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The Effectiveness of Mindfulness-Based Interventions in Patients with COPD: A systematic review and meta-analysis protocol

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Abstract

Introduction Chronic obstructive pulmonary disease (COPD) is a common chronic respiratory disease, accompanied by the main symptoms of coughing, shortness of breath, and dyspnea. It has adverse effects on the physical health, mental well-being, and quality of life of the patients. The mindfulness-based interventions(MBIs) aim to raise awareness of present moment experience, help us to enjoy our daily experiences and manage our lives better. At present, there were some studies to explore the intervention effect of MBIs on COPD patients, but the results were not consistent. It is necessary to systematically review and provide the available evidence about the efficacy of MBIs on patients with COPD.

Methods and analysis Randomized controlled trials(RCTs) that evaluated the effect of MBIs for the treatment of COPD patients ,which with acute exacerbations within the 4 weeks before studies would be excluded, will be searched in the databases of PubMed, Embase, Web of Science, the Cochrane Library, and China National Knowledge Infrastructure(CNKI). Primary outcome measures will include exercise capacity, dyspnea, fatigue, scores of depression, scores of anxiety. Secondary outcome measures will include quality of life, scores of mindfulness and lung function. Two researchers will independently conduct data extraction, and the bias risk in each included study will be evaluated based on the Cochrane Handbook of Systematic Reviews of Interventions by two researchers. All analyses will be conducted by Review Manager 5.3. and Stata12.0.

Ethics and dissemination This systematic review does not need to be examined and agreed by the ethics committee. And the results of the study will be exchanged as a conference paper or published in a journal.

PROSPERO registration number CRD42018102323

strengths and limitations of this study

- This study will be the first time to systematically review the efficacy of MBIs in COPD patients comprehensively.
- The results of this study may offer some help to patients, clinical medical workers

and health policy makers concerning the application of MBIs in the treatment of COPD.

Although detailed retrieval strategies have been formulated in our study, unpublished trials may not be included, which may lead to publication bias.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a common and frequently occurring disease that endangers human health. The mortality of COPD is high, and the quality of patients' life is poor, which brings heavy financial burden to patients and their families and society.[1] COPD is characterized by persistent and progressive airflow limitation, accompanied by an increase in chronic inflammatory responses caused by harmful particles or gases in the airway and lungs, and acute exacerbation and comorbidities affect the overall severity of the disease.[2]

The study have pointed out that, by 2020, COPD may be leaping from the current fourth to the third place in the cause of death all around the world, and will be ranked fifth in the global economic burden. [3] Studies have shown that the incidence of COPD worldwide is about 10%.[4] An epidemiological survey of COPD in China has shown that the prevalence of COPD is 8.2% for people older than 40 years old, the number of deaths caused by COPD is more than 1 million a year, and about 5~10 million people were disabled. [5] In rural areas, the mortality rate of respiratory diseases ranked first among all kinds of causes of death in China.[6]

Numerous studies have shown that COPD is a chronic airway disease with a characteristic of persistent airflow limitation, as well as a systematic disease with extensive extrapulmonary injuries and general effects. General effects are mainly manifested in skeletal muscle consumption (SMW) and dysfunction (SMD), weight loss, cardiovascular complications, malnutrition , body composition change and so on .[7-9] As the amount of activity decreases, the muscle strength of each part of patient's body gradually weakens, the resistance decreases, and the symptom of dyspnea become serious, thus forming a vicious cycle from breathing difficulty to

activity reduction to aggravation of dyspnea, [10,11] finally resulting in accelerated deterioration of physical condition. Patients may gradually develop self-blame, inferiority, anxiety and depression.[12] In recent years, many studies have confirmed that anxiety and depression are the most common and most easily overlooked complications in COPD patients.[13-15] Anxiety and depression can, in turn, reduce the will of COPD patients, make them lose confidence in life, and reduce their medical aspirations and treatment compliance, as well as increase the number of acute exacerbations, hospitalization frequency and time.[16] Therefore, COPD has a serious impact on patients' physical health, mental well-being, and quality of life.

Mindfulness is a state of consciousness, which is characterized by the self-regulation of attention to present moment experiences, acceptance of these experiences, and a non-judgmental position on these experiences. [17] Mindfulness-based interventions (MBIs) are usually short interventions (generally eight courses) provided in a group environment, including mindfulness meditation exercises and principles.[18]

Mindfulness interventions aim to raise awareness of present moment experience, help us to enjoy our daily experiences and manage our lives better. The common mindfulness interventions at present are mindfulness-based cognitive therapy (MBCT), mindfulness-based stress reduction (MBSR), and brief mindfulness meditation training intervention. There are also many MBIs which include mindfulness training exercises as part of a broader treatment program represented by acceptance and commitment therapy, dialectical behavior therapy, cognitive behavioral stress management, and integrative body-mind training, which have been proved to be beneficial to patients.

Current research have found that active meditation can not only enhance the perception of interoceptive information, [19] but also increase the accuracy of respiratory load [20]. Meditation may improve anxious COPD patients' ability to detect and monitor immediate ventilatory needs and respiratory load, improve their mental acuity, promote their active participation in daily life activities, and achieve better

self-care management of disease.[21-23] However, study has found no significant improvement in the patient's 6 minute walk, the symptom burden and quality of life in COPD patients basing on an 8-week program of MBSR. [24]

Therefore, this study aims to evaluate the effectiveness and safety of MBIs for improving the psychological and physical conditions of COPD patients.

METHODS And ANALYSIS

Study registration

This meta-analysis protocol has been registered in the PROSPERO. The protocol will be strictly reported by the requirements of Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P). [25]

Inclusion criteria for study selection

Types of included studies.

All RCTs evaluating the efficacy of MBIs for COPD patients will be included in the study, and no restrictions on the language and time of publication. Others like animal mechanism studies, case reports, RCT protocol, non-RCTs, review articles , repetitive study or meta-analysis will be excluded.

Participants.

The participants with a clinical diagnosis of COPD were included in accordance with the global initiative for COPD, [26] the American Thoracic Society, the British Thoracic Society, the European Respiratory Society or Chinese COPD guideline. [27] in which patients with acute exacerbations within the 4 weeks before studies would be excluded.

Intervention.

The study aims at the effectiveness of MBIs for COPD patients. thus, different types of MBIs including MBSR, MBCT, acceptance and commitment therapy, brief mindfulness meditation training interventions, cognitive behavioral stress management, dialectical behavior therapy and integrative body-mind training will be covered. The intervention measures taken by the experimental group must be MBIs or MBIs combined with other treatment methods. The treatment of control group must

be only therapies as usual or active comparison interventions, or combined with other treatment methods.

Outcome measures.

The primary outcomes will include exercise capacity(e.g.6-minute walk test, bicycle cardiopulmonary exercise test) ,dyspnea, fatigue, scores of depression, scores of anxiety. And the secondary outcomes will include quality of life, scores of mindfulness and lung function (FVC and FEV1%).

Search strategy

We will retrieve PubMed, Web of Science, Embase, the Cochrane Library and CNKI in accordance with each database rule specification. For each database, we have worked out a detailed search strategy to ensure all eligible studies. All databases search strategies are showed in Appendix A.

Data collection and analysis

Studies selection .

The selection of research literature will be carried out independently by two researchers. First, make a preliminary selection by reading the abstract and title. Then, all relevant studies need to be downloaded in full and further selected according to the inclusion criteria. If the two researchers in the selection process have different opinions and fail to reach a consensus through discussion, the third researcher will make the final decisions. The selection process is displayed in the PRISMA flowchart (Fig. 1).

Data extraction .

Two researchers will independently conduct data extraction, which includes year of publication, authors, region, participants, study design, interventions both the observation group and the control intervention and outcomes. If the two researchers have different opinions and cannot to reach a consensus through discussion, the third researcher will make final decisions.

Bias risk assessment.

For the bias risk in each study, we will evaluate it based on the Cochrane Handbook of Systematic Reviews of Interventions.[28] The content of the assessment involves the

random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. Two researchers will independently evaluate each study. If there are different opinions, the third researcher will make judgment and decision.

Statistical analysis

We will conduct all data analysis by data statistics software of Review Manager 5.3. and Stata12.0.. [29]the analysis of continuous variables by the mean difference (MD) or standardized mean difference (SMD) with 95% confidence intervals (CIs), and the analysis of classified variables by the risk ratio(RR) with 95% confidence intervals (CIs) . We will use the random effects model to conduct meta-analysis based on research recommendations.[30] Heterogeneity is calculated based on X^2 test, and the judgement of heterogeneity degree depends on the I^2 value(I^2 >50% or not)or P-value(P<0.10 or not). [31] Sensitivity and subgroup analysis will be used to explore the source of heterogeneity. The potential publication bias of studies will be assessed by funnel plot combined with Egger's regression test.[32]

DISSCUSSION

At present, our study should be the first time to systematically review the efficacy of MBIs in COPD patients comprehensively. It will provide a detailed overview of MBIs effective evidence for improving dyspnea, exercise capacity ,fatigue, depression, anxiety, lung function , quality of life and mindfulness levels of COPD patients. And the evidence may offer some help to patients, clinical medical workers and health policy makers concerning the application of MBIs in the treatment of COPD.

ETHICS AND DISSEMINATION

This systematic review does not need to be examined and agreed by the ethics committee. And the results of the study will be exchanged as a conference paper or published in a journal.

