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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

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9 3 The effect of stress management based on cognitive behavioral therapy on nurses as a universal
10 4 prevention in the workplace: a systematic review and meta-analysis protocol

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41 35 **Keywords:** Nurse, Cognitive behavioral therapy, Universal prevention, Systematic review, Meta-
42 36 analysis

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1 **ABSTRACT**

2 **Introduction**

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

9 **Methods and analysis**

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

20 **Ethics and dissemination**

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

27 **Strengths and limitations of this study**

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

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

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

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

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- 6 1 included in the selected studies.
- 7 2
- 8 3 PROSPERO registration number CRD42020152837.
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1 INTRODUCTION

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

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

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

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

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

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

26 **METHODS AND ANALYSIS**

27 **Study design**

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

33 **Eligibility criteria**

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

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

12 CBT is defined as an intervention that provides new ways to rationally think and/or behave in stressful
13 situations, such as through cognitive restructuring, behavioral activation, problem solving,
14 [mindfulness-based cognitive therapy \(MBCT\)](#), and acceptance and commitment therapy (ACT).[25,
15 26] The comparisons will be defined as no intervention; waiting-list control; treatment as usual, such
16 as education or training (but not CBT) that is provided by the nursing association; or alternative (not
17 CBT) interventions. Aspects of mental health (i.e., [primary outcome](#)) will include burnout, anxiety, or
18 depression, which are the adverse effects of occupational stress.[3] These will be assessed using such
19 self-reported measures as the Maslach Burnout Inventory,[27] the General Health Questionnaire,[28]
20 and the Beck Depression Inventory,[29] as well as structured interviews, including the Hamilton
21 Rating Scale for Depression.[30] [As secondary outcomes, we will consider occupational outcomes,
22 which can be the adverse effects of mental health problems. These will include absenteeism, intention
23 to leave employment, work performance, or work engagement.](#) Studies that did not conduct a statistical
24 analysis to examine the intervention effects will be excluded.

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

31 **Information sources, search strategy, and data management**

32 Systematic searches of published studies will be performed using the following electronic databases:
33 [Cochrane Central Register of Controlled Trials \(CENTRAL\)](#), PubMed (MEDLINE), CINAHL,
34 PsycINFO, PsycARTICLES, Web of Science, and the Japan Medical Abstracts Society. The search
35 terms will include words related to the research PICO. The search strategy (i.e., the key terms) is listed
36

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

5 6 **Study selection process**

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

19 20 **Data extraction**

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

1 Risk-of-bias assessment

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

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11 Data synthesis and statistical methods

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

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

30 Since the effect of the CBT may differ according to the specific population, subgroup analyses will be
31 conducted to compare the results. The major possible grouping characteristics will include newly
32 graduated nurses (i.e., less than 1 year of nursing experience) because they have been reported to have
33 higher stress-related outcomes, including depressive symptoms, compared to veteran nurses. [11, 37–
34 39] We will treat participants with more/less than 1 year of nursing experience as another stratification
35 factor and conduct a subgroup analysis. In addition, the mode of CBT delivery (e.g., face-to-face vs
36 computer-based CBT including iCBT) or outcome variables (i.e., burnout, anxiety, and depressive

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

7 8 **Patient and public involvement statement**

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

11 12 **Ethics and dissemination**

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

17 18 **STRENGTHS AND LIMITATIONS**

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

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

30 31 **Acknowledgments**

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

34 35 **Author Contributions**

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

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

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5 This research received no specific grant from any funding agency in the public, commercial, or not-
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7 **Competing interests statement**

8 The authors declare no conflict of interest.

9 **References**

- 10 1. Mimura C, Griffiths P. The effectiveness of current approaches to workplace stress management
11 in the nursing profession: An evidence based literature review. *Occup Environ Med* 2003;60:10–
12 5.
- 13 2. Marine A, Ruotsalainen J, Serra C, et al. Preventing occupational stress in healthcare workers.
14 *Cochrane database Syst Rev* 2006;134:CD002892.
- 15 3. McVicar A. Workplace stress in nursing: A literature review. *J Adv Nurs* 2003;44:633–42.
- 16 4. Welsh D. Predictors of depressive symptoms in female medical-surgical hospital nurses. *Issues*
17 *Ment Health Nurs* 2009;30:320–6.
- 18 5. Letvak S, Ruhm CJ, McCoy T. Depression in hospital-employed nurses. *Clin Nurse Spec*
19 2012;26:177–82.
- 20 6. Innstrand ST, Langballe EM, Falkum E. A longitudinal study of the relationship between work
21 engagement and symptoms of anxiety and depression. *Stress Heal* 2012;28:1–10.
- 22 7. Baba V V, Galperin BL, Lituchy TR. Occupational mental health: A study of work-related
23 depression among nurses in the Caribbean. *Int J Nurs Stud* 1999;36:163–9.
- 24 8. Letvak S, Ruhm C, Gupta S. Nurses' presenteeism and its effects on self-reported quality of care
25 and costs. *Am J Nurs* 2012;112:30-8; quiz 48, 39.
- 26 9. Yung PMB, Fung MY, Chan TMF, Lau BWK. Relaxation training methods for nurse managers
27 in Hong Kong: A controlled study. *Int J Ment Health Nurs* 2004;13:255–61.
- 28 10. Ruotsalainen JH, Verbeek JH, Mariné A, et al. Preventing occupational stress in healthcare
29 workers. *Cochrane database Syst Rev* 2015;CD002892.
- 30 11. Brandford AA, Reed DB. Depression in Registered Nurses: A State of the Science. *Workplace*
31 *Health Saf* 2016;64:488–511.
- 32 12. Joyce S, Modini M, Christensen H, et al. Workplace interventions for common mental disorders:
33 A systematic meta-review. *Psychol Med* 2016;46:683–97.

