PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	The Efficacy of Mindfulness-Based Interventions for COPD Patients: A systematic review and meta-analysis protocol
AUTHORS	tian, lingyun; zhang, ying; li, li; wu, ying; Li, Ying-lan

VERSION 1 - REVIEW

REVIEWER	Ingeborg Farver-Vestergaard Unit for Psychooncology and Health Psychology Aarhus University Hospital Denmark
REVIEW RETURNED	29-Aug-2018

GENERAL COMMENTS	The timing of the present review is timely, as an increasing number of studies of mindfulness-based interventions have been conducted in COPD over the recent years. Overall, the idea and the timing of the present study is therefore good. However, there are some major concerns with respect to design and English language of the present manuscript. The manuscript should be revised accordingly before publication. Please see my specific comments below: 1. Is the research question or study objective clearly defined?: The authors appear to use the terms "efficacy" and "effectiveness" interchangeably. As the authors want to include only RCTs, their aim appears to be explanatory, not pragmatic, and they should therefore consider using the term "efficacy" throughout the paper (see the following reference for a discussion of the terms: Haynes B. Can it work? Does it work? Is it worth it? The testing of healthcare interventions is evolving. BMJ. 1999;319:652–653). Moreover, the authors state on p. 5, line 9 that they aim to evaluate the safety of mindfulness-based interventions (MBIs). However, they do not describe the procedures for evaluation of safety anywhere in the manuscript. Such procedures should be described in detail. 2. Is the abstract accurate, balanced and complete?: Generally, the abstract lacks precision and is imbalanced in terms of previous literature, and it does not correspond adequately to what is written in the rest of the manuscript. Examples regarding imprecision: A) in line 9, the terms "shortness of breath" and "dyspnea" – what is the difference when it comes to the operationalisation of the symptom as variables that can be assessed as outcomes in the study? Only the outcome of "dyspnea" is stated as an outcome in the present study. There needs to be clear alignment between the variables and language throughout the manuscript. B) It is stated that MBIs "help us to enjoy our daily experiences and manage our lives better" – this is,

	from my perspective, an imprecise description of MBIs. The purpose is broader than helping people to enjoy their lives - it rather concerns developing a non-judgemental attitude towards both moments of joy AND moments of despair, with the purpose of obtaining a more balanced view of difficulties in life with less striving towards unobtainable goals (such as “I wish my breathlessness would disappear”), and responding to difficult situations based on a clearer view of what is going on in the present moment. I suggest that the authors consult some of the “core” literature on this matter – e.g. “Full catastrophe living by Jon Kabat-Zinn or “Mindfulness-based cognitive therapy for depression” by Segal, Teasdale and Williams. C) In line 51, the authors state that “the study will be the first to systematically review the efficacy of MBIs in COPD patients comprehensively”. The terms “comprehensively” is imprecise. The authors need to describe how this is more “comprehensive” than other reviews. D) In line 55, the expression “offer some help” is imprecise, and should be omitted. Instead, it should be described exactly how the authors imagine that it could be applied by patients, clinical medical workers and health policy makers. Regarding imbalance and lack of alignment with the rest of the manuscript: E) It is stated in line 14 that results of previous studies were not consistent. It is not described further in what way studies are not consistent, nor is this described in throughout the rest of the manuscript. (see also point 8). 3. Is the study design appropriate to answer the research question? A) The authors describe that they plan to include studies of interventions such as ACT and DBT under the overall term of MBIs. From a clinical perspective, this may be problematic as it can be argued that ACT and DBT are not “mindfulness-BASED” as such, but only integrates a few mindfulness-components. Moreover, there are other programmes integrating mindfulness components, such as compassion-focused therapy, which is not mentioned by the authors. My suggestion is therefore EITHER to only include mindfulness-BASED interventions, where mindfulness-training is a primary component, OR to include all programmes that uses mindfulness components (e.g. ACT, DBT, CFT etc) and then describe clearly how they will assess the differential effects – e.g. through statistical moderator/subgroup analyses. B) The authors have decided to include only RCTs/quantitative designs. Taking the expected amount of studies in this area into account, it should be considered to widen inclusion criteria to other designs (e.g. case studies, qualitative studies). Of course, subsequent meta-analyses should only be performed on the basis of selected appropriate studies (RCTs). I believe that this would give a better overview of the current state of evidence in this area, as also many qualitative and case studies have been conducted and fewer RCTs. 4. Are the methods described sufficiently to allow the study to be repeated? A) The inclusion and exclusion criteria are not sufficiently described and will be difficult to replicate. For example, the specific criteria for a COPD diagnosis should be described. The authors could also consider if studies report exacerbations within the last 4 weeks at all (p. 5, line 39. And why should this be an exclusion criteria? Many rehabilitation interventions are initiated shortly after exacerbation with good effects. B) Variables for data extraction are