Contributors T-LY is responsible for the writing of the entire manuscript. The electronic database retrieval strategy is formulated by T-LY and ZY. LL and WY will independently screen the research, extract the needed research data and assess the bias

risk. If LL and WY fail to reach an agreement in the above process, the final decision will be made by L -YL. The statistical analysis will be done by T-LY.

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Competing interests None declared.

Patient consent This systematical review protocol does not require.

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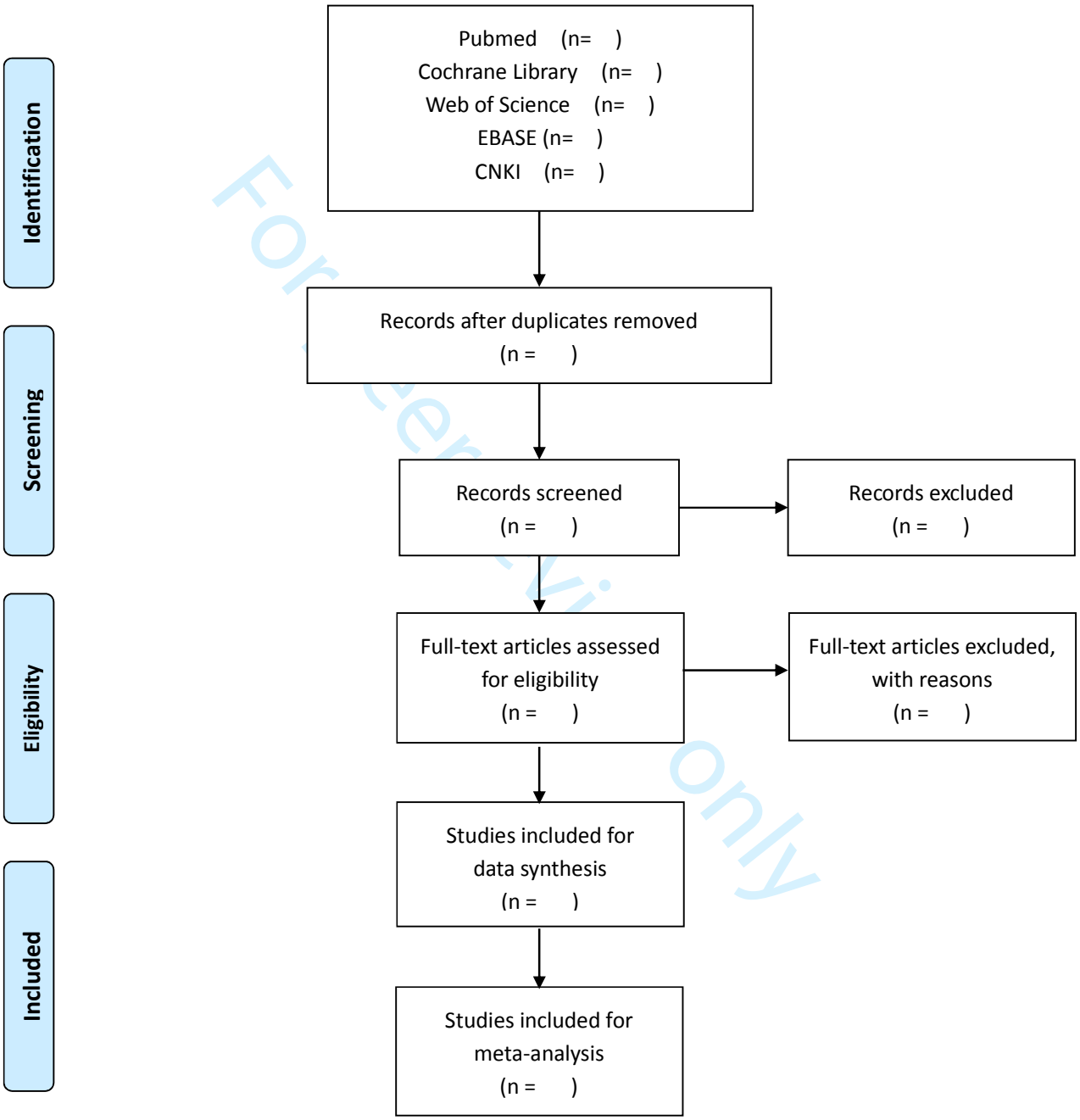

Figure 1. Flow diagram of studies identified.

Appendix A

Pubmed search strategy

#1 randomized controlled trial[Publication Type]
#2 Randomized Controlled Trials as Topic"[Majr]
#3 random[Text Word]
#4 RCT[Text Word]
#5 controlled clinical trial[Publication Type]
#6 Clinical Trials as Topic"[Majr]
#7 Single-Blind Method"[Majr]
#8 Double-Blind Method"[Majr]
#9 single blind[Text Word]
#10 double blind[Text Word]
#11 placebo[Text Word]
#12 allocation[Text Word]
#13 random allocation[Text Word]
#14 #1OR#2 OR #3OR#4 OR#5 OR#6 OR #7OR #8OR#9 OR#10 OR #11OR#12 OR #13
#15 "Pulmonary Disease, Chronic Obstructive"[Majr]
#16 Airflow Obstruction[Title/Abstract] AND chronic[Title/Abstract]
#17 COAD[Title/Abstract]
#18 COPD[Title/Abstract]
#19 Chronic Airflow Obstruction[Title/Abstract]
#20 Chronic Obstructive Airway Disease[Title/Abstract]
#21 Chronic Obstructive Lung Disease[Title/Abstract]
#22 Chronic Obstructive Pulmonary Disease[Title/Abstract]
#23 #15OR #16OR #17OR#18 OR#19 OR#20 OR#21 OR#22
#24 "Mindfulness"[Majr]
#25 Mindfulness[Title/Abstract]
#26 Mindfulness-based cognitive therapy[Title/Abstract]
#27 MBCT[Text Word]
#28 mindfulness-based stress reduction[Title/Abstract]
#29 MBSR[Text Word]
#30 "Meditation"[Majr]
#31 meditation[Title/Abstract]
#32 mindfulness meditation[Title/Abstract]
#33 acceptance[Title/Abstract] AND commitment therapy[Title/Abstract]
#34 dialectical behavior therapy[Title/Abstract]
#35 cognitive behavioral stress management[Title/Abstract]
#36 integrative body–mind training[Title/Abstract]

#37 mindfulness-related interventions[Title/Abstract]
#38 Vipassana[Title/Abstract]
#39 Zen[Title/Abstract]
#40 mantra meditation[Title/Abstract]
#41 #24 OR#25 OR #26OR#27 OR#28 OR #29OR#30 OR #31OR #32OR#33 OR #34OR#35 OR#36 OR #37OR#38 OR #39OR #40
#42 "Humans"[Majr]
#43 "Animals"[Majr]
#44 #42NOT#43
#45 #15 AND #23 AND #41 AND #44

Embase search strategy

#1 'randomization'/exp OR 'placebo'/exp OR 'placebo effect'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'randomized controlled trial'/exp OR 'randomized controlled trial (topic)'/exp OR 'controlled clinical trial'/exp OR 'controlled clinical trial (topic)'/exp OR 'clinical trial'/exp OR 'clinical trial (topic)'/exp
#2 random*:ab,ti OR allocation:ab,ti OR placebo:ab,ti OR single AND blind:ab,ti OR double AND blind:ab,ti OR rct:ab,ti OR clinical AND trial*:ab,ti
#3 #1 OR #2
#4 'Chronic Airflow Obstruction':ab,ti OR 'Chronic Obstructive Airway Disease ':ab,ti OR ' Chronic Obstructive Lung Disease ':ab,ti ' Chronic Obstructive Pulmonary Disease ':ab,ti OR ' COAD ':ab,ti OR ' COPD ':ab,ti
#5 'Mindfulness':ab,ti OR 'Mindfulness-based cognitive therapy ':ab,ti OR ' MBCT ':ab,ti 'mindfulness-based stress reduction':ab,ti OR 'MBSR ':ab,ti OR 'meditation ':ab,ti OR 'mindfulness meditation':ab,ti OR 'acceptance commitment therapy':ab,ti OR ' dialectical behavior therapy':ab,ti 'cognitive behavioral stress management':ab,ti OR ' integrative body–mind training':ab,ti OR 'mindfulness-related interventions':ab,ti OR 'Vipassana':ab,ti OR 'Zen':ab,ti OR 'mantra meditation':ab,ti
#6 #3 AND #4 AND #5

The Cochrane Library search strategy

#1 "random*" or allocation or "random allocation" or placebo or single blind or double blind or "randomized controlled trial*" or RCT or "clinical trial *"
#2 randomized controlled trial:pt or clinical trial:pt
#3 #1 or #2
#4 Chronic Airflow Obstruction:ti,ab,kw or Chronic Obstructive Airway Disease:ti,ab,kw or Chronic Obstructive Lung Disease:ti,ab,kw or Chronic Obstructive Pulmonary Disease:ti,ab,kw or COAD:ti,ab,kw or COPD:ti,ab,kw
#5 Mindfulness:ti,ab,kw or Mindfulness-based cognitive therapy:ti,ab,kw or MBCT:ti,ab,kw or mindfulness-based stress reduction:ti,ab,kw or MBSR:ti,ab,kw or

meditation:ti,ab,kw or mindfulness meditation:ti,ab,kw or acceptance commitment therapy:ti,ab,kw or dialectical behavior therapy:ti,ab,kw or cognitive behavioral stress management:ti,ab,kw or integrative body–mind training:ti,ab,kw or mindfulness-related interventions:ti,ab,kw or Vipassana:ti,ab,kw or Zen:ti,ab,kw or mantra meditation:ti,ab,kw
#6 #3 and #4 and #5