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2
3
4
5
6 1 13. Richardson KM, Rothstein HR. Effects of occupational stress management intervention
7 2 programs: A meta-analysis. *J Occup Health Psychol* 2008;13:69–93.
8 3 14. van der Klink JJ, Blonk RW, Schene AH, et al. The benefits of interventions for work-related
9 4 stress. *Am J Public Health* 2001;91:270–6.
10 5 15. McLaughlin KA. The Public Health Impact of Major Depression: A Call for Interdisciplinary
11 6 Prevention Efforts. *Prev Sci* 2011;12:361–71.
12 7 16. World Health Organization. Prevention of mental disorders: Effective interventions and policy
13 8 implications. Geneva: WHO, 2004.
14 9 17. Miller, J. E. Mental illness prevention. Alexandria, VA: American Mental Health Counselors
15 10 Association, 2014.
16 11 18. Tan L, Wang MJ, Modini M, et al. Preventing the development of depression at work: A
17 12 systematic review and meta-analysis of universal interventions in the workplace. *BMC Med*
18 13 2014;12.
19 14 19. Lynch FL, Hornbrook M, Clarke GN, et al. Cost-effectiveness of an intervention to prevent
20 15 depression in at-risk teens. *Arch Gen Psychiatry* 2005;62:1241–8.
21 16 20. Edwards D, Burnard P. A systematic review of stress and stress management interventions for
22 17 mental health nurses. *J Adv Nurs* 2003;42:169–200.
23 18 21. Romppanen J, Häggman-Laitila A. Interventions for nurses' well-being at work: A quantitative
24 19 systematic review. *J Adv Nurs* 2017;73:1555–69.
25 20 22. Westermann C, Kozak A, Harling M, et al. Burnout intervention studies for inpatient elderly care
26 21 nursing staff: Systematic literature review. *Int J Nurs Stud* 2014;51:63–71.
27 22 23. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-
28 23 analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4:1.
29 24 24. Moher D, Liberati A, Tetzlaff J, et al. Preferred Reporting Items for Systematic Reviews and
30 25 Meta-Analyses: The PRISMA Statement. *Ann Intern Med* 2009;151:264–9.
31 26 25. Hofmann SG, Sawyer AT, Fang A. The empirical status of the “new wave” of CBT. *Psychiatr*
32 27 *Clin North Am* 2010;33:701–10.
33 28 26. Beck AT, Dozois DJ. Cognitive therapy: Current status and future directions. *Annu Rev Med*
34 29 2011;62:397–409.
35 30 27. Maslach C, Jackson SE, Leiter MP. The Maslach Burnout Inventory Manual. 3rd Edition. Palo
36 31 Alto, CA: Consulting Psychologists Press 1996.
37 32 28. Goldberg D, Williams P. A User's Guide to the General Health Questionnaire. London: NFER-
38 33 Nelson 1991.
39 34 29. Beck A, Steer R, Brown G. BDI-II, Beck depression inventory: Manual. vi. San Antonio, Tex,
40 35 Boston: Psychological Corp 1996.
41 36 30. Cusin C, Yang H, Yeung A, et al. Chapter 2 Rating Scales for Depression. pp.7-35; In: L.Baer,
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- 1 M. A. Blais, editors: Handbook of clinical rating scales and assessment in psychiatry and mental
2 health. New York: Humana Press 2010.
- 3 31. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing
4 risk of bias in randomised trials. *BMJ* 2011;343:1–9.
- 5 32. Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic
6 Cochrane Centre, The Cochrane Collaboration, 2014.
- 7 33. Cohen J. A power primer. *Psychol Bull* 1992;112:155–159.
- 8 34. Higgins JPT, Thompson SG. Quantifying heterogeneity in a meta-analysis. *Stat Med*
9 2002;21:1539–58.
- 10 35. Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions
11 Version 5.1.0 [updated March 2011]. United Kingdom: The Cochrane Collaboration 2011.
- 12 36. Hunter JE, Schmidt FL. Fixed Effects vs. random effects Meta-Analysis models: implications for
13 Cumulative Research Knowledge. *INT J Select Assess* 2000;8:275–92.
- 14 37. Labrague LJ, McEnroe-Petitte DM. Job stress in new nurses during the transition period: An
15 integrative review. *Int Nurs Rev* 2018;65:491–504.
- 16 38. Feng R-F, Tsai Y-F. Socialisation of new graduate nurses to practising nurses. *J Clin Nurs*
17 2012;21:2064–71.
- 18 39. Theisen JL, Sandau KE. Competency of new graduate nurses: A review of their weaknesses and
19 strategies for success. *J Contin Educ Nurs* 2013;44:406–14.

