysis, sampling framework, participants' demographic characteristics (i.e., mean age, sex proportions, years of nursing experience, and employment status), number of participants who were excluded or lost to follow-up, the contents of the intervention program, control condition (i.e., no intervention, waiting-list control,

or other), outcome variables (i.e., stress-related outcomes such as burnout, anxiety, and depressive symptoms, or occupational outcomes such as absenteeism, intention to leave current employment, quality of care, work performance, or work engagement), length of follow-up, and sufficient data (i.e., the number of participants in each group (N), mean differences (MD) between groups, and SD for outcomes) for calculating the effect size with 95% CIs for determining the effect of CBT on the mental health of nurses for universal prevention. This extraction format is experimental and can be modified as needed. The relevant research teams of the studies will be contacted about the availability of unpublished or missing data.

Risk-of-bias assessment

Three review authors (KK, AT, and AI) will independently assess the methodological quality of the included studies using the Cochrane Collaboration's risk-of-bias tool.[35] The tool evaluates possible sources of bias in intervention studies based on seven main categories: (1) random sequence generation, (2) allocation concealment, (3) blinding of the participants and personnel, (4) blinding of the outcome assessment, (5) incomplete outcome data, (6) selective outcome reporting, and (7) other biases. Inconsistencies in the quality assessment of the methodology will be recorded and discussed by all of the authors until a consensus is reached. For the assessment of the meta-bias, the publication bias will be assessed using funnel plots for asymmetry and Egger's test.

Data synthesis and statistical methods

The included studies will be statistically synthesized by a meta-analysis to estimate the pooled effect (SMD) of CBT on the mental health of nurses as a universal prevention in the workplace. We will combine studies that we determine to be similar in terms of follow-up time. We will consider the effects over the following follow-up periods: (i) Up to one month, (ii) From one month to six months, or (iii) Over six months. Forest plots of the between-group and post-intervention effect sizes for mental health and the 95% CIs will be produced. The number of participants and the scores, such as the means and *SDs* for the intervention and the control group for the psychological outcomes, will be entered into Review Manager (RevMan).[36] The magnitude of the effect size will be interpreted as being small (0.2), medium (0.5), or large (0.8).[37]

The meta-analysis will be performed when at least three eligible studies can be collected. If it is not appropriate to perform a meta-analysis (i.e., no more than two studies are eligible and included), the results will be presented in a narrative form. The publication bias will be examined using a funnel plot and Egger's test. Statistical heterogeneity will be assessed using the chi-square (χ^2) test with Cochran's Q statistic and the I^2.[38] The I^2 values of 25%, 50%, and 75% indicate low, medium, and high heterogeneity, respectively.[39] An I^2 value of 50% or more will be deemed to indicate considerable heterogeneity. If there is little or no statistical heterogeneity (i.e., an I^2 value of less than 50%) in a

comparison, we will pool the results using a fixed-effects model. If the I^2 statistic is more than 50%, we will use a random-effects model.[40]

Since the effect of the CBT may differ according to the specific population, subgroup analyses will be conducted to compare the results. The major possible grouping characteristics will include newly graduated nurses because they have been reported to have higher stress-related outcomes, including depressive symptoms, compared to veteran nurses. [14,41–43] We will treat participants with more/less than 1 year of nursing experience as another stratification factor and conduct a subgroup analysis. In addition, the mode of CBT delivery (e.g., face-to-face vs computer-based CBT including iCBT) or outcome variables (i.e., burnout, anxiety, and depressive symptoms) will be considered as possible grouping characteristics. Any subgroup differences will be reported, and our findings will be explained by considering these differences. To assess the effect of the risk of bias on the pooled results, a sensitivity analysis will be conducted of the included studies that are only classified as low risk according to the Cochrane Collaboration's risk-of-bias tool.[35] All of the extracted data and analyzed results will be deposited by the corresponding author and they will be available for external reviewers and readers upon request.

Patient and public involvement statement

This study will not involve any patients or participants because this study protocol is for a systematic review and meta-analysis.

Ethics and dissemination

As this systematic review and meta-analysis will be based on previously published studies, it does not require ethical approval. The results and findings of this study will be published in peer-reviewed international journals and be presented at related research conferences, academic symposiums, and seminars.

STRENGTHS AND LIMITATIONS

The greatest strength of this study is that, to the best of our knowledge, it will be the first systematic review and meta-analysis to offer evidence regarding the effect of CBT-based interventions on the mental health of nurses as a universal prevention in the workplace. Because the mental health status of nurses deleteriously affects not only the individuals but also the organizations and the quality of patient care,[2,14] if the effect of the CBT provided in the workplace as universal prevention is confirmed by this meta-analysis, it will be beneficial for nurses', occupation's, and patients' health. In addition, it will provide economic and productivity boosts in the workplace. The findings from this study will be helpful for conducting CBT-based stress management interventions for nurses as a universal prevention in the workplace and for managing stress-related outcomes.