Web of science search strategy
#1 TS=("random *" OR allocation OR "random allocation" OR placebo OR single blind OR single blind method OR double blind OR double blind method OR "randomized controlled trial*" OR "randomized controlled trial*" OR "RCT" OR "clinical trial *")
#2 TS=(Chronic Airflow Obstruction OR Chronic Obstructive Airway Disease OR Chronic Obstructive Lung Disease OR Chronic Obstructive Pulmonary Disease OR COAD OR COPD)
#3 TS=(Mindfulness OR Mindfulness-based cognitive therapy OR MBCT OR mindfulness-based stress reduction OR MBSR OR meditation OR mindfulness meditation OR acceptance commitment therapy OR dialectical behavior therapy OR cognitive behavioral stress management OR integrative body–mind training OR mindfulness-related interventions OR Vipassana OR Zen OR mantra meditation)
#4 #3 AND #2 AND #1

CNKI search strategy

(SU = '随机' OR SU = '随机分配' OR SU = '随机对照' OR SU = '对照' OR SU = '盲法' OR SU = '单盲' OR SU = '双盲' OR SU = '随机对照实验' OR SU = '随机对照研究' OR SU = 'RCT' OR SU = '临床试验' OR SU = '临床研究' OR SU = '临床观察' OR SU = '临床试验') AND (SU = '慢性阻塞性肺炎' OR SU = '慢性阻塞性肺部疾病' OR SU = 'COPD' OR SU = 'COAD') AND (SU = '正念' OR SU = '冥想' OR SU = '正念认知疗法' OR SU = ' MBCT' OR SU = '正念减压疗法' OR SU = 'MBSR' OR SU = '正念冥想' OR SU = '接受与承诺疗法' OR SU = '辩证行为疗法' OR SU = '认知行为压力管理' OR SU = '整合身心训练' OR SU = '内观' OR SU = '禅' OR SU = '曼陀罗禅修')

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on page#
ADMINISTRATIVE INFORMATION			
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	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	7-8
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	8
Sponsor	5b	Provide name for the review funder and/or sponsor	8
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	8
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3-5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3-5
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	5
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	6
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	13-15
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	6
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)	6
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	6
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
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
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 study level, or both; state how this information will be used in data synthesis	6-7
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	7
	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 I^2, Kendall's τ)	7
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	7
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	7

Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	7
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Primary Subject Heading:	Evidence based practice
Secondary Subject Heading:	Respiratory medicine
Keywords:	MEDICAL EDUCATION & TRAINING, Chronic airways disease < THORACIC MEDICINE, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

The Efficacy of Mindfulness-Based Interventions for COPD Patients: A systematic study and meta-analysis protocol

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Abstract

Introduction Chronic obstructive pulmonary disease (COPD) is a common chronic respiratory disease. It has adverse effects on patients' physical health, mental well-being and life quality. The purpose of mindfulness-based interventions (MBIs) is to raise non-judgemental awareness and attention to the current internal and external experience. Namely the attention is shifted from the perceived and involuntary inner activities to current experience, keeping more curious, open and accepting attitudes towards current experience. Although some studies on the intervention effect of MBIs in COPD patients have been conducted, whose results are controversial, especially on the dyspnea, the level of mindfulness and life quality. Therefore, the systematical study of MBIs in COPD patients is required to provide the available evidence for the further study.

Methods and analyses In this study, different studies from various databases will be involved. Randomized controlled trials (RCTs), qualitative studies and case studies on the effect of MBIs in COPD patients aged over 18 will be concluded. We will search the literature search from the databases of PubMed, Embase, Web of Science, CINAHL, the Cochrane Library, PsycINFO and China National Knowledge

Infrastructure (CNKI). The primary outcomes will include the MBIs efficacy for COPD patients in terms of the dyspnea, depression and anxiety. The secondary outcomes will include that in terms of life quality, mindful awareness, 6-minute walk test and nutritional risk index. Data extraction will be conducted by two researchers independently, and bias risk of the meta-analysis will be evaluated based on the Cochrane Handbook of Systematic Reviews of Interventions. All data analyses will be conducted by data statistics software of Review Manager 5.3. and Stata12.0.

Ethics and dissemination The examination and agreement of the ethics committee are not required in this study. We intend to publish the study results in a journal or conference presentations.

PROSPERO registration number CRD42018102323

Strengths and limitations of this study

- This study provides a detailed and evidence-based study on the efficacy of MBIs in COPD patients.
- Extensive search strategies and inclusion criteria will be included in this study, indicating a comprehensive narrative of the available evidence.
- Data extraction and bias risk of studies involved in the meta-analysis will be independently conducted.
- Sensitivity and subgroup analysis will be used to explore the source of heterogeneity for the meta-analysis, and the potential publication bias will be assessed by the funnel plot combined with Egger's regression tests.
- Although detailed retrieval strategies have been formulated in our study, unpublished trials may not be included.

INTRODUCTION

As a common disease, chronic obstructive pulmonary disease (COPD) is characterized by persistent and progressive airflow limitation, accompanied by an increase in chronic inflammatory responses caused by harmful particles or gases in the airway and lungs. Besides, the acute exacerbation and comorbidities affect the overall severity of this disease.[1] Due to the high mortality, COPD endangers patients' health and lives, placing a heavy financial burden on their families and society.[2]

It is reported that the incidence of COPD is about 10% in the worldwide.[3] COPD might jump from the fourth to the third cause of the global death by 2020, ranking the fifth in the global economic burden.[4] An epidemiological survey of COPD in China shows that the prevalence rate of COPD is 8.2% for people older than 40 years old, the number of death and disabled caused by COPD are more than 1 million and 5~10 million a year.[5] In rural areas, the mortality rate of respiratory diseases ranks first among all causes of death in China.[6]

COPD has a serious impact on patients' physical health, mental well-being and life quality. General adverse physiological effects are mainly manifested in skeletal muscle consumption (SMW) and dysfunction (SMD), weight loss, cardiovascular complications, malnutrition and body composition change.[7-9] With the decreased amount of activity, the muscle strength and resistance of the patient's body are gradually weakened, and the symptom of dyspnea becomes more serious. Thus, a vicious cycle is formed, namely from the breathing difficulty to activity reduction to the dyspnea aggravation, finally resulting in accelerated deterioration of physical condition.[10] [11] Besides, mood disorders are common symptoms among COPD patients. In recent years, studies have confirmed that anxiety and depression are the most common and most easily overlooked complications in COPD patients.[12-14] Anxiety and depression can discourage patients in their lives, reduce their confidence in medical aspirations and treatment compliance, in turn the number of acute

exacerbations, hospitalization frequency and time are increased with greater disability and dyspnoea.[15 16] Life quality is a key indicator for estimating the disease burden, especially for chronic diseases.[17] Research has indicated that COPD patients may have a poor life quality.[17 18]Depressive symptoms negatively influence their mental life quality, and dyspnea often interferes with their health-related life quality.[18 19]

Mindfulness-based interventions (MBIs) are usually referred to short interventions (generally eight courses) provided in a group environment, including mindfulness meditation exercises and principles.[20] The purpose of MBIs is to raise non-judgemental awareness and attention to the current internal and external experience. Namely the attention is shifted from the perceived and involuntary inner activities to current experience, keeping more curious, open and accepting attitudes toward current experience.[21-23]Present mindfulness interventions include mindfulness-based cognitive therapy (MBCT), mindfulness-based stress reduction (MBSR), and brief mindfulness meditation training intervention.[24] There are also other MBIs which include mindfulness training exercises as a part of treatment program, such as the acceptance and commitment therapy, compassion focused therapy, dialectical behavior therapy, integrative body-mind training and cognitive behavioral stress management.[24 25]These methods have been proved to be beneficial to patients.[24 25]

It is proved that mindfulness interventions can reduce symptoms of chronic disease and improve accurate symptom assessment, which may improve disease management and well-being in patients with COPD.[26] The following themes are proposed in the qualitative evidence on MBCT positive effect of anxious and depressed asthma and COPD patients: combine lung rehabilitation advice with mindfulness; greater acceptance and reduction of disease-related stigma; developing a new relationship between breathing, activity and related thoughts; noticing subtle physical sensations and early signs of difficulty breathing; being creative with limitations and removing mental barriers to become more active; having a stronger sense of control.[27]

It is verified that mindfulness interventions are effective in improving the mindful awareness, $CD3^+$ T cell number, $CD4^+$ T cell number[28] and depression in COPD,[29] reducing the nutritional risk index and $CD8^+$ T cell number[28]. Systematic health education combined mindfulness interventions can lower the dyspnea and the nutritional risk index, improve the mindful awareness, compared with the only used systematic health education intervention.[30] A 10-minute mindfulness intervention in COPD patients has shown that there is a changing tendency in outcomes of the intervention group, including depression, anxiety, happiness, dyspnoea, mindfulness and stress. While no significant difference exists among groups, most participants supposed that the mindfulness interventions are useful and they are glad to recommend it.[16] It is concluded that meditation may improve the detection ability, monitor immediate ventilatory needs and respiratory load, improve the mental acuity, promote their active participation in daily life activities, and achieve better self-care management of disease for anxious COPD patients.[31-33] MBSR is verified to improve the life quality of veterans with chemical lung injury, but not their lung function[34]. However, compared with the support group, no significant improvement is observed in exacerbation rates of the RCT trial, health-related life quality measures, mindfulness, 6MWT distance, dyspnea, stress, or symptom scores for COPD patients after receiving the mindfulness-based breathing therapy[35].