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3 Supplementary File 1.
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6 Search terms for PubMed
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8 (nurse[tiab] OR nurses[tiab] OR nursing[tw] OR nursery[tw] OR “health personnel”[tw] OR
9 “health care personnel”[tw] OR “healthcare personnel”[tw] OR “health care worker”[tw] OR
10 “health care workers”[tw] OR “healthcare worker”[tw] OR “healthcare workers”[tw] OR “health
11 worker”[tw] OR “health workers”[tw] OR “health professional”[tw] OR “health professionals”[tw]
12 OR “health care professional”[tw] OR “health care professionals”[tw] OR “healthcare
13 professional”[tw] OR “healthcare professionals”[tw] OR “medical care personnel”[tw] OR “health
14 staff”[tw] OR “health staffs”[tw] OR “healthcare staff”[tw] OR “healthcare staffs”[tw] OR “health
15 care staff”[tw] OR “health care staffs”[tw]) AND (cognitive[tw] OR behavio*[tw] OR
16 mindfulness[tw] OR CBT[tw] OR ACT[tw]) AND (burnout[tw] OR anxiety[tw] OR anxious*[tw]
17 OR depression[tw] OR depress*[tw] OR “mental health”[tw] OR stress*[tw] OR distress[tw])
18 AND (“randomized controlled trial”[pt] OR (randomized[tiab] AND controlled[tiab] AND
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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	<p>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.</p> <p>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.</p> <p>DESIGN: A randomized controlled trial with a matched pair design was conducted.</p> <p>METHODS: Seventy Registered Nurses and licensed practical nurses were randomized to MBSR (N = 37) or a waitlist control condition (N = 33).</p> <p>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.</p> <p>CONCLUSION: These initial findings suggest that the benefits of MBSR may extend to nursing errors.</p>		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-Reporting 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

1 **Registration**

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4 [#2](#) If registered, provide the name of the registry PROSPERO

5 (such as PROSPERO) and registration number registration number

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11 **Authors**

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15 **Contact** [#3a](#) Provide name, institutional affiliation, e-mail 1

16 address of all protocol authors; provide

17 physical mailing address of corresponding

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25 **Contribution** [#3b](#) Describe contributions of protocol authors and 10-11

26 identify the guarantor of the review

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30 **Amendments**

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33 [#4](#) If the protocol represents an amendment of a n/a

34 previously completed or published protocol,

35 identify as such and list changes; otherwise,

36 state plan for documenting important protocol

37 amendments

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45 **Support**

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48 **Sources** [#5a](#) Indicate sources of financial or other support 11

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1	Role of sponsor	#5c	Describe roles of funder(s), sponsor(s), and / or	n/a
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3	or funder		institution(s), if any, in developing the protocol	
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11			context of what is already known	
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15	Objectives	#7	Provide an explicit statement of the question(s)	6
16			the review will address with reference to	
17			participants, interventions, comparators, and	
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28	Eligibility criteria	#8	Specify the study characteristics (such as	6-7
29			PICO, study design, setting, time frame) and	
30			report characteristics (such as years	
31			considered, language, publication status) to be	
32			used as criteria for eligibility for the review	
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40	Information	#9	Describe all intended information sources	7-8
41			(such as electronic databases, contact with	
42	sources		study authors, trial registers or other grey	
43			literature sources) with planned dates of	
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52	Search strategy	#10	Present draft of search strategy to be used for	7-8
53			at least one electronic database, including	
54			planned limits, such that it could be repeated	
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1	Study records -	#11a	Describe the mechanism(s) that will be used to	7-8
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33	Data items	#12	List and define all variables for which data will	6-7
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35			be sought (such as PICO items, funding	
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37			sources), any pre-planned data assumptions	
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51	Risk of bias in	#14	Describe anticipated methods for assessing	8-9
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1		study level, or both; state how this information	
2		will be used in data synthesis	
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6	Data synthesis	#15a Describe criteria under which study data will be	9-10
7		quantitatively synthesised	
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11	Data synthesis	#15b If data are appropriate for quantitative	9-10
12		synthesis, describe planned summary	
13		measures, methods of handling data and	
14		methods of combining data from studies,	
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16		consistency (such as I ² , Kendall's τ)	
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27		meta-regression)	
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40		studies, selective reporting within studies)	
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- 1 • 2: PROSPERO registration number CRD42020152837 The PRISMA-P elaboration and
2 explanation paper is distributed under the terms of the Creative Commons Attribution License
3 CC-BY. This checklist was completed on 18. January 2022 using <https://www.goodreports.org/>, a
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5 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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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:	<i>BMJ Open</i>
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

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Manuscripts

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9 3 The effect of stress management based on cognitive behavioral therapy on nurses as a universal
10 4 prevention in the workplace: a systematic review and meta-analysis protocol

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41 35 **Keywords:** Nurse, Cognitive behavioral therapy, Universal prevention, Systematic review, Meta-
42 36 analysis