	not adequately described. Potential moderation variables should be described (e.g. gender, age, n, intervention duration etc.). 6. Are the outcomes clearly defined? A large number of primary measures are listed, and the rationale for choosing these outcomes over other outcomes (e.g. secondary) is not clearly stated. The authors should preferably choose one (or two) primary outcomes in a hypothesis-based/top-dowm approach, and the theoretical/empirical foundations for choosing exactly that should be clearly described in the introduction. Alternatively, the authors could take a more exploratory/bottom-up approach where they summarise the psychological and physical outcomes that appears in the literature that is eligible for inclusion in the study. 7. If statistics are used are they appropriate and described fully? Statistical procedures for assessing subgroup differences/moderators should be described. 8. Are the references up-to-date and appropriate? As mentioned previously, the authors state that previous research yields inconsistent results (p. 2, line 16). In the introduction, however, only one study is mentioned (ref 24, p. 5, line 7). The authors should give a more full and balanced account of what research has been conducted, including mentioning other relevant reviews of MBIs in COPD (e.g. Harrison, S. L., Lee, A., Janaudis-Ferreira, T., Goldstein, R. S., & Brooks, D. (2016). Mindfulness in people with a respiratory diagnosis: A systematic review. Patient Education and Counseling, 99(3), 348–355.) but preferably also in other chronic conditions Gotink, R. A., Chu, P., Busschbach, J. J. V, Benson, H., Fricchione, G. L., & Hunink, M. G. M. (2015). Standardised mindfulness-based interventions in healthcare: An overview of systematic reviews and meta-analyses of RCTs. PLoS ONE, 10(4), e0124344.). Moreover, many statements in the introduction should be supported by a reference, e.g. “The common mindfulness interventions at present are…” (p. 4, line 30-46). 12. Are the study limitations discussed adequately? The authors mention the risk of publication bias in the study (p. 3, line 8), and it should be stated how they will respond to such a bias if it occurs (e.g. adjusting results statistically) 15. Is the standard of written English acceptable for publication? Spelling is generally acceptable, but several grammar and wording mistakes challenge the understanding and the precision of the manuscript. For example, (p. 2, line 38) “all analyses will be conducted by Review Manager 5.3”; (p.2 line 44) “The results of the study will be exchanged as a conference paper”; (p. 6 line 17) “We will retrieve PubMed..”. Therefore, the manuscript should be subjected to professional language revision.

REVIEWER	Samantha Harrison School of Health and Social Care, Teesside University, Middlesbrough, UK
REVIEW RETURNED	29-Aug-2018

GENERAL COMMENTS	Well done on producing a well-structured and interesting protocol for a systematic review, with planned meta-analysis, exploring the impact of mindfulness-based interventions (MBI) delivered to people with COPD. I have provided detailed comments for your consideration. • My main concern is that a systematic review looking at mindfulness in people with respiratory diagnosis was published recently (Harrison et al 2016). This review identified just two papers including people with COPD. Has there been a sufficient increase in literature since 2015 when the searches were completed to warrant another review? You may wish to conduct a scoping exercise. Also please reference this previous review in the introduction and make clear what this updated review adds. Introduction • Page 3, line 41 – the introduction is a little long, there is a lot of information about the disease with some repetition. Please remove repetition (e.g. “chronic airway disease with characteristics of persistent airflow limitation”) and present more concisely. • Page 4, line 5 – please add a linking sentence to explain why breathlessness and reduced activity may lead to self-blame and inferiority. • Page 4 – please add a rationale for why you are choosing to consider MBI for people with COPD rather than other psychological interventions such as CBT. How might MBI reduce anxiety and depression and other psychological symptoms prominent in people with COPD? • Page 4, line 46 – please add a reference to support that many MBIs have proved beneficial to patients? • Page 4, line 48 – please add a description of what is meant by introspection and why this is a good thing to promote. Method • It states in the introduction that MBI has not been successful in improving exercise capacity. Therefore I wonder why exercise capacity is a primary outcome of interest? Please specify by which pathway/process MBIs would lead to an improvement in exercise capacity. • Please consider adding CINAHL and psychINFO to the databases included in the search as a lot of the literature in this area appears in nursing/AHP/psychology journals rather than medical ones. • Please detail how the search strategy was developed e.g. using MESH terms? Was there any input from an information specialist? Did you do a scoping exercise to identify key terms? Discussion • Please correct the statement hat this is the first systematic review exploring MBIs for people with COPD. General comments • At times the review is referred to as study, please correct throughout • The paper is generally well written but may benefit from an English review to improve some sentence structure.