In 2016, a systematic study was conducted to examine the effect of mindfulness on mindful awareness, health-related life quality and stress in adults with respiratory illnesses. In this meta-analysis, three studies propose that mindfulness cannot improve the health-related life quality, while other two studies claim that mindfulness can not improve the level of mindfulness and relieve stress. Different conclusions are largely caused by the inconsistent research methodologies[36]. In the former study of adult respiratory diagnosis published in 2016, three outcomes were obtained for the MBSR intervention. In this paper, COPD patients with different types of MBIs and more outcomes are investigated. Considering the small number of eligible studies, we intended to involve RCTs/quantitative designs,qualitative studies and case studies in

this study to describe the application status of MBIs in COPD patients. Besides, meta-analyses should be only performed on the basis of RCTs.

The updated systematic study and meta-analysis is performed for two objectives:(1) describe the application status of MBIs delivered for COPD patients and (2) examine the effect of MBIs on outcomes including depression, anxiety, life quality, mindful awareness, 6-minute walk test and nutritional risk index.

METHODS And ANALYSIS

Study registration

This systematic study and meta-analysis protocol have been registered in the PROSPERO. The protocol is strictly reported by the requirements of Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P).[37]

Inclusion criteria for study selection

Types of included studies

For the meta-analytic purpose of objective 2, all RCTs evaluating the efficacy of MBIs in COPD patients will be included in the study. In addition, we intend to add qualitative studies and case studies for describing the application status of MBIs in patients with COPD of objective 1. No restrictions on the language and time of publication. Others like animal mechanism studies, RCT protocol, repetitive study will be excluded.

Participants

Patients aged at least 18 years old with a clinical diagnosis of COPD confirmed by postbronchodilator forced expiratory volume in 1 second (FEV_1) <80% of the predicted value in combination with an FEV_1 =forced vital capacity <70% in accordance with the global initiative for COPD,[38] the American Thoracic Society, the British Thoracic Society, the European Respiratory Society or Chinese COPD

guideline[39] will be included.

Intervention

The study aims at the efficacy of MBIs in COPD patients. Thus, different types of MBIs should be covered, including MBSR, MBCT, acceptance and commitment therapy, brief mindfulness meditation training interventions, cognitive behavioral stress management, dialectical behavior therapy, integrative body-mind training and compassion focused therapy etc. The intervention measures taken by the experimental group must be MBIs or MBIs with other combined treatment methods. The treatment of control group must be the only therapy as usual or active comparison interventions, or combined with other treatment methods.

Outcome measures

The primary outcomes will include the MBIs efficacy for COPD patients in terms of the dyspnea, depression, anxiety. The secondary outcomes will include that in terms of life quality, mindful awareness, 6-minute walk test and nutritional risk index.

Search strategy

We intend to retrieve the literature search from PubMed, Web of Science, Embase, the Cochrane Library, CINAHL,PsycINFO, and CNKI in accordance with database rules. During the literature retrieval, information expert and lung diseases expert have offered the help and guidance. To fully retrieve the eligible studies, a comprehensive retrieval strategy will be adopted, combing with MeSH terms, text word, title/abstract and synonyms. These detailed search strategies for different databases are shown in Appendix A.

Data collection and analyses

Studies selection

The selection of research literature will be independently carried out by two researchers. Firstly, we will make a preliminary selection by reading the abstract and

title. Secondly, we will download all relevant studies for the further selection according to the inclusion criteria. If there is a different opinion between two researchers, the issue will be discussed to reach an agreement. If it fails to reach a consensus through discussion, the third researcher will make the final decisions. The selection process is displayed in the PRISMA flowchart (Fig. 1).

Data extraction

We will explore the characteristics of different studies qualitatively. Data extraction will be dependently conducted by two researchers, including the publication time, authors, region, participants (n, gender and age), study design, intervention methods, intervention duration, outcomes, assessment method, significant findings and duration of follow-up. If two researchers have different opinions and cannot to reach a consensus through discussion, the third researcher will make final decisions.

Bias risk assessment

To evaluate bias risk in the meta-analysis, all studies involved in the meta-analysis will be evaluated based on the Cochrane Handbook of Systematic Reviews of Interventions.[40] Assessment items will involve the random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. If there are different opinions, the third researcher will make the final decision.

Statistical analysis

We will conduct data analyses by data statistics software of Review Manager 5.3. and Stata12.0.[41] The continuous variables will be analyzed by the mean difference (MD) or standardized mean difference (SMD) with 95% confidence intervals (CIs), and classified variables will be analyzed by the risk ratio(RR) with 95% confidence intervals (CIs). We will use the random effects model to conduct the meta-analysis based on research recommendations.[42] Heterogeneity will be calculated based on the X^2 test, and the judgement of heterogeneity degree will be depended on the I^2 value(I^2

>50% or not) or P-value(P<0.10 or not).[43] We will use sensitivity and subgroup analysis to explore the source of heterogeneity. The following subgroup analyses will be performed on different types of MBIs (e.g. MBSR, MBCT, acceptance commitment therapy, meditation, dialectical behavior therapy and cognitive behavioral stress management etc), types of patients, intervention duration and duration of follow-up. The potential publication bias of all used studies in the meta-analysis will be assessed by funnel plot combined with Egger's regression test.[44]

Patient and public involvement

We currently collect data from previously published studies in this study protocol of a meta-analysis,hence no patients and the general public has been involved in.

DISSCUSSION

This study aims to systematically review the efficacy of MBIs in COPD patients. It will provide a detailed and evidence-based overview of the effect of MBIs on improving COPD patients' dyspnea, depression, anxiety, life quality, mindful awareness, 6-minute walk test and nutritional risk index.This result will provide an evidence-based basis for clinical practitioners in selecting mindfulness-based therapies for COPD patients, and offer patients with appropriate personalized interventions.

Contributors T-LY is responsible for the writing of the entire manuscript. The electronic database retrieval strategy is formulated by T-LY and ZY. LL and WY will independently screen the research, extract the needed research data and assess the bias risk. If LL and WY fail to reach an agreement in the above process, the final decision will be made by L -YL. The statistical analysis will be performed by T-LY.

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Competing interests None declared.

Patient consent It is not required in this systematical study protocol.

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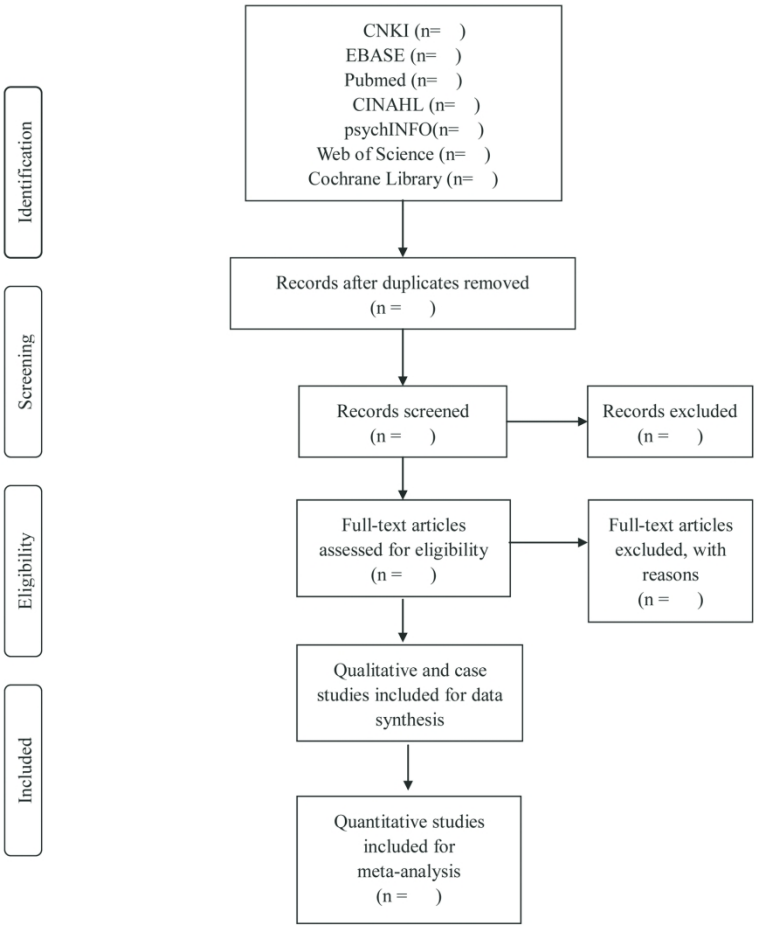
Figure captions:

Figure 1 Flow diagram of studies identified



90x90mm (600 x 600 DPI)

Appendix A

Pubmed search strategy

#1 randomized controlled trial[Publication Type]

#2 Randomized Controlled Trials as Topic"[Majr]

#3 random[Text Word]

#4 RCT[Text Word]

#5 controlled clinical trial[Publication Type]

#6 Clinical Trials as Topic"[Majr]