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2 **Word count: 2,821**

For peer review only

1 **ABSTRACT**

2 **Introduction**

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

10 **Methods and analysis**

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

20 **Ethics and dissemination**

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

27 **Strengths and limitations of this study**

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

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

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

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

- 1 included in the selected studies.
- 2
- 3 PROSPERO registration number CRD42020152837.
- 4

For peer review only

1 INTRODUCTION

2 Studies of stress in nursing workplaces have reported that nurses have a high prevalence of probable
3 occupational stress.[1,2] The main causes of the work-related stress among nurses are heavy
4 workloads, interpersonal conflicts, the emotional impacts of care, lack of reward or control, and shift
5 work.[3] Occupational stress is known to be a major risk factor for burnout, anxiety, and depression.[3]
6 These mental health problems can lead to the worsening of the nurses' somatic symptoms or
7 disorder,[4] insomnia,[5] the degradation of their quality of life,[6] and their work engagement,[7,8]
8 and it can have adverse effects in the workplace (e.g., an increase in absenteeism [9] and the intention
9 to leave employment[10]) and lead to a deterioration in the quality of care that the nurses provide.[2]
10 As in nursing workplaces, there are seldom Employee Assistance Programs (EAP) that provide any
11 formal stress management initiatives for employees to improve their mental health by learning coping
12 mechanisms, due to lack of manpower, resources, and managers' awareness,[11] nurses can be
13 vulnerable to depression due to the lack of stress management skills.[12] According to two surveys in
14 the United States, the prevalence of depression in nurses varies from 18% to 35%, which is higher
15 than in the general population.[4,13] Maintaining and improving nurses' mental health as a primary
16 prevention (to prevent diseases before it occurs) is necessary not only for their well-being but also for
17 improving their productivity, reducing workplace costs, and guaranteeing the quality of care for the
18 patients.[14] Therefore, stress management for nurses is needed in nursing workplaces.
19 Cognitive behavioral therapy (CBT) is one of the major stress management techniques for workers
20 and it has been shown to have positive effects as a primary prevention. According to a meta-review[15]
21 and several meta-analyses,[16,17] it has been proved that CBT, as a stress management technique,
22 significantly improves occupational stress, anxiety, and depression for workers in the workplace.
23 These meta-analyses concluded that CBT was more effective than other interventions.[16,17] In
24 addition, in studies targeting nurses, a Cochrane review showed that CBT stress management
25 interventions had significant positive effects on stress-related outcomes, including occupational stress
26 and depressive symptoms, among nurses (standardized mean difference [SMD] = -0.34 at the six-
27 month follow-up).[12] Thus, evidence about CBT-based stress management for nurses has
28 accumulated.
29 Primary prevention strategies for mental health problems can be classified into three categories; 1)
30 universal prevention, which targets the general population and is not directed at a specific risk group,
31 2) selective prevention, which targets individuals considered to be at potential risk for mental illness
32 as based on the presence of an identified risk factor such as parental mental illness, and 3) indicated
33 prevention which targets individuals who are screened for already having early signs or subthreshold
34 symptoms of mental illness.[18–21] There are theoretical and practical reasons why universal
35 prevention can be more appropriate for the workplace.[22] As universal prevention can reach more

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

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

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

26 **METHODS AND ANALYSIS**

27 **Study design**

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

33 **Eligibility criteria**

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

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6 1 CBT-based intervention, and (O) mental health. We will include intervention studies (RCTs)
7 2 conducted on the entire nurse population, including new graduate nurses (i.e., those with less than one
8 3 year of nursing experience). Studies will be excluded if they correspond to selective or indicated
9 4 prevention among primary prevention. This systematic review and meta-analysis focus on universal
10 5 prevention as a primary strategy. Therefore, studies of selective or indicated prevention will be
11 6 excluded from this review. In addition, we will exclude studies in which participants were practical
12 7 nurses or nursing aides and those that involved other healthcare workers such as doctors in this
13 8 systematic review and meta-analysis. There will be no exclusion criteria regarding participants'
14 9 employment status or the healthcare settings in which they were employed. However, we will exclude
15 10 studies that targeted individuals considered to be at potentially risk for mental illness according to an
16 11 identified risk factor such as parental mental illness, or that exclusively targeted nurses who had been
17 12 screened as being high risk in terms of their mental health. We will include studies with a CBT-based
18 13 intervention that aimed to reduce burnout, anxiety, or depressive symptoms in the entire nursing
19 14 population.

20 15 CBT is defined as an intervention that provides new ways to rationally think and/or behave in stressful
21 16 situations, such as through cognitive restructuring, behavioral activation, problem solving,
22 17 mindfulness-based cognitive therapy (MBCT), and acceptance and commitment therapy
23 18 (ACT).[29,30] The comparisons will be defined as no intervention; waiting-list control; treatment as
24 19 usual, such as education or training (but not CBT) that is provided by the nursing association; or
25 20 alternative (not CBT) interventions. Aspects of mental health (i.e., primary outcome) will include
26 21 burnout, anxiety, or depression, which are the adverse effects of occupational stress.[3] These will be
27 22 assessed using such self-reported measures as the Maslach Burnout Inventory,[31] the General Health
28 23 Questionnaire,[32] and the Beck Depression Inventory,[33] as well as structured interviews, including
29 24 the Hamilton Rating Scale for Depression.[34] As secondary outcomes, we will consider occupational
30 25 outcomes, which can be the adverse effects of mental health problems. These will include absenteeism,
31 26 intention to leave current employment, degradation of care quality, work performance, or work
32 27 engagement. Studies that did not conduct a statistical analysis to examine the intervention effects will
33 28 be excluded.