VERSION 1 – AUTHOR RESPONSE

Reviewer :1

1. Is the research question or study objective clearly defined?:

The authors appear to use the terms “efficacy” and “effectiveness” interchangeably. As the authors want to include only RCTs, their aim appears to be explanatory, not pragmatic, and they should therefore consider using the term “efficacy” throughout the paper (see the following reference for a discussion of the terms: Haynes B. Can it work? Does it work? Is it worth it? The testing of healthcare interventions is evolving. BMJ. 1999;319:652–653). Moreover, the authors state on p. 5, line 9 that they aim to evaluate the safety of mindfulness-based interventions (MBIs). However, they do not describe the procedures for evaluation of safety anywhere in the manuscript. Such procedures should be described in detail.

Response:Thank you for the suggestion,we have used the term “efficacy” throughout the paper instead of “effectiveness”.We are sorry the word

of “safety”used not accurately enough,we have deleted it,and given a more detailed study objectives on p.6,line10-13.

2. Is the abstract accurate, balanced and complete?:

Generally, the abstract lacks precision and is imbalanced in terms of previous literature, and it does not correspond adequately to what is written in the rest of the manuscript. Examples regarding imprecision: A) in line 9, the terms “shortness of breath” and “dyspnea” – what is the difference when it comes to the operationalisation of the symptom as variables that can be assessed as outcomes in the study? Only the outcome of “dyspnea” is stated as an outcome in the present study. There needs to be clear alignment between the variables and language throughout the manuscript. B) It is stated that MBIs “help us to enjoy our daily experiences and manage our lives better” – this is, from my perspective, an imprecise description of MBIs. The purpose is broader than helping people to enjoy their lives - it rather concerns developing a non-judgemental attitude towards both moments of joy AND moments of despair, with the purpose of obtaining a more balanced view of difficulties in life with less striving towards unobtainable goals (such as “I wish my breathlessness would disappear”), and responding to difficult situations based on a clearer view of what is going on in the present moment. I suggest that the authors consult some of the “core” literature on this matter – e.g. “Full catastrophe living by Jon Kabat-Zinn or “Mindfulness-based cognitive therapy for depression” by Segal, Teasdale and Williams. C) In line 51, the authors state that “the study will be the first to systematically review the efficacy of MBIs in COPD patients comprehensively”. The terms “comprehensively” is imprecise. The authors need to describe how this is more “comprehensive” than other reviews. D) In line 55, the expression “offer some help” is imprecise, and should be omitted. Instead, it should be described exactly how the authors imagine that it could be applied by patients, clinical medical workers and health policy makers. Regarding imbalance and lack of alignment with the rest of the manuscript: E) It is stated in line 14 that results of previous studies were not consistent. It is not described further in what way studies are not consistent, nor is this described in throughout the rest of the manuscript. (see also point 8).

Response:Our apologies that the abstract is not accurate. We have made extensive modifications of the abstract focusing on your suggestions on on p.2,line1-11.For example,we have deleted the expression of “shortness of breath”,made a more professional exposition of the concept of MBIs through consulting the literatures,deleted the imprecise expression of the terms “comprehensively” and “offer some help”,pointed out that the results of some studies on the intervention effect of MBIs in COPD patients are controversial, especially on the dyspnea, the level of mindfulness and life quality.