#7 Single-Blind Method"[Majr]

#8 Double-Blind Method"[Majr]

#9 single blind[Text Word]

#10 double blind[Text Word]

#11 placebo[Text Word]

#12 allocation[Text Word]

#13 random allocation[Text Word]

#14 case study[Text Word]

#15 qualitative study[Text Word]

#16 #1OR#2 OR #3OR#4 OR#5 OR#6 OR #7OR #8OR#9 OR#10 OR #11OR#12 OR #13 OR #14 OR #15

#17 "Pulmonary Disease, Chronic Obstructive"[Majr]

#18 Airflow Obstruction[Title/Abstract] AND chronic[Title/Abstract]

#19 COAD[Title/Abstract]

#20 COPD[Title/Abstract]

#21 Chronic Airflow Obstruction[Title/Abstract]

#22 Chronic Obstructive Airway Disease[Title/Abstract]

#23 Chronic Obstructive Lung Disease[Title/Abstract]

#24 Chronic Obstructive Pulmonary Disease[Title/Abstract]

#25 #15OR #16OR #17OR#18 OR#19 OR#20 OR#21 OR#22

#26 "Mindfulness"[Majr]

#27 Mindfulness[Title/Abstract]

#28 Mindfulness-based cognitive therapy[Title/Abstract]

#29 MBCT[Text Word]

#30 mindfulness-based stress reduction[Title/Abstract]

#31 MBSR[Text Word]

#32 "Meditation"[Majr]

#33 meditation[Title/Abstract]

#34 mindfulness meditation[Title/Abstract]

#35 acceptance[Title/Abstract] AND commitment therapy[Title/Abstract]

#36 dialectical behavior therapy[Title/Abstract]

#37 cognitive behavioral stress management[Title/Abstract]

#38 integrative body–mind training[Title/Abstract]

#39 mindfulness-related interventions[Title/Abstract]

#40 Vipassana[Title/Abstract]

#41 Zen[Title/Abstract]

#42 mantra meditation[Title/Abstract]

#43 compassion focused therapy[Title/Abstract]

#44 #24 OR#25 OR #26OR#27 OR#28 OR #29OR#30 OR #31OR #32OR#33 OR #34OR#35 OR#36 OR #37OR#38 OR #39OR #40OR #41 OR #42OR #43OR #44

#45 "Humans"[Majr]

#46 "Animals"[Majr]

#47 #42NOT#43

#48 #16 AND #25 AND #44 AND #47

Embase search strategy

#1 'randomization'/exp OR 'placebo'/exp OR 'placebo effect'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'randomized controlled trial'/exp OR 'randomized controlled trial (topic)'/exp OR 'controlled clinical trial'/exp OR 'controlled clinical trial (topic)'/exp OR 'clinical trial'/exp OR 'clinical trial (topic)'/exp OR 'case study'/exp OR 'qualitative study'/exp

#2 random*:ab,ti OR allocation:ab,ti OR placebo:ab,ti OR single AND blind:ab,ti OR double AND blind:ab,ti OR rct:ab,ti OR clinical AND trial*:ab,ti

#3 #1 OR #2

#4 'Chronic Airflow Obstruction':ab,ti OR 'Chronic Obstructive Airway Disease ':ab,ti OR ' Chronic Obstructive Lung Disease ':ab,ti ' Chronic Obstructive Pulmonary Disease ':ab,ti OR ' COAD ':ab,ti OR ' COPD ':ab,ti

#5 'mindfulness':ab,ti OR 'mindfulness-based cognitive therapy ':ab,ti OR ' MBCT ':ab,ti 'mindfulness-based stress reduction':ab,ti OR 'MBSR ':ab,ti OR 'meditation ':ab,ti OR 'mindfulness meditation':ab,ti OR 'acceptance commitment therapy':ab,ti OR ' dialectical behavior therapy':ab,ti 'cognitive behavioral stress management':ab,ti OR ' integrative body–mind training':ab,ti OR 'mindfulness-related interventions':ab,ti OR 'Vipassana':ab,ti OR 'Zen':ab,ti OR 'mantra meditation':ab,ti OR 'compassion focused therapy':ab,ti

#6 #3 AND #4 AND #5

The Cochrane Library search strategy

#1 "random*" or allocation or "random allocation" or placebo or single blind or double blind or "randomized controlled trial*" or RCT or "clinical trial *" or "case stud*" or "qualitative stud*"

#2 randomized controlled trial:pt or clinical trial:pt

#3 #1 or #2

#4 Chronic Airflow Obstruction:ti,ab,kw or Chronic Obstructive Airway Disease:ti,ab,kw or Chronic Obstructive Lung Disease:ti,ab,kw or Chronic Obstructive Pulmonary Disease:ti,ab,kw or COAD:ti,ab,kw or COPD:ti,ab,kw

#5 mindfulness:ti,ab,kw or mindfulness-based cognitive therapy:ti,ab,kw or MBCT:ti,ab,kw or mindfulness-based stress reduction:ti,ab,kw or MBSR:ti,ab,kw or meditation:ti,ab,kw or mindfulness meditation:ti,ab,kw or acceptance commitment therapy:ti,ab,kw or dialectical behavior therapy:ti,ab,kw or cognitive behavioral stress management:ti,ab,kw or integrative body–mind training:ti,ab,kw or

mindfulness-related interventions:ti,ab,kw or Vipassana:ti,ab,kw or Zen:ti,ab,kw or mantra meditation:ti,ab,kw or 'compassion focused therapy:ti,ab,kw

#6 #3 and #4 and #5

Web of science search strategy

#1 TS=("random *" OR allocation OR "random allocation" OR placebo OR single blind OR single blind method OR double blind OR double blind method OR "randomized controlled trial*" OR "randomized controlled trial*" OR "RCT" OR "clinical trial *"OR "case stud*" OR "qualitative stud*")

#2 TS=(Chronic Airflow Obstruction OR Chronic Obstructive Airway Disease OR Chronic Obstructive Lung Disease OR Chronic Obstructive Pulmonary Disease OR COAD OR COPD)

#3 TS=(mindfulness OR mindfulness-based cognitive therapy OR MBCT OR mindfulness-based stress reduction OR MBSR OR meditation OR mindfulness meditation OR acceptance commitment therapy OR dialectical behavior therapy OR cognitive behavioral stress management OR integrative body–mind training OR mindfulness-related interventions OR Vipassana OR Zen OR mantra meditation OR compassion focused therapy)

#4 #3 AND #2 AND #1

CNKI search strategy

(SU = '随机' OR SU = '随机分配' OR SU = '随机对照' OR SU = '对照' OR SU = '盲法' OR SU = '单盲' OR SU = '双盲' OR SU = '随机对照实验' OR SU = '随机对照研究' OR SU = 'RCT' OR SU = '临床试验' OR SU = '临床研究' OR SU = '临床观察' OR SU = '临床试验'OR SU = '个案研究' OR SU = '质性研究') AND (SU = '慢性阻塞性肺炎' OR SU = '慢性阻塞性肺部疾病' OR SU = 'COPD' OR SU = 'COAD') AND (SU = '正念' OR SU = '冥想' OR SU = '正念认知疗法' OR SU = ' MBCT' OR SU = '正念减压疗法' OR SU = 'MBSR' OR SU = '正念冥想' OR SU = '接受与承诺疗法' OR SU = '辩证行为疗法' OR SU = '认知行为压力管理' OR SU = '整合身心训练' OR SU = '内观' OR SU = '禅' OR SU = '曼陀罗禅修'OR SU = 同情聚焦治疗)

CINAHL search strategy

S1 MH("Random Assignment" OR "Placebos" OR "Placebo Effect" OR "Single-Blind" OR "Double-Blind" OR "Randomized Controlled Trial*" OR "Clinical Trial*" OR "Case Stud*" OR "qualitative stud*")

S2 TX(random OR allocation OR "random allocation" OR placebo OR single blind OR double blind OR "random controlled trial*" OR RCT OR "Clinical Trial*"OR "Case stud*" OR "qualitative stud*")

S3 S1 OR S2

S4 AB(Chronic Airflow Obstruction OR Chronic Obstructive Airway Disease OR Chronic Obstructive Lung Disease OR Chronic Obstructive Pulmonary Disease OR COAD OR COPD)

S5 AB(mindfulness OR mindfulness-based cognitive therapy OR MBCT OR mindfulness-based stress reduction OR MBSR OR meditation OR mindfulness meditation OR acceptance commitment therapy OR dialectical behavior therapy OR cognitive behavioral stress management OR integrative body–mind training OR mindfulness-related interventions OR Vipassana OR Zen OR mantra meditation OR compassion focused therapy)

S6 S3 AND S4 AND S5

psychINFO search strategy

1 ((doubl* or singl*) adj blind*).mp.or ((random* or clinical or control*) adj (trial* or study or studies)).mp.or (clinical trial*).mp.or((case or qualitative) adj (study or studies)).mp.or(case stud*).mp.or (qualitative stud*).mp.

2 (Chronic Airflow Obstruction).mp.or(Chronic Obstructive Airway Disease).mp.or (Chronic Obstructive Lung Disease).mp.or(Chronic Obstructive Pulmonary Disease).mp.or (COAD).mp.or(COPD).mp.