34 29 Studies will be included in this systematic review and meta-analysis that (1) were conducted to
35 30 evaluate the effect of CBT-based interventions on the mental health of nurses as a universal prevention,
36 31 (2) used an RCT design, (3) did not exclusively target nurses who had been screened as being at high
37 32 risk in terms of their mental health, (4) provide sufficient data (sample sizes, means, and standard
38 33 deviations [SDs]) for calculating the effect sizes with 95% confidence intervals (CIs), (5) were
39 34 published as original articles written in English or Japanese, and (6) were published up to 2022.

40 35
41 36 **Information sources, search strategy, and data management**

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6 1 Systematic searches of published studies will be performed using the following electronic databases:
7 2 Cochrane Central Register of Controlled Trials (CENTRAL), PubMed (MEDLINE), CINAHL,
8 3 PsycINFO, PsycARTICLES, Web of Science, and the Japan Medical Abstracts Society. The search
9 4 terms will include words related to the research PICO. The search strategy (i.e., the key terms) is listed
10 5 in the online Supplementary File 1. Through systematic searches, we will also obtain information
11 6 regarding studies that may have been completed but are not yet published. This search is essential to
12 7 reduce publication bias in this systematic review. All identified studies will be managed using
13 8 Microsoft Excel (Microsoft Corp., Redmond, WA, USA) files. Prior to the study selection process,
14 9 duplicate citations in the Excel files will be excluded by KK who is a first author. Decisions about all
15 10 of the studies will be recorded.
16 11

12 **Study selection process**

13 13 The study selection process will include two phases. The first is a sifting phase. According to the
14 14 inclusion criteria, three review authors (KK, AT, and AI) will independently conduct the screening of
15 15 the studies. The titles and abstracts will be screened according to the eligibility criteria created earlier
16 16 in the sifting phase. The second is the full text review phase. The full text of all eligible studies will
17 17 be obtained and reviewed using a standardized form (see the online Supplementary File 2) to assess
18 18 their eligibility for inclusion in this review. Any discrepancies in the assessment will be recorded, and
19 19 if they cannot be resolved, they will be settled by discussion among all of the authors until a consensus
20 20 is reached. The reference lists from the studies will be carefully examined for any additional eligible
21 21 studies. We will directly contact the corresponding authors of the eligible studies if (1) the results of
22 22 the publication are unclear or may be related to multiple interpretations, (2) the reported results did
23 23 not show data relevant to our study analysis, or (3) the study has been registered for clinical trials but
24 24 are not yet published. If we contact those corresponding authors but do not receive a reply, we will
25 25 not include their articles in the analysis. We will describe the process in the paper, including contact
26 26 with the corresponding authors. A flow chart will be provided to show the entire review process.
27 27

28 **Data extraction**

29 29 The data will be independently extracted from the included studies by three review authors (KK, AT,
30 30 and AI) using a standardized data extraction form (see the online Supplementary File 3). Any
31 31 disagreement or inconsistencies will be recorded and solved by discussion among all of the authors
32 32 until a consensus is reached. The extracted data will include the following: the year of publication,
33 33 country where the study was conducted, number of participants included in the analysis, sampling
34 34 framework, participants' demographic characteristics (i.e., mean age, sex proportions, years of nursing
35 35 experience, and employment status), number of participants who were excluded or lost to follow-up,
36 36 the contents of the intervention program, control condition (i.e., no intervention, waiting-list control,

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6 1 or other), outcome variables (i.e., stress-related outcomes such as burnout, anxiety, and depressive
7 2 symptoms, or occupational outcomes such as absenteeism, intention to leave current employment,
8 3 quality of care, work performance, or work engagement), length of follow-up, and sufficient data (i.e.,
9 4 the number of participants in each group (N), mean differences (MD) between groups, and SD for
10 5 outcomes) for calculating the effect size with 95% CIs for determining the effect of CBT on the mental
11 6 health of nurses for universal prevention. This extraction format is experimental and can be modified
12 7 as needed. The relevant research teams of the studies will be contacted about the availability of
13 8 unpublished or missing data.
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20 **Risk-of-bias assessment**

21 11 Three review authors (KK, AT, and AI) will independently assess the methodological quality of the
22 12 included studies using the Cochrane Collaboration's risk-of-bias tool.[35] The tool evaluates possible
23 13 sources of bias in intervention studies based on seven main categories: (1) random sequence generation,
24 14 (2) allocation concealment, (3) blinding of the participants and personnel, (4) blinding of the outcome
25 15 assessment, (5) incomplete outcome data, (6) selective outcome reporting, and (7) other biases.
26 16 Inconsistencies in the quality assessment of the methodology will be recorded and discussed by all of
27 17 the authors until a consensus is reached. For the assessment of the meta-bias, the publication bias will
28 18 be assessed using funnel plots for asymmetry and Egger's test.
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34 **Data synthesis and statistical methods**