We also change the expression of “the first time”,because we find it is not precise by our extensive literature reviewing this time.

3. Is the study design appropriate to answer the research question?

A) The authors describe that they plan to include studies of interventions such as ACT and DBT under the overall term of MBIs. From a clinical perspective, this may be problematic as it can be argued that ACT and DBT are not “mindfulness-BASED” as such, but only integrates a few mindfulness-components. Moreover, there are other programmes integrating mindfulness components, such as compassion-focused therapy, which is not mentioned by the authors. My suggestion is therefore EITHER to only include mindfulness-BASED interventions, where mindfulness-training is a primary component, OR to include all programmes that uses mindfulness components (e.g. ACT, DBT, CFT etc) and then describe clearly how they will assess the differential effects – e.g. through statistical moderator/subgroup analyses. B) The authors have decided to include only RCTs/quantitative designs. Taking the expected amount of studies in this area into account, it should be considered to widen inclusion criteria to other designs (e.g. case studies, qualitative studies). Of course, subsequent meta-analyses should only be performed on the basis of selected appropriate studies (RCTs). I believe that this would give a better overview of the current state of evidence in this area, as also many qualitative and case studies have been conducted and fewer RCTs.

Response:Thank you very much for your advice. We also conducted a preliminary search of literature, and found that the number of randomized controlled trials is not much. Your suggestion can allow us to further elaborate the effect of MBIs on COPD patients through the overview of qualitative and cased studies, which is a very good supplementary part. We fully accept your proposal and have revised the corresponding parts in the manuscript on p.2,line13-15,on p.6,line6-13,on p.2 in the types of included studies section,and Figure 1.In addition,we agree with your suggestion of including all programmes that uses mindfulness components (e.g. ACT, DBT, CFT etc) and then describing clearly the differential effects through subgroup analyses on p.8,line 27-31.

4. Are the methods described sufficiently to allow the study to be repeated?

A) The inclusion and exclusion criteria are not sufficiently described and will be difficult to replicate. For example, the specific criteria for a COPD diagnosis should be described. The authors could also consider if studies report exacerbations within the last 4 weeks at all (p. 5, line 39. And why should this be an exclusion criteria? Many rehabilitation interventions are initiated shortly after exacerbation with good effects. B) Variables for data extraction are not adequately described. Potential moderation variables should be described (e.g. gender, age, n, intervention duration etc.).

Response:We have removed the expression of “ exacerbations within the last 4 weeks”,added the detailed inclusion criteria of participants on p.6-7 in the participants section and variables for data extraction on p.8 in the data extraction section.

5. Are the outcomes clearly defined?

A large number of primary measures are listed, and the rationale for choosing these outcomes over other outcomes (e.g. secondary) is not clearly stated. The authors should preferably choose one (or two) primary outcomes in a hypothesis-based/top-dowm approach, and the theoretical/empirical foundations for choosing exactly that should be clearly described in the introduction. Alternatively, the authors could take a more exploratory/bottom-up approach where they summarise the psychological and physical outcomes that appears in the literature that is eligible for inclusion in the study.

Response:We deeply appreciate your valuable suggestions.we have chosen four primary outcomes,such as dyspnea,anxiety, depression and life quality, clearly described in the introduction on p.3-4.

6. If statistics are used are they appropriate and described fully?

Statistical procedures for assessing subgroup differences/moderators should be described.

Response:We have added the contents of subgroup analysis on p.8-9 in the statistical analysis section.

7. Are the references up-to-date and appropriate?

As mentioned previously, the authors state that previous research yields inconsistent results (p. 2, line 16). In the introduction, however, only one study is mentioned (ref 24, p. 5, line 7). The authors should give a more full and balanced account of what research has been conducted, including mentioning other relevant reviews of MBIs in COPD (e.g. Harrison, S. L., Lee, A., Janaudis-Ferreira, T., Goldstein, R. S., & Brooks, D. (2016). Mindfulness in people with a respiratory diagnosis: A systematic review. Patient Education and Counseling, 99(3), 348–355.) but preferably also in other chronic conditions Gotink, R. A., Chu, P., Busschbach, J. J. V, Benson, H., Fricchione, G. L., & Hunink, M. G. M. (2015). Standardised mindfulness-based interventions in healthcare: An overview of systematic reviews and meta-analyses of RCTs. PLoS ONE, 10(4), e0124344.). Moreover, many statements in the introduction should be supported by a reference, e.g. “The common mindfulness interventions at present are…” (p. 4, line 30-46).