3 (mindfulness).mp.or(mindfulness-based cognitive therapy).mp.or (MBCT).mp.or(mindfulness-based stress reduction).mp.or (MBSR).mp.or(meditation).mp.or (mindfulness meditation).mp.or(acceptance

commitment therapy).mp.or (dialectical behavior therapy).mp.or(cognitive behavioral stress management).mp.or (integrative body–mind training).mp.or(mindfulness-related interventions).mp.or (Vipassana).mp.or(Zen).mp.or (mantra meditation).mp.or(compassion focused therapy).mp.

4 1 and 2 and 3

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on page#
ADMINISTRATIVE INFORMATION			
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	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	9
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	9
Sponsor	5b	Provide name for the review funder and/or sponsor	9
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	9
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3-6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3-6
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	6-7
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	15-20
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	7-8
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)	7-8
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	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	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 study level, or both; state how this information will be used in data synthesis	8
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	8
	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 I^2, Kendall's τ)	8
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	8-9
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	N/A

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)	N/A

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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BMJ Open

The Efficacy of Mindfulness-Based Interventions for COPD Patients: A systematic review and meta-analysis protocol

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The Efficacy of Mindfulness-Based Interventions for COPD Patients: A systematic review and meta-analysis protocol

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ABSTRACT

Introduction Chronic obstructive pulmonary disease (COPD) is a common chronic respiratory disease. It has adverse effects on patients' physical health, mental well-being and life quality. The purpose of mindfulness-based interventions (MBIs) is to raise non-judgemental awareness and attention to the current internal and external experience. Namely the attention is shifted from the perceived and involuntary inner activities to current experience, keeping more curious, open and accepting attitudes towards current experience. Although some studies on the intervention effect of MBIs in COPD patients have been conducted, whose results are controversial, especially on the dyspnea, the level of mindfulness and life quality. Therefore, the systematic review of MBIs in COPD patients is required to provide the available evidence for the further study.

Methods and analysis In this study, different studies from various databases will be involved. Randomized controlled trials (RCTs)/quantitative studies, qualitative studies and case studies on the effect of MBIs in COPD patients aged over 18 will be included.We will search the literature in the databases of PubMed, Embase, Web of Science, CINAHL, the Cochrane Library, PsycINFO and China National Knowledge

Infrastructure (CNKI). The primary outcomes will include the MBIs efficacy for COPD patients in terms of the dyspnea, depression and anxiety. The secondary outcomes will include that in terms of life quality, mindful awareness, 6-minute walk test and nutritional risk index. Data extraction will be conducted by two researchers independently, and bias risk of the meta-analysis will be evaluated based on the Cochrane Handbook of Systematic Reviews of Interventions. All data analysis will be conducted by data statistics software of Review Manager 5.3. and Stata12.0.

Ethics and dissemination The examination and agreement of the ethics committee are not required in this study. We intend to publish the study results in a journal or conference presentations.

PROSPERO registration number CRD42018102323

Strengths and limitations of this study

- This study provides a detailed and evidence-based study on the efficacy of MBIs in COPD patients.
- Extensive search strategies and inclusion criteria will be included in this study, indicating a comprehensive narrative of the available evidence.
- Data extraction and bias risk of studies involved in the meta-analysis will be independently conducted.
- Sensitivity and subgroup analysis will be used to explore the source of heterogeneity for the meta-analysis, and the potential publication bias will be assessed by the funnel plot combined with Egger's regression tests.
- Although detailed retrieval strategies have been formulated in our study, unpublished trials may not be included.

INTRODUCTION

As a common disease, chronic obstructive pulmonary disease (COPD) is characterized by persistent and progressive airflow limitation, accompanied by an increase in chronic inflammatory responses caused by harmful particles or gases in the airway and lungs. Besides, the acute exacerbation and comorbidities affect the overall severity of this disease.[1] Due to the high mortality, COPD endangers patients' health and lives, placing a heavy financial burden on their families and society.[2]

It is reported that the incidence of COPD is about 10% in the worldwide.[3] COPD might jump from the fourth to the third cause of the global death by 2020, ranking the fifth in the global economic burden.[4] An epidemiological survey of COPD in China shows that the prevalence rate of COPD is 8.2% for people older than 40 years old, the number of death and disabled caused by COPD are more than 1 million and 5~10 million a year.[5] In rural areas, the mortality rate of respiratory diseases ranks first among all causes of death in China.[6]

COPD has a serious impact on patients' physical health, mental well-being and life quality. General adverse physiological effects are mainly manifested in skeletal muscle consumption (SMW) and dysfunction (SMD), weight loss, cardiovascular complications, malnutrition and body composition change.[7-9] With the decreased amount of activity, the muscle strength and resistance of the patient's body are gradually weakened, and the symptom of dyspnea becomes more serious. Thus, a vicious cycle is formed, namely from the breathing difficulty to activity reduction to the dyspnea aggravation, finally resulting in accelerated deterioration of physical condition.[10] [11] Besides, mood disorders are common symptoms among COPD patients. In recent years, studies have confirmed that anxiety and depression are the most common and most easily overlooked complications in COPD patients.[12-14] Anxiety and depression can discourage patients in their lives, reduce their confidence in medical aspirations and treatment compliance, in turn the number of acute

exacerbations, hospitalization frequency and time are increased with greater disability and dyspnoea.[15 16] Life quality is a key indicator for estimating the disease burden, especially for chronic diseases.[17] Research has indicated that COPD patients may have a poor life quality.[17 18]Depressive symptoms negatively influence their mental life quality, and dyspnea often interferes with their health-related life quality.[18 19]

Mindfulness-based interventions (MBIs) are usually referred to short interventions (generally eight courses) provided in a group environment, including mindfulness meditation exercises and principles.[20] The purpose of MBIs is to raise non-judgemental awareness and attention to the current internal and external experience. Namely the attention is shifted from the perceived and involuntary inner activities to current experience, keeping more curious, open and accepting attitudes toward current experience.[21-23] Present mindfulness interventions include mindfulness-based cognitive therapy (MBCT), mindfulness-based stress reduction (MBSR), and brief mindfulness meditation training intervention.[24] There are also other MBIs which include mindfulness training exercises as a part of treatment program, such as the acceptance and commitment therapy, compassion focused therapy, dialectical behavior therapy, integrative body-mind training and cognitive behavioral stress management.[24 25]These methods have been proved to be beneficial to patients.[24 25]

It is proved that mindfulness interventions can reduce symptoms of chronic disease and improve accurate symptom assessment, which may improve disease management and well-being in patients with COPD.[26] The following themes are proposed in the qualitative evidence on MBCT positive effect of anxious and depressed asthma and COPD patients: combining lung rehabilitation advice with mindfulness; greater acceptance and reduction of disease-related stigma; developing a new relationship between breathing, activity and related thoughts; noticing subtle physical sensations and early signs of difficulty breathing; being creative with limitations and removing mental barriers to become more active; having a stronger sense of control.[27]

It is verified that mindfulness interventions are effective in improving the mindful awareness, $CD3^+$ T cell number, $CD4^+$ T cell number[28] and depression in COPD,[29] reducing the nutritional risk index and $CD8^+$ T cell number.[28] Systematic health education combined mindfulness interventions can lower the dyspnea and the nutritional risk index, improve the mindful awareness, compared with the only used systematic health education intervention.[30] A 10-minute mindfulness intervention in COPD patients has shown that there is a changing tendency in outcomes of the intervention group, including depression, anxiety, happiness, dyspnoea, mindfulness and stress. While no significant difference exists among groups, most participants supposed that the mindfulness interventions are useful and they are glad to recommend it.[16] It is concluded that meditation may improve the detection ability, monitor immediate ventilatory needs and respiratory load, improve the mental acuity, promote their active participation in daily life activities, and achieve better self-care management of disease for anxious COPD patients.[31-33] MBSR is verified to improve the life quality of veterans with chemical lung injury, but not their lung function.[34] However, compared with the support group, no significant improvement is observed in exacerbation rates of the RCT trial, health-related life quality measures, mindfulness, 6MWT distance, dyspnea, stress, or symptom scores for COPD patients after receiving the mindfulness-based breathing therapy.[35]

In 2016, a systematic review was conducted to examine the effect of mindfulness on mindful awareness, health-related life quality and stress in adults with respiratory illnesses. In this meta-analysis, three studies propose that mindfulness cannot improve the health-related life quality, while other two studies claim that mindfulness can not improve the level of mindfulness and relieve stress. Different conclusions are largely caused by the inconsistent research methodologies. [36]In the former study of adult respiratory diagnosis published in 2016, three outcomes were obtained for the MBSR intervention. In this paper, COPD patients with different types of MBIs and more outcomes are investigated. Considering the small number of eligible studies, we intended to involve RCTs/quantitative studies,qualitative studies and case studies in

this study to describe the application status of MBIs in COPD patients. Besides, meta-analysis should be only performed on the basis of RCTs.

The updated systematic review and meta-analysis is performed for two objectives:(1) describe the application status of MBIs delivered for COPD patients and (2) examine the effect of MBIs on outcomes including depression, anxiety, life quality, mindful awareness, 6-minute walk test and nutritional risk index.