35 21 The included studies will be statistically synthesized by a meta-analysis to estimate the pooled effect
36 22 (SMD) of CBT on the mental health of nurses as a universal prevention in the workplace. We will
37 23 combine studies that we determine to be similar in terms of follow-up time. We will consider the
38 24 effects over the following follow-up periods: (i) Up to one month, (ii) From one month to six months,
39 25 or (iii) Over six months. Forest plots of the between-group and post-intervention effect sizes for mental
40 26 health and the 95% CIs will be produced. The number of participants and the scores, such as the means
41 27 and *SDs* for the intervention and the control group for the psychological outcomes, will be entered
42 28 into Review Manager (RevMan).[36] The magnitude of the effect size will be interpreted as being
43 29 small (0.2), medium (0.5), or large (0.8).[37]

44 30 The meta-analysis will be performed when at least three eligible studies can be collected. If it is not
45 31 appropriate to perform a meta-analysis (i.e., no more than two studies are eligible and included), the
46 32 results will be presented in a narrative form. The publication bias will be examined using a funnel plot
47 33 and Egger's test. Statistical heterogeneity will be assessed using the chi-square (χ^2) test with Cochran's
48 34 Q statistic and the *I*². [38] The *I*² values of 25%, 50%, and 75% indicate low, medium, and high
49 35 heterogeneity, respectively.[39] An *I*² value of 50% or more will be deemed to indicate considerable
50 36 heterogeneity. If there is little or no statistical heterogeneity (i.e., an *I*² value of less than 50%) in a
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1 comparison, we will pool the results using a fixed-effects model. If the I^2 statistic is more than 50%,
2 we will use a random-effects model.[40]

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

17 **Patient and public involvement statement**

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

21 **Ethics and dissemination**

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

27 **STRENGTHS AND LIMITATIONS**

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

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6 1 However, this study has the limitation that the generalization of our study findings to countries or
7 2 groups that are not included in the selected studies will be limited. In addition, there is a limitation
8 3 that the article search will be conducted only in two languages, which can exclude potentially
9 4 important data published in other languages.
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13 6 **Acknowledgments**

14 7 We would like to thank Editage [<http://www.editage.com>] for editing and reviewing this manuscript
15 8 for English language.
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19 10 **Author Contributions**

20 11 The study was conceived and designed by KK, KI, AT, AI, and NK. The initial draft of the manuscript
21 12 was written by KK, and all authors revised it critically for important intellectual content and
22 13 contributed to the final manuscript. All authors read and approved the final manuscript. The entire
23 14 study process (i.e., the data collection, assessment, and synthesis) will be conducted by all of the
24 15 authors.
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30 17 **Funding statement**

31 18 This research received no specific grant from any funding agency in the public, commercial, or not-
32 19 for-profit sectors.
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36 21 **Competing interests statement**

37 22 The authors declare no conflict of interest.
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42 25 **References**

- 43 26 1. Mimura C, Griffiths P. The effectiveness of current approaches to workplace stress management
44 27 in the nursing profession: An evidence based literature review. *Occup Environ Med* 2003;60:10–
45 28 5.
- 46 29 2. Jun J, Ojemeni MM, Kalamani R, et al. Relationship between nurse burnout, patient and
47 30 organizational outcomes: Systematic review. *Int J Nurs Stud* 2021;119:103933.
- 48 31 3. McVicar A. Workplace stress in nursing: A literature review. *J Adv Nurs* 2003;44:633–42.
- 49 32 4. Welsh D. Predictors of depressive symptoms in female medical-surgical hospital nurses. *Issues*
50 33 *Ment. Health Nurs.* 2009;30:320–6.
- 51 34 5. Pappa S, Ntella V, Giannakas T, et al. Prevalence of depression, anxiety, and insomnia among
52 35 healthcare workers during the COVID-19 pandemic: A systematic review and meta-analysis.
53 36 *Brain Behav Immun* 2020;88:901-907.