However, this study has the limitation that the generalization of our study findings to countries or groups that are not included in the selected studies will be limited. In addition, there is a limitation that the article search will be conducted only in two languages, which can exclude potentially important data published in other languages.

Acknowledgments

We would like to thank Editage [http://www.editage.com] for editing and reviewing this manuscript for English language.

Author Contributions

The study was conceived and designed by KK, KI, AT, AI, and NK. The initial draft of the manuscript was written by KK, and all authors revised it critically for important intellectual content and contributed to the final manuscript. All authors read and approved the final manuscript. The entire study process (i.e., the data collection, assessment, and synthesis) will be conducted by all of the authors.

Funding statement

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Competing interests statement

The authors declare no conflict of interest.

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Supplementary File 1.

Search terms for PubMed

(nurse[tiab] OR nurses[tiab] OR nursing[tw] OR nursery[tw] OR "health personnel"[tw] OR "health care personnel"[tw] OR "healthcare personnel"[tw] OR "health care worker"[tw] OR "health care workers"[tw] OR "healthcare worker"[tw] OR "healthcare workers"[tw] OR "health worker"[tw] OR "health workers"[tw] OR "health professional"[tw] OR "health professionals"[tw] OR "health care professional"[tw] OR "health care professionals"[tw] OR "healthcare professional"[tw] OR "healthcare professionals"[tw] OR "medical care personnel"[tw] OR "health staff"[tw] OR "health staffs"[tw] OR "healthcare staff"[tw] OR "healthcare staffs"[tw] OR "health care staff"[tw] OR "health care staffs"[tw]) AND (cognitive[tw] OR behavio*[tw] OR mindfulness[tw] OR CBT[tw] OR ACT[tw]) AND (burnout[tw] OR anxiety[tw] OR anxious*[tw] OR depression[tw] OR depress*[tw] OR "mental health"[tw] OR stress*[tw] OR distress[tw]) AND ("randomized controlled trial"[pt] OR (randomized[tiab] AND controlled[tiab] AND trial[tiab]))

Supplementary File 2. Standardized form to assess eligibility for inclusion

ID	Database	No	Title	Author name	Source	Abstract	URL	reviewer 1	reviewer 2	Result_ screening 1	Result_ screening 2	Result_ discussion
1	PubMed	1	Mindfulness-based stress reduction training yields improvements in well-being and rates of perceived nursing errors among hospital nurses.	Daigle S, Talbot F, French DJ.	J Adv Nurs 2018; 74: 2427–2430. Date of Publication: 8 Jul 2018	INTRODUCTION: This pilot study aims to further document mindfulness-based stress reduction (MBSR)'s effect on well-being while exploring its impact on errors among hospital nurses. BACKGROUND: The concept of mindfulness has been found to be highly relevant to holistic nursing practices but remains understudied and underused. Preliminary evidence suggests that MBSR can reduce stress among nurses. As stress and mental processes such as inattention are potential sources of error, MBSR may also help to improve patient safety. Reducing errors is of significant relevance in healthcare settings. DESIGN: A randomized controlled trial with a matched pair design was conducted. METHODS: Seventy Registered Nurses and licensed practical nurses were randomized to MBSR (N = 37) or a waitlist control condition (N = 33). RESULTS: Intention-to-treat ANCOVAs revealed that MBSR produced significant improvements in distress. High levels of treatment satisfaction were reported by a majority of participants. Of the nurses who reported that errors had been a problem for them (28.6%), a perceived improvement was noticed by over a third (37.5%) at 3 months post-treatment. CONCLUSION: These initial findings suggest that the benefits of MBSR may extend to nursing errors.		KK	MS	○	×	×

Supplementary File 3. Standardized data extraction form

ID	No	Title	Author	Source (Database, Journal, Year)	Country where the study was conducted	Number of participants included in the analysis	Sampling framework	Participants' demographic characteristics (imean age, sex proportions, years of nursing experience, and employment status)	Number of participants who were excluded or lost to follow-up	Contents of the intervention program	Control condition (no intervention, waiting-list control, or other)	Outcome variables	Length of follow-up	Sufficient data (the number of participants in each group (N), mean differences (MD) between groups, and SD for outcomes)

Reporting checklist for protocol of a systematic review and meta analysis.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	n/a

Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	PROSPERO registration number CRD42020152837
Authors			
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	10-11
Amendments			
	#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a
Support			
Sources	#5a	Indicate sources of financial or other support for the review	11
Sponsor	#5b	Provide name for the review funder and / or sponsor	n/a

Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	n/a
Introduction			
Rationale	#6	Describe the rationale for the review in the context of what is already known	5-6
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
Methods			
Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6-7
Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	7-8
Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	7-8

Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	7-8
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8
Study records - data collection process	#11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	8
Data items	#12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6-7
Outcomes and prioritization	#13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6-7
Risk of bias in individual studies	#14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or	8-9

		study level, or both; state how this information will be used in data synthesis	
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	9-10
Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's τ)	9-10
Data synthesis	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	9-10
Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	9
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	9
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	10

Notes:

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