METHODS AND ANALYSIS

Study registration

This systematic review and meta-analysis protocol have been registered in the PROSPERO. The protocol is strictly reported by the requirements of Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P).[37]

Inclusion criteria for study selection

Types of included studies

We intend to perform quantitative studies, qualitative studies and case studies in this systematic review to describe the application status of MBIs in COPD patients. And all RCTs evaluating the efficacy of MBIs in COPD patients will also be included in this study. No restrictions on the language and time of publication. Animal mechanism studies, RCT protocol and duplicate publication will be excluded. It should be noted that duplicate publication refers to an article substantially overlaps with another published one in printing or electronic media.[38]

Participants

Patients aged at least 18 years old with a clinical diagnosis of COPD confirmed by postbronchodilator forced expiratory volume in 1 second (FEV_1) <80% of the predicted value in combination with an FEV_1 =forced vital capacity <70% in accordance with the global initiative for COPD,[39] the American Thoracic Society, the British Thoracic Society, the European Respiratory Society or Chinese COPD

guideline[40] will be included.

Intervention

The study aims at the efficacy of MBIs in COPD patients. Thus, different types of MBIs should be covered, including MBSR, MBCT, acceptance and commitment therapy, brief mindfulness meditation training interventions, cognitive behavioral stress management, dialectical behavior therapy, integrative body-mind training and compassion focused therapy etc. The intervention measures taken by the experimental group must be MBIs or MBIs with other combined treatment methods. The treatment of control group must be the only therapy as usual or active comparison interventions, or combined with other treatment methods.

Outcome measures

The primary outcomes will include the MBIs efficacy for COPD patients in terms of the dyspnea based on the scale, such as the modified Medical Research Council (mMRC) scale [30]and the Borg Dyspnea Scale,[35] depression and anxiety evaluated by the scale, such as the Hospital Anxiety and Depression Scale(HADS).[16] The secondary outcomes will include that the evaluation of life quality (based on SF-36 questionnaire[34] and the Saint George Respiratory Questionnaire (SGRQ)[35]), mindful awareness (based on the Philadelphia Mindfulness Scale[16] and the 5-Factor Mindfulness Questionnaire[35]), 6-minute walk test (based on the Borg Dyspnea Scale[35]) and nutritional risk index (based on the nutritional risk screening 2002 (NRS2002) scale[28 30]).

Search strategy

We intend to retrieve the literature search from PubMed, Web of Science, Embase, the Cochrane Library, CINAHL,PsycINFO, and CNKI in accordance with database rules. During the literature retrieval, information expert and lung disease expert have offered the help and guidance. To fully retrieve the eligible studies, a comprehensive retrieval strategy will be adopted, combing with MeSH terms, text word, title/abstract

and synonyms. These detailed search strategies for different databases are shown in Appendix A.

Data collection and analysis

Studies selection

The selection of research literature will be independently carried out by two researchers. Firstly, we will make a preliminary selection by reading the abstract and title. Secondly, we will download all relevant studies for the further selection according to the inclusion criteria. If there is a different opinion between two researchers, the issue will be discussed to reach an agreement. If it fails to reach a consensus through discussion, the third researcher will make the final decisions. The selection process is displayed in the PRISMA flowchart (Fig. 1).

Data extraction

We will explore the characteristics of different studies qualitatively. Data extraction will be dependently conducted by two researchers, including the publication time, authors, region, participants (n, gender and age), study design, intervention methods, intervention duration, outcomes, assessment method, significant findings and duration of follow-up. If two researchers have different opinions and cannot to reach a consensus through discussion, the third researcher will make final decisions.

Bias risk assessment

To evaluate bias risk in the meta-analysis, all studies involved in the meta-analysis will be evaluated based on the Cochrane Handbook of Systematic Reviews of Interventions.[41] Assessment items will involve the random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. If there are different opinions, the third researcher will make the final decision.

Statistical analysis

We will conduct data analysis by data statistics software of Review Manager 5.3. and Stata12.0.The continuous variables will be analyzed by the mean difference (MD) or standardized mean difference (SMD) with 95% confidence intervals (CIs), and classified variables will be analyzed by the risk ratio(RR) or the odd ratio(OR) with 95% confidence intervals (CIs). When extracting raw data from studies, we will estimate RR in longitudinal, cohort and cross-sectional studies and OR in case-control studies.[42] We will use the random effects model to conduct the meta-analysis based on research recommendations.[43] Heterogeneity will be calculated based on the X^2 test, and the judgement of heterogeneity degree will be depended on the I^2 value(I^2 >50% or not) or *P*-value(P<0.10 or not).[44] We will use sensitivity and subgroup analysis to explore the source of heterogeneity. The following subgroup analysis will be performed on different types of MBIs (e.g. MBSR, MBCT, acceptance commitment therapy, meditation, dialectical behavior therapy and cognitive behavioral stress management etc), types of patients, intervention duration and duration of follow-up. The potential publication bias of all used studies in the meta-analysis will be assessed by funnel plot combined with Egger's regression test.[45]

Patient and public involvement

We currently collect data from previously published studies in this study protocol of a meta-analysis,hence no patients and the general public have been involved in.

DISSCUSSION

This study aims to systematically review the efficacy of MBIs in COPD patients. It will provide a detailed and evidence-based overview of the effect of MBIs on improving COPD patients' dyspnea, depression, anxiety, life quality, mindful awareness, 6-minute walk test and nutritional risk index.This result will provide an evidence-based basis for clinical practitioners in selecting mindfulness-based therapies for COPD patients, and offer patients with appropriate personalized interventions.

ETHICS AND DISSEMINATION

Since this study is a systematic review, the findings are based on the published evidence. Therefore, the examination and agreement of the ethics committee are not required in this study. We intend to publish the study results in a journal or conference presentations.

Contributors T-LY is responsible for the writing of the entire manuscript. The electronic database retrieval strategy is formulated by T-LY and ZY. LL and WY will independently screen the research, extract the needed research data and assess the bias risk. If LL and WY fail to reach an agreement in the above process, the final decision will be made by L -YL. The statistical analysis will be performed by T-LY.

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Competing interests None declared.

Patient consent It is not required in this systematic review protocol.

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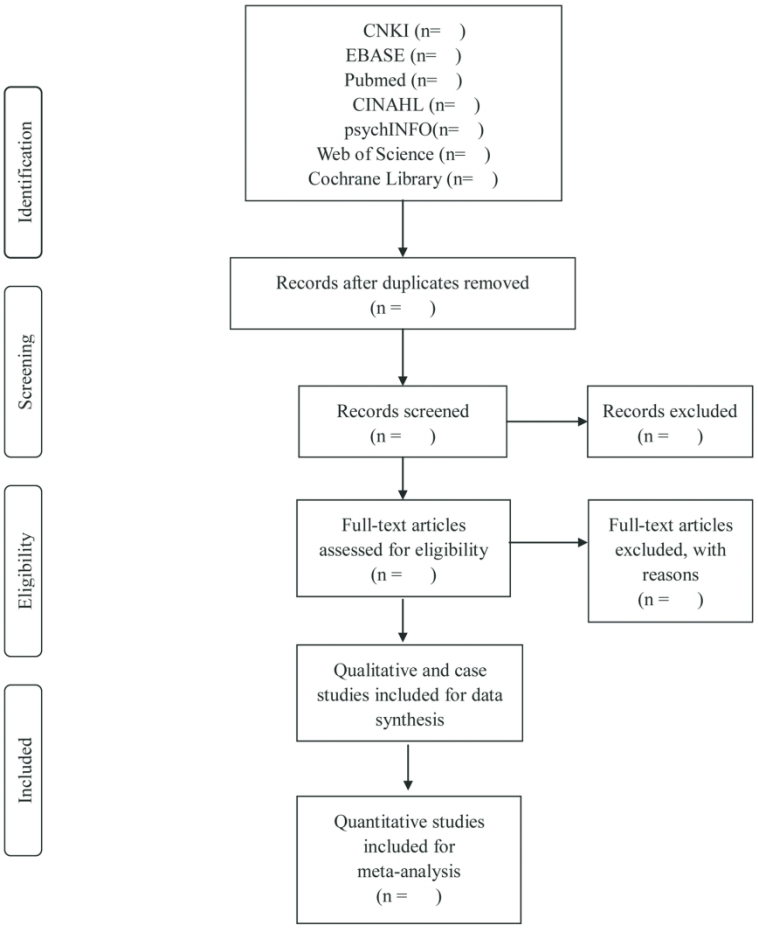
Figure captions:

Figure 1 Flow diagram of studies identified



90x90mm (600 x 600 DPI)

Appendix A

Pubmed search strategy

#1 randomized controlled trial[Publication Type]

#2 Randomized Controlled Trials as Topic"[Majr]

#3 random[Text Word]

#4 RCT[Text Word]

#5 controlled clinical trial[Publication Type]

#6 Clinical Trials as Topic"[Majr]

#7 Single-Blind Method"[Majr]

#8 Double-Blind Method"[Majr]

#9 single blind[Text Word]

#10 double blind[Text Word]

#11 placebo[Text Word]

#12 allocation[Text Word]

#13 random allocation[Text Word]

#14 case study[Text Word]

#15 qualitative study[Text Word]

#16 #1OR#2 OR #3OR#4 OR#5 OR#6 OR #7OR #8OR#9 OR#10 OR #11OR#12 OR #13 OR #14 OR #15

#17 "Pulmonary Disease, Chronic Obstructive"[Majr]

#18 Airflow Obstruction[Title/Abstract] AND chronic[Title/Abstract]

#19 COAD[Title/Abstract]

#20 COPD[Title/Abstract]

#21 Chronic Airflow Obstruction[Title/Abstract]

#22 Chronic Obstructive Airway Disease[Title/Abstract]