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- 2
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- 4
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- 6 1 6. Nowrouzi B, Lightfoot N, Larivière M, et al. Occupational Stress Management and Burnout
- 7 2 Interventions in Nursing and Their Implications for Healthy Work Environments: A Literature
- 8 3 Review. *Workplace Health Saf* 2015;63:308-15.
- 9
- 10 4 7. Innstrand ST, Langballe EM, Falkum E. A longitudinal study of the relationship between work
- 11 5 engagement and symptoms of anxiety and depression. *Stress Heal* 2012;28:1–10.
- 12
- 13 6 8. García-Sierra R, Fernández-Castro J, Martínez-Zaragoza F. Work engagement in nursing: An
- 14 7 integrative review of the literature. *J Nurs Manag* 2016;24:E101-11.
- 15
- 16 8 9. Davey MM, Cummings G, Newburn-Cook CV, et al. Predictors of nurse absenteeism in
- 17 9 hospitals: A systematic review. *J Nurs Manag* 2009;17:312-30.
- 18
- 19 10 10. Halter M, Boiko O, Pelone F, et al. The determinants and consequences of adult nursing staff
- 20 11 turnover: A systematic review of systematic reviews. *BMC Health Serv Res* 2017;17:824.
- 21
- 22 12 11. Yung PMB, Fung MY, Chan TMF, et al. Relaxation training methods for nurse managers in
- 23 13 Hong Kong: A controlled study. *Int J Ment Health Nurs* 2004;13:255–61.
- 24
- 25 14 12. Ruotsalainen JH, Verbeek JH, Mariné A, et al. Preventing occupational stress in healthcare
- 26 15 workers. *Cochrane database Syst Rev* 2015;CD002892.
- 27
- 28 16 13. Letvak S, Ruhm CJ, McCoy T. Depression in hospital-employed nurses. *Clin Nurse Spec*
- 29 17 2012;26:177-82.
- 30
- 31 18 14. Brandford AA, Reed DB. Depression in Registered Nurses: A State of the Science. *Workplace*
- 32 19 *Health Saf* 2016;64:488–511.
- 33
- 34 20 15. Joyce S, Modini M, Christensen H, et al. Workplace interventions for common mental disorders:
- 35 21 A systematic meta-review. *Psychol Med* 2016;46:683–97.
- 36
- 37 22 16. van der Klink JJ, Blonk RW, Schene AH, et al. The benefits of interventions for work-related
- 38 23 stress. *Am J Public Health* 2001;91:270–6.
- 39
- 40 24 17. Richardson KM, Rothstein HR. Effects of occupational stress management intervention
- 41 25 programs: A meta-analysis. *J Occup Health Psychol* 2008;13:69–93.
- 42
- 43 26 18. McLaughlin KA. The Public Health Impact of Major Depression: A Call for Interdisciplinary
- 44 27 Prevention Efforts. *Prev Sci* 2011;12:361–71.
- 45
- 46 28 19. World Health Organization. Prevention of mental disorders: Effective interventions and policy
- 47 29 implications. Geneva: WHO, 2004.
- 48
- 49 30 20. Miller, J. E. Mental illness prevention. Alexandria, VA: American Mental Health Counselors
- 50 31 Association, 2014.
- 51
- 52 32 21. Estradé A, Salazar de Pablo G, Zanotti A, et al. Public health primary prevention implemented by
- 53 33 clinical high-risk services for psychosis. *Transl Psychiatry* 2022;12:43.
- 54
- 55 34 22. Tan L, Wang MJ, Modini M, et al. Preventing the development of depression at work: A
- 56 35 systematic review and meta-analysis of universal interventions in the workplace. *BMC Med*
- 57 36 2014;12.
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- 1 23. Lynch FL, Hornbrook M, Clarke GN, et al. Cost-effectiveness of an intervention to prevent depression in at-risk teens. *Arch Gen Psychiatry* 2005;62:1241–8.
- 2
- 3 24. Edwards D, Burnard P. A systematic review of stress and stress management interventions for mental health nurses. *J Adv Nurs* 2003;42:169–200.
- 4
- 5 25. Romppanen J, Häggman-Laitila A. Interventions for nurses' well-being at work: A quantitative systematic review. *J Adv Nurs* 2017;73:1555–69.
- 6
- 7 26. Westermann C, Kozak A, Harling M, et al. Burnout intervention studies for inpatient elderly care nursing staff: Systematic literature review. *Int J Nurs Stud* 2014;51:63–71.
- 8
- 9 27. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4:1.
- 10
- 11 28. Moher D, Liberati A, Tetzlaff J, et al. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *Ann Intern Med* 2009;151:264–9.
- 12
- 13 29. Hofmann SG, Sawyer AT, Fang A. The empirical status of the “new wave” of CBT. *Psychiatr Clin North Am* 2010;33:701–10.
- 14
- 15 30. Beck AT, Dozois DJ. Cognitive therapy: Current status and future directions. *Annu Rev Med* 2011;62:397–409.
- 16
- 17 31. Maslach C, Jackson SE, Leiter MP. *The Maslach Burnout Inventory Manual*. 3rd Edition. Palo Alto, CA: Consulting Psychologists Press 1996.
- 18
- 19 32. Goldberg D, Williams P. *A User's Guide to the General Health Questionnaire*. London: NFER-Nelson 1991.
- 20
- 21 33. Beck A, Steer R, Brown G. *BDI-II, Beck depression inventory: Manual*. vi. San Antonio, Tex, Boston: Psychological Corp 1996.
- 22
- 23 34. Cusin C, Yang H, Yeung A, et al. Chapter 2 Rating Scales for Depression. pp.7-35; In: L.Baer, M. A. Blais, editors: *Handbook of clinical rating scales and assessment in psychiatry and mental health*. New York: Humana Press 2010.
- 24
- 25
- 26 35. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ* 2011;343:1–9.
- 27
- 28 36. Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.
- 29
- 30 37. Cohen J. A power primer. *Psychol Bull* 1992;112:155–159.
- 31
- 32 38. Higgins JPT, Thompson SG. Quantifying heterogeneity in a meta-analysis. *Stat Med* 2002;21:1539–58.
- 33
- 34 39. Higgins JPT, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]*. United Kingdom: The Cochrane Collaboration 2011.
- 35
- 36 40. Hunter JE, Schmidt FL. Fixed Effects vs. random effects Meta-Analysis models: implications for Cumulative Research Knowledge. *INT J Select Assess* 2000;8:275–92.

