

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Long-term effectiveness of group-based diabetes self-management on glycated hemoglobin for people with type 2 diabetes in community: a protocol of systematic review and meta-analysis
<b>AUTHORS</b>	Xia, Zhang; Jiang, Ying-ying; Shang, Wei-jing; Guo, Hai-jun; Mao, Fan; Dong, Wen-lan; Dong, Jian-qun

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Zimbudzi, Edward Monash University
<b>REVIEW RETURNED</b>	07-Feb-2021

<b>GENERAL COMMENTS</b>	<p>Thank you for an opportunity to review this protocol for a systematic review and meta-analysis which seeks to determine the long-term effectiveness of group-based diabetes self-management for people with type 2 diabetes in community.</p> <p>Title</p> <ul style="list-style-type: none"><li>-The title appears very broad. Suggest identifying the outcome of interest in the title for instance, 'Effectiveness of group-based diabetes self-management on glycated hemoglobin for people with type 2 diabetes in community: a protocol of systematic review and meta-analysis'. (Always reads well if the title identifies most of the PICO components).</li></ul> <p>Abstract</p> <p>Introduction</p> <ul style="list-style-type: none"><li>-There are a few sentences here with some grammatical errors e.g. lines 10 to 11; 17 to 20.</li><li>-In terms of justification for further studies, just having few studies is not a good reason. You need to comment on the quality of the studies (lines 20-22).</li><li>-The last sentence needs to be rephrased.</li></ul> <p>Methods and analysis</p> <ul style="list-style-type: none"><li>-Please provide justification for this, the retrieval time range will be 'from the establishment' of the database to July 2020.</li><li>-You need to decide whether your intervention is referred to as, 'diabetes self-management activity' or 'diabetes self-management activities' and be consistent.</li></ul> <p>Introduction (main paper)</p> <ul style="list-style-type: none"><li>-Page 7, lines 7-9. Please rephrase this sentence.</li><li>-Page 7, lines 12-22, suggest "Furthermore, we have searched PubMed, Science Direct and Cochrane Library, and found that few systematic reviews have NOT made clear provisions on the content of self-management, nor have they specifically evaluated the long term effect of self-management (<math>\geq 12</math> months), although</li></ul>
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	<p>some systematic reviews have evaluated the effect of self-management”.</p> <p>-Page 8, line 4-8, attend to grammar.</p> <p>Methods</p> <p>-Page 9, line 20, this is not clear, ‘The number of activities is not less than once’.</p> <p>Outcomes</p> <p>-It’s standard criteria to include ‘death’ as a secondary outcome in systematic reviews that utilise data from RCTs.</p> <p>Study design-how did the authors determine that a follow up period of ‘12 months and over’ is deemed as long term?</p> <p>Data extraction</p> <p>Page 14, lines 7-15. Reference is made to quantitative data. Are the authors referring to ‘continuous vs categorical data’?</p> <p>Additional comments</p> <p>-Since your review is based on patients attending community services, you may want to refer to them as ‘people with T2DM’ consistently throughout the paper. There are also some sections in the paper where you refer to ‘diabetic patients’. Please note that there is a shift from using such terminology which appears as if it gives people a ‘label’ (page 10, line 22).</p>
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<b>REVIEWER</b>	Wake, Deborah The University of Edinburgh, usher institute
<b>REVIEW RETURNED</b>	07-Feb-2021

<b>GENERAL COMMENTS</b>	<p>This study is generally welcome, and well written with methodology well described and generally of a high standard and appropriate for systematic review. There are lot of publications/ systemic reviews already in this area. The author aims to differentiate themselves from this body of work by a focus on longer term outcomes and ensuring the the self-management activity complies with a clear definition. The definition used for self-management education is based on a definition from a single publication. Give this is the premise/ criteria for inclusion or exclusion of studies, I would be keen that perhaps a wider body of literature is used to justify the criteria, or at least there is more discussion as to why this criterion was selected. Given the focus is on long-term effectiveness, I would be keen fo the authors to define what they mean by "long term" and then focus their findings on this rather than discussion of all time periods, to differentiate form existing systemic review publications which already break HbA1C outcomes into short, medium and long term. The review will exclude digital group intervention which I think is reasonable, as a separate review is needed to determine if face to face vs digital/ online groups result in different outcomes. Finally the authors focus only on ' objective measures' e.g. metabolic outcomes which they say is a strength. I welcome the inclusion of wider metabolic outcomes such as weight, cholesterol, BP etc. as part of the analysis as secondary outcomes. The lack of inclusion of patient reported outcomes such as quality of life, confidence in self-management, reduced distress, mental health outcomes etc., I think should be stated as both a positive and negative of the study, as these are important factors in health. In addition cessation of smoking , reducing alcohol are key risk factors for complications and so may want to acknowledge these as important outcomes that are not being covered also.</p>
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<b>REVIEWER</b>	Angkurawaranon, Chaisiri Faculty of Medicine, Chiang Mai University, Department of Family Medicine
<b>REVIEW RETURNED</b>	17-Feb-2021
<b>GENERAL COMMENTS</b>	This is a nice protocol that addresses an important topic. I have no further comments and look forward to the results.

### VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Mr. Edward Zimbudzi, Monash University

Comment1

Title

-The title appears very broad. Suggest identifying the outcome of interest in the title for instance, 'Effectiveness of group-based diabetes self-management on glycated hemoglobin for people with type 2 diabetes in community: a protocol of systematic review and meta-analysis'. (Always reads well if the title identifies most of the PICO components).

Response1

Thank you, glycated hemoglobin is the outcome of interest, and I add "on glycated hemoglobin" in the title as your suggestion.

Comment2

Abstract

Introduction

-There are a few sentences here with some grammatical errors e.g. lines 10 to 11; 17 to 20.

Response2

In lines 10 to 11, I change the sentence to 'The rapid rise in the prevalence of diabetes has a negative impact on patients' quality of life.'

In lines 17 to 20, I change the sentence to 'However, there is no consistent standards for self-management group activity, and its long-term effects ( $\geq 12$  months) are unclear.'

Comment3

-In terms of justification for further studies, just having few studies is not a good reason. You need to comment on the quality of the studies (lines 20-22).

Response3

I discuss the weaknesses of published systematic reviews from the angle of misclassification bias and reporting bias. Example is shown below.

'Although a few systematic reviews evaluate the long-term effects, they did not make clear provisions on the content of self-management, and the number and sample size of included studies were small, which may lead to misclassification bias and reporting bias.'

Comment4

-The last sentence needs to be rephrased.

Response4

I rephrase the last sentence using 'we' as subject. I also use 'characteristics' to replace 'components'

because I think 'characteristics' maybe more suitable here. Example is shown below.

'Therefore, we plan to conduct this systematic review to evaluate the long-term effects of self-management group education and the effects of different self-management characteristics on glycosylated hemoglobin (HbA1c).'

Methods and analysis

Comment5

-Please provide justification for this, the retrieval time range will be 'from the establishment' of the database to July 2020.

Response5

I am not sure when the first group-based diabetes self-management was carried out so my retrieval time range will be from the establishment of the database to July 2020 to avoid omitting relevant studies. Example is shown below.

'The retrieval time range will be from the establishment of the database to July 2020 to avoid omitting relevant studies.'

Comment6

-You need to decide whether your intervention is referred to as, 'diabetes self-management activity' or 'diabetes self-management activities' and be consistent.

Response6

After my serious consideration, I think using 'education' to replace 'activity' is a better choice because 'education' is more commonly used in self-management field and can help me to avoid the problem of singular and plural of activity.

Comment7

Introduction (main paper)

-Page 7, lines 7-9. Please rephrase this sentence.

Response7

I rephrase this sentence. Example is shown below.

'For other clinical indicators such as blood pressure and blood lipids, there is no consistent conclusion with respect to the long-term effects either.'

Comment8

-Page 7, lines 12-22, suggest "Furthermore, we have searched PubMed, Science Direct and Cochrane Library, and found that few systematic reviews have NOT made clear provisions on the content of self-management, nor have they specifically evaluated the long term effect of self-management ( $\geq 12$  months), although some systematic reviews have evaluated the effect of self-management".

Response8

Thank you for your suggestion, but I don't change my sentence as your suggestion because I add more details about deficiency of published systematic reviews. After reviewing, the sentences are changed to 'Furthermore, we have searched PubMed, ScienceDirect and Cochrane Library, and found that a few systematic reviews evaluated the effect of self-management, but there are some deficiencies. First, they did not make clear provisions on the content of self-management, which may lead to misclassification bias. Second, for the long-term effect ( $\geq 12$  months) evaluation, the number and sample size of included studies were small, which may introduce reporting bias.'

Comment9

-Page 8, line 4-8, attend to grammar.

#### Response9

I delete words such as 'in community compared with other interventions' to make the sentence more concise and avoid grammar problems. Example is shown below.

'What are the long-term effects of group-based diabetes self-management on HbA1c, blood pressure, blood lipid, body weight and death event.'

#### Comment10

##### Methods

-Page 9, line 20, this is not clear, 'The number of activities is not less than once'.

#### Response10

I change the sentence to 'The group activity should be carried out more than once'.

#### Comment11

##### Outcomes

-It's standard criteria to include 'death' as a secondary outcome in systematic reviews that utilise data from RCTs.

#### Response11

Thank you for your suggestion, I add this indicator as a secondary outcome.

#### Comment12

Study design-how did the authors determine that a follow up period of '12 months and over' is deemed as long term?

#### Response12

I have read three relevant articles. These articles defined measurement at 12 or more months from baseline as long term. Unfortunately, they did not present the definition of long term. Therefore, for my study, I define a follow up period of '12 months and over' as long term in order to make a comparison of results. In the introduction, I add the reason why the time start point is baseline survey and the end point is the last follow-up survey.

The three articles are:

1. Steinsbekk A, Rygg L, Lisulo M, Rise MB, Fretheim A. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. BMC Health Services Research. 2012;12(1). 10.1186/1472-6963-12-213
2. Odgers-Jewell K, Ball LE, Kelly JT, Isenring EA, Reidlinger DP, Thomas R. Effectiveness of group-based self-management education for individuals with Type 2 diabetes: a systematic review with meta-analyses and meta-regression. Diabetic Medicine. 2017;34(8):1027-39. 10.1111/dme.13340
3. Deakin T, McShane CE, Cade JE, Williams RD. Group based training for self-management strategies in people with type 2 diabetes mellitus. The Cochrane database of systematic reviews. 2005(2):CD003417. 10.1002/14651858.CD003417.pub2

Reason I add is:

'Since participants may attempt to carry out self-management after the first group activity, and may continue to carry out self-management on their own after the end of all group activities, the time interval between the baseline survey and the last follow-up survey was taken as the influence period of self-management group education.'

#### Comment13

##### Data extraction

Page 14, lines 7-15. Reference is made to quantitative data. Are the authors referring to 'continuous

vs categorical data'?

#### Response13

Yes, I change 'quantitative data' to 'continuous data'. Example is shown below.

'Since outcomes such as blood glucose, blood pressure and blood lipids are mostly expressed as continuous data, which cannot be analyzed together with categorical data, reviewers will contact the author to obtain continuous data if the outcome is presented in categories.'

#### Comment14

Additional comments

-Since your review is based on patients attending community services, you may want to refer to them as 'people with T2DM' consistently throughout the paper. There are also some sections in the paper where you refer to 'diabetic patients'. Please note that there is a shift from using such terminology which appears as if it gives people a 'label' (page 10, line 22).

#### Response14

I delete 'diabetic patients' in page 10 line 22 and also check whole paper to avoid this 'label'.

Reviewer: 2

Dr. Deborah Wake, The University of Edinburgh

Comments to the Author:

This study is generally welcome, and well written with methodology well described and generally of a high standard and appropriate for systematic review.

#### Comment15

There are lot of publications/ systemic reviews already in this area. The author aims to differentiate themselves from this body of work by a focus on longer term outcomes and ensuring the self-management activity complies with a clear definition. The definition used for self-management education is based on a definition from a single publication. Give this is the premise/ criteria for inclusion or exclusion of studies, I would be keen that perhaps a wider body of literature is used to justify the criteria, or at least there is more discussion as to why this criterion was selected.

#### Response15

Thank you for your suggestion, I add three reasons why I adopt this definition in the discussion. Example is shown below.

1. First, the definition proposed explicit content that self-management interventions should involve, which helps us to easily distinguish self-management from any other form of education or behavioral intervention.
2. Second, the definition can be used to make a distinct selection of self-management interventions without being too restrictive because it only set boundaries for intervention content but not intensity, duration, mode of delivery and so forth.
3. Third, the definition was generated by consensus meetings with self-management experts and practitioners, which may guarantee its external validity.

#### Comment16

Given the focus is on long-term effectiveness, I would be keen for the authors to define what they mean by "long term" and then focus their findings on this rather than discussion of all time periods, to differentiate from existing systemic review publications which already break HbA1C outcomes into short, medium and long term.

#### Response16

I have read three relevant articles. These articles defined measurement at 12 or more months from baseline as long term. Unfortunately, they did not present the definition of long term. Thus, I have to admit that it's hard for me to define the meaning of "long term" without enough references. Besides, for my study, I define a follow up period of '12 months and over' as long term in order to make a comparison of results.

As your suggestion, I have planned to focus findings on long term rather than all time periods. Thanks for your reminder.

The three articles are:

1. Steinsbekk A, Rygg L, Lisulo M, Rise MB, Fretheim A. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. BMC Health Services Research. 2012;12(1). 10.1186/1472-6963-12-213
2. Odgers-Jewell K, Ball LE, Kelly JT, Isenring EA, Reidlinger DP, Thomas R. Effectiveness of group-based self-management education for individuals with Type 2 diabetes: a systematic review with meta-analyses and meta-regression. Diabetic Medicine. 2017;34(8):1027-39. 10.1111/dme.13340
3. Deakin T, McShane CE, Cade JE, Williams RD. Group based training for self-management strategies in people with type 2 diabetes mellitus. The Cochrane database of systematic reviews. 2005(2):CD003417. 10.1002/14651858.CD003417.pub2

Comment17

The review will exclude digital group intervention which I think is reasonable, as a separate review is needed to determine if face to face vs digital/ online groups result in different outcomes.

Response17

Thank you for your support.

Comment18

Finally the authors focus only on ' objective measures' e.g. metabolic outcomes which they say is a strength. I welcome the inclusion of wider metabolic outcomes such as weight, cholesterol, BP etc. as part of the analysis as secondary outcomes. The lack of inclusion of patient reported outcomes such as quality of life, confidence in self-management, reduced distress, mental health outcomes etc., I think should be stated as both a positive and negative of the study, as these are important factors in health. In addition cessation of smoking , reducing alcohol are key risk factors for complications and so may want to acknowledge these as important outcomes that are not being covered also.

Response18

In the study limitations, I acknowledge that I will not collect these outcomes, and give an explanation, and state the negative impact. Example is shown below.

'Some important patient reported outcomes such as quality of life, self-efficacy, reduced distress, mental health, cessation of smoking, reducing alcohol are not covered in the study because the definitions and measurement methods for these outcomes are various, which may cause great heterogeneity