#23 Chronic Obstructive Lung Disease[Title/Abstract]

#24 Chronic Obstructive Pulmonary Disease[Title/Abstract]

#25 #15OR #16OR #17OR#18 OR#19 OR#20 OR#21 OR#22

#26 "Mindfulness"[Majr]

#27 Mindfulness[Title/Abstract]

#28 Mindfulness-based cognitive therapy[Title/Abstract]

#29 MBCT[Text Word]

#30 mindfulness-based stress reduction[Title/Abstract]

#31 MBSR[Text Word]

#32 "Meditation"[Majr]

#33 meditation[Title/Abstract]

#34 mindfulness meditation[Title/Abstract]

#35 acceptance[Title/Abstract] AND commitment therapy[Title/Abstract]

#36 dialectical behavior therapy[Title/Abstract]

#37 cognitive behavioral stress management[Title/Abstract]

#38 integrative body–mind training[Title/Abstract]

#39 mindfulness-related interventions[Title/Abstract]

#40 Vipassana[Title/Abstract]

#41 Zen[Title/Abstract]

#42 mantra meditation[Title/Abstract]

#43 compassion focused therapy[Title/Abstract]

#44 #24 OR#25 OR #26OR#27 OR#28 OR #29OR#30 OR #31OR #32OR#33 OR #34OR#35 OR#36 OR #37OR#38 OR #39OR #40OR #41 OR #42OR #43OR #44

#45 "Humans"[Majr]

#46 "Animals"[Majr]

#47 #42NOT#43

#48 #16 AND #25 AND #44 AND #47

Embase search strategy

#1 'randomization'/exp OR 'placebo'/exp OR 'placebo effect'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'randomized controlled trial'/exp OR 'randomized controlled trial (topic)'/exp OR 'controlled clinical trial'/exp OR 'controlled clinical trial (topic)'/exp OR 'clinical trial'/exp OR 'clinical trial (topic)'/exp OR 'case study'/exp OR 'qualitative study'/exp

#2 random*:ab,ti OR allocation:ab,ti OR placebo:ab,ti OR single AND blind:ab,ti OR double AND blind:ab,ti OR rct:ab,ti OR clinical AND trial*:ab,ti

#3 #1 OR #2

#4 'Chronic Airflow Obstruction':ab,ti OR 'Chronic Obstructive Airway Disease ':ab,ti OR ' Chronic Obstructive Lung Disease ':ab,ti ' Chronic Obstructive Pulmonary Disease ':ab,ti OR ' COAD ':ab,ti OR ' COPD ':ab,ti

#5 'mindfulness':ab,ti OR 'mindfulness-based cognitive therapy ':ab,ti OR ' MBCT ':ab,ti 'mindfulness-based stress reduction':ab,ti OR 'MBSR ':ab,ti OR 'meditation ':ab,ti OR 'mindfulness meditation':ab,ti OR 'acceptance commitment therapy':ab,ti OR ' dialectical behavior therapy':ab,ti 'cognitive behavioral stress management':ab,ti OR ' integrative body–mind training':ab,ti OR 'mindfulness-related interventions':ab,ti OR 'Vipassana':ab,ti OR 'Zen':ab,ti OR 'mantra meditation':ab,ti OR 'compassion focused therapy':ab,ti

#6 #3 AND #4 AND #5

The Cochrane Library search strategy

#1 "random*" or allocation or "random allocation" or placebo or single blind or double blind or "randomized controlled trial*" or RCT or "clinical trial *" or "case stud*" or "qualitative stud*"

#2 randomized controlled trial:pt or clinical trial:pt

#3 #1 or #2

#4 Chronic Airflow Obstruction:ti,ab,kw or Chronic Obstructive Airway Disease:ti,ab,kw or Chronic Obstructive Lung Disease:ti,ab,kw or Chronic Obstructive Pulmonary Disease:ti,ab,kw or COAD:ti,ab,kw or COPD:ti,ab,kw

#5 mindfulness:ti,ab,kw or mindfulness-based cognitive therapy:ti,ab,kw or MBCT:ti,ab,kw or mindfulness-based stress reduction:ti,ab,kw or MBSR:ti,ab,kw or meditation:ti,ab,kw or mindfulness meditation:ti,ab,kw or acceptance commitment therapy:ti,ab,kw or dialectical behavior therapy:ti,ab,kw or cognitive behavioral stress management:ti,ab,kw or integrative body–mind training:ti,ab,kw or

mindfulness-related interventions:ti,ab,kw or Vipassana:ti,ab,kw or Zen:ti,ab,kw or mantra meditation:ti,ab,kw or 'compassion focused therapy:ti,ab,kw

#6 #3 and #4 and #5

Web of science search strategy

#1 TS=("random *" OR allocation OR "random allocation" OR placebo OR single blind OR single blind method OR double blind OR double blind method OR "randomized controlled trial*" OR "randomized controlled trial*" OR "RCT" OR "clinical trial *"OR "case stud*" OR "qualitative stud*")

#2 TS=(Chronic Airflow Obstruction OR Chronic Obstructive Airway Disease OR Chronic Obstructive Lung Disease OR Chronic Obstructive Pulmonary Disease OR COAD OR COPD)

#3 TS=(mindfulness OR mindfulness-based cognitive therapy OR MBCT OR mindfulness-based stress reduction OR MBSR OR meditation OR mindfulness meditation OR acceptance commitment therapy OR dialectical behavior therapy OR cognitive behavioral stress management OR integrative body–mind training OR mindfulness-related interventions OR Vipassana OR Zen OR mantra meditation OR compassion focused therapy)

#4 #3 AND #2 AND #1

CNKI search strategy

(SU = '随机' OR SU = '随机分配' OR SU = '随机对照' OR SU = '对照' OR SU = '盲法' OR SU = '单盲' OR SU = '双盲' OR SU = '随机对照实验' OR SU = '随机对照研究' OR SU = 'RCT' OR SU = '临床试验' OR SU = '临床研究' OR SU = '临床观察' OR SU = '临床试验'OR SU = '个案研究' OR SU = '质性研究') AND (SU = '慢性阻塞性肺炎' OR SU = '慢性阻塞性肺部疾病' OR SU = 'COPD' OR SU = 'COAD') AND (SU = '正念' OR SU = '冥想' OR SU = '正念认知疗法' OR SU = ' MBCT' OR SU = '正念减压疗法' OR SU = 'MBSR' OR SU = '正念冥想' OR SU = '接受与承诺疗法' OR SU = '辩证行为疗法' OR SU = '认知行为压力管理' OR SU = '整合身心训练' OR SU = '内观' OR SU = '禅' OR SU = '曼陀罗禅修'OR SU = 同情聚焦治疗)

CINAHL search strategy

S1 MH("Random Assignment" OR "Placebos" OR "Placebo Effect" OR "Single-Blind" OR "Double-Blind" OR "Randomized Controlled Trial*" OR "Clinical Trial*" OR "Case Stud*" OR "qualitative stud*")

S2 TX(random OR allocation OR "random allocation" OR placebo OR single blind OR double blind OR "random controlled trial*" OR RCT OR "Clinical Trial*"OR "Case stud*" OR "qualitative stud*")

S3 S1 OR S2

S4 AB(Chronic Airflow Obstruction OR Chronic Obstructive Airway Disease OR Chronic Obstructive Lung Disease OR Chronic Obstructive Pulmonary Disease OR COAD OR COPD)

S5 AB(mindfulness OR mindfulness-based cognitive therapy OR MBCT OR mindfulness-based stress reduction OR MBSR OR meditation OR mindfulness meditation OR acceptance commitment therapy OR dialectical behavior therapy OR cognitive behavioral stress management OR integrative body–mind training OR mindfulness-related interventions OR Vipassana OR Zen OR mantra meditation OR compassion focused therapy)

S6 S3 AND S4 AND S5

psychINFO search strategy

1 ((doubl* or singl*) adj blind*).mp.or ((random* or clinical or control*) adj (trial* or study or studies)).mp.or (clinical trial*).mp.or((case or qualitative) adj (study or studies)).mp.or(case stud*).mp.or (qualitative stud*).mp.

2 (Chronic Airflow Obstruction).mp.or(Chronic Obstructive Airway Disease).mp.or (Chronic Obstructive Lung Disease).mp.or(Chronic Obstructive Pulmonary Disease).mp.or (COAD).mp.or(COPD).mp.

3 (mindfulness).mp.or(mindfulness-based cognitive therapy).mp.or (MBCT).mp.or(mindfulness-based stress reduction).mp.or (MBSR).mp.or(meditation).mp.or (mindfulness meditation).mp.or(acceptance

commitment therapy).mp.or (dialectical behavior therapy).mp.or(cognitive behavioral stress management).mp.or (integrative body–mind training).mp.or(mindfulness-related interventions).mp.or (Vipassana).mp.or(Zen).mp.or (mantra meditation).mp.or(compassion focused therapy).mp.

4 1 and 2 and 3

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on page#
ADMINISTRATIVE INFORMATION			
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	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	10
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	10
Sponsor	5b	Provide name for the review funder and/or sponsor	10
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	10
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3-6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3-6
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	6-8
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	16-21
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	8-9
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)	8-9
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	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	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 study level, or both; state how this information will be used in data synthesis	8
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	8-9
	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 I^2, Kendall's τ)	8-9
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	9
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	N/A

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)	N/A

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.