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5
6 1 41. Labrague LJ, McEnroe-Petitte DM. Job stress in new nurses during the transition period: An
7 2 integrative review. *Int Nurs Rev* 2018;65:491–504.
8
9 3 42. Feng R-F, Tsai Y-F. Socialisation of new graduate nurses to practising nurses. *J Clin Nurs*
10 4 2012;21:2064–71.
11 5 43. Theisen JL, Sandau KE. Competency of new graduate nurses: A review of their weaknesses and
12 6 strategies for success. *J Contin Educ Nurs* 2013;44:406–14.
13 7
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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	<p>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.</p> <p>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.</p> <p>DESIGN: A randomized controlled trial with a matched pair design was conducted.</p> <p>METHODS: Seventy Registered Nurses and licensed practical nurses were randomized to MBSR (N = 37) or a waitlist control condition (N = 33).</p> <p>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.</p> <p>CONCLUSION: These initial findings suggest that the benefits of MBSR may extend to nursing errors.</p>		KK	MS	○	×	×

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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)
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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-Reporting 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

1 **Registration**

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4 [#2](#) If registered, provide the name of the registry PROSPERO

5 (such as PROSPERO) and registration number registration number

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11 **Authors**

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15 **Contact** [#3a](#) Provide name, institutional affiliation, e-mail 1

16 address of all protocol authors; provide

17 physical mailing address of corresponding

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25 **Contribution** [#3b](#) Describe contributions of protocol authors and 10-11

26 identify the guarantor of the review

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30 **Amendments**

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33 [#4](#) If the protocol represents an amendment of a n/a

34 previously completed or published protocol,

35 identify as such and list changes; otherwise,

36 state plan for documenting important protocol

37 amendments

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45 **Support**

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49 **Sources** [#5a](#) Indicate sources of financial or other support 11

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54 **Sponsor** [#5b](#) Provide name for the review funder and / or n/a

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1	Role of sponsor	#5c	Describe roles of funder(s), sponsor(s), and / or	n/a
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3	or funder		institution(s), if any, in developing the protocol	
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6	Introduction			
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10	Rationale	#6	Describe the rationale for the review in the	5-6
11			context of what is already known	
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15	Objectives	#7	Provide an explicit statement of the question(s)	6
16			the review will address with reference to	
17			participants, interventions, comparators, and	
18			outcomes (PICO)	
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25	Methods			
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28	Eligibility criteria	#8	Specify the study characteristics (such as	6-7
29			PICO, study design, setting, time frame) and	
30			report characteristics (such as years	
31			considered, language, publication status) to be	
32			used as criteria for eligibility for the review	
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40	Information	#9	Describe all intended information sources	7-8
41			(such as electronic databases, contact with	
42	sources		study authors, trial registers or other grey	
43			literature sources) with planned dates of	
44			coverage	
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52	Search strategy	#10	Present draft of search strategy to be used for	7-8
53			at least one electronic database, including	
54			planned limits, such that it could be repeated	
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1	Study records -	#11a	Describe the mechanism(s) that will be used to	7-8
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3	data		manage records and data throughout the	
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5	management		review	
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9	Study records -	#11b	State the process that will be used for selecting	8
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11	selection		studies (such as two independent reviewers)	
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13	process		through each phase of the review (that is,	
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15			screening, eligibility and inclusion in meta-	
16			analysis)	
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21	Study records -	#11c	Describe planned method of extracting data	8
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23	data collection		from reports (such as piloting forms, done	
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25	process		independently, in duplicate), any processes for	
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27			obtaining and confirming data from	
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33	Data items	#12	List and define all variables for which data will	6-7
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35			be sought (such as PICO items, funding	
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37			sources), any pre-planned data assumptions	
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39			and simplifications	
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43	Outcomes and	#13	List and define all outcomes for which data will	6-7
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45	prioritization		be sought, including prioritization of main and	
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47			additional outcomes, with rationale	
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51	Risk of bias in	#14	Describe anticipated methods for assessing	8-9
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55	studies		whether this will be done at the outcome or	
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1		study level, or both; state how this information	
2		will be used in data synthesis	
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6	Data synthesis	#15a Describe criteria under which study data will be	9-10
7		quantitatively synthesised	
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11	Data synthesis	#15b If data are appropriate for quantitative	9-10
12		synthesis, describe planned summary	
13		measures, methods of handling data and	
14		methods of combining data from studies,	
15		including any planned exploration of	
16		consistency (such as I ² , Kendall's τ)	
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25	Data synthesis	#15c Describe any proposed additional analyses	9-10
26		(such as sensitivity or subgroup analyses,	
27		meta-regression)	
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33	Data synthesis	#15d If quantitative synthesis is not appropriate,	9
34		describe the type of summary planned	
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38	Meta-bias(es)	#16 Specify any planned assessment of meta-	9
39		bias(es) (such as publication bias across	
40		studies, selective reporting within studies)	
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46	Confidence in	#17 Describe how the strength of the body of	10
47		evidence will be assessed (such as GRADE)	
48	cumulative		
49	evidence		
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54	Notes:		
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