Response:Thanks.We have given a more full and balanced account of what researches has been conducted by adding another eight references,which includes mentioning other relevant reviews of MBIs for COPD patients in the introduction section of p.4-6. We also support references 24-25 focusing on your suggestion.

8. Are the study limitations discussed adequately?

The authors mention the risk of publication bias in the study (p. 3, line 8), and it should be stated how they will respond to such a bias if it occurs (e.g. adjusting results statistically)

Response:We got editorial requests that we should revise the ‘Strengths and limitations’ section,so we have made great changes.And we remove the risk of publication bias in this section.The descriptions of publication bias are showed in the statistical analysis section.

9. Is the standard of written English acceptable for publication?

Spelling is generally acceptable, but several grammar and wording mistakes challenge the understanding and the precision of the manuscript. For example, (p. 2, line 38) “all analyses will be conducted by Review Manager 5.3”; (p.2 line 44) “The results of the study will be exchanged as a conference paper”; (p. 6 line 17) “We will retrieve PubMed..”. Therefore, the manuscript should be subjected to professional language revision.

Response: We have improved the quality of language in our manuscript with the professional assistance.

Once again,thank you very much for your comments and suggestions.

Reviewer:2

1.My main concern is that a systematic review looking at mindfulness in people with respiratory diagnosis was published recently (Harrison et al 2016). This review identified just two papers including people with COPD. Has there been a sufficient increase in literature since 2015 when the searches were completed to warrant another review? You may wish to conduct a scoping exercise.

Also please reference this previous review in the introduction and make clear what this updated review adds.

Response: we deeply appreciate your suggestions.We have conducted a preliminary search of literature, and found that there has been a sufficient increase in literature since 2015.And we expand our search scope by adding more databases, for example,we have found there are two relating studies in China National Knowledge Infrastructure (CNKI).In addition,we have made clear what this updated review adds in the introduction section on p.5-6.Considering the small number of eligible studies, we intend 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.

2.Page 3, line 41 – the introduction is a little long, there is a lot of information about the disease with some repetition. Please remove repetition (e.g. "chronic airway disease with characteristics of persistent airflow limitation") and present more concisely.

Response:we have deleted some repetition information about the disease on p.3,line 1-7.

3.Page 4, line 5 – please add a linking sentence to explain why breathlessness and reduced activity may lead to self-blame and inferiority.

Response:In order to make the introduction more logical, we deleted this sentence, because considering it can not play a role in the elaboration of our problem. And we have made great changes to the introduction.

4.Page 4 – please add a rationale for why you are choosing to consider MBI for people with COPD rather than other psychological interventions such as CBT. How might MBI reduce anxiety and depression and other psychological symptoms prominent in people with COPD?

Response:Thanks,we have given detailed explanation why we choose to consider MBI for people with COPD on p.4-5 by references 26-27.

5.Page 4, line 46 – please add a reference to support that many MBIs have proved beneficial to patients?

Response:we have added reference 24-25 to support that many MBIs have proved beneficial to patients.

6.Page 4, line 48 – please add a description of what is meant by introspection and why this is a good thing to promote.

Response:thanks.In order to make the introduction more logical and concise, we removed the original sentence of "active meditation can not only enhance the perception of interoceptive information, 19 but also increase the accuracy of respiratory load 20", because considering the meaning of this sentence a little repeat with the following sentence on p.5,line19-22.

7.It states in the introduction that MBI has not been successful in improving exercise capacity. Therefore I wonder why exercise capacity is a primary outcome of interest? Please specify by which pathway/process MBIs would lead to an improvement in exercise capacity.

Response:After consulting the literatures, we found that some studies indicated that the effect of MBIS in improving exercise capacity was not obvious. Based on this, we took it as the secondary outcome.We elaborate on the primary outcomes,such as dyspnea,anxiety, depression and life quality, clearly described in the introduction on p.3-4.

8.Please consider adding CINAHL and psychINFO to the databases included in the search as a lot of the literature in this area appears in nursing/AHP/psychology journals rather than medical ones.

Response:Thank you for the suggestion,we have added CINAHL and psychINFO to the databases in the abstract and search strategy sections,and also given detailed search strategies for the two databases shown in Appendix A.

9.Please detail how the search strategy was developed e.g. using MESH terms? Was there any input from an information specialist? Did you do a scoping exercise to identify key terms?

Response:Thanks.we have added details how the search strategies were developed in search strategy section and done a scoping exercise to identify key terms.In addition,we have acquired the help and guidance from the information expert and lung diseases expert.Moreover,the first author has also received professional learning for document retrieval and meta analysis,and published several meta analysis studies,such as “The influence of physical therapy and respiratory muscle training on rehabilitation of patients with chronic obstructive pulmonary disease: Meta-analysis.” and “The Efficacy of Tai Chi in patients with stable chronic obstructive pulmonary disease: A systematic review and meta-analysis ”.

10.Please correct the statement hat this is the first systematic review exploring MBIs for people with COPD.

Response:Thanks. We have corrected the statement that this is the first systematic review exploring MBIs for people with COPD.

11. At times the review is referred to as study, please correct throughout

Response:Thanks. We have corrected throughout.

12.The paper is generally well written but may benefit from an English review to improve some sentence structure.

Response: We have improved the quality of language in our manuscript with the professional assistance.

Once again,thank you very much for your comments and suggestions.

VERSION 2 – REVIEW

REVIEWER	Tiago Jacinto Porto Health School, Polytechnic Institute of Porto CINTESIS, Faculty of Medicine of University of Porto
REVIEW RETURNED	02-Feb-2019

GENERAL COMMENTS	The authors present a protocol for a systematic review that addresses a very interesting set of interventions in COPD patients. I have a few comments on the methods and statistical analysis: 1) In the section "Type of included studies", the description should follow the order of the objectives. 2) Please define "repetitive study". 3) The English in this section could be improved, mainly the sentences starting in line 42.

	4) In the section "Outcome Measures", the outcomes should be cleared stated, in terms of scales, questionnaires and/or indexes used. 5) The statistical analysis should also reflect the possiblity of the inclusion of ORs in addition to RRs. 6) In the abstract: a) Page 2, line 57: replace "concluded" with "included". b) Page 2, line 58: Suggested sentence: "We will search the literature in the databases (...)"

VERSION 2 – AUTHOR RESPONSE

Reviewer: 3

1.In the section "Type of included studies", the description should follow the order of the objectives.

Response:Thank you for the suggestion,we have revised the description following the order of the objectives on p.6,line21-23.

2.Please define "repetitive study".

Response:We have replaced the "repetitive study" with “duplicate publication”,and defined it as an article substantially overlaps with another published one in printing or electronic media on p.6,line25-27.

3.The English in this section could be improved, mainly the sentences starting in line 42.

Response:We have improved the quality of language in the section "Type of included studies" with the professional assistance.

4. In the section "Outcome Measures", the outcomes should be cleared stated, in terms of scales, questionnaires and/or indexes used.

Response:Our apologies that the outcomes were not described in detail. We have made extensive modifications of the outcome measures focusing on your suggestions on p.7,line16-25.

5.The statistical analysis should also reflect the possiblity of the inclusion of ORs in addition to RRs.

Response:We deeply appreciate your valuable suggestions.we have added the contents of the possibility of the inclusion of ORs in addition to RRs on p.9,line1-4 in the statistical analysis section.

6) In the abstract: a) Page 2, line 57: replace "concluded" with "included". b) Page 2, line 58: Suggested sentence: "We will search the literature in the databases (...)"

Response:thanks.We have revised the language in the abstract focusing on your suggestions.

Once again,thank you very much for your comments and suggestions.

VERSION 3 - REVIEW

REVIEWER	Tiago Jacinto Porto Health School, Polytechnic Institute of Porto CINTESIS, Faculty of Medicine of University of Porto
REVIEW RETURNED	28-Feb-2019

GENERAL COMMENTS	The authors have answered my questions satisfactorily. I still think that a minor English revision is needed, but the main components that I mentioned in the previous review were corrected and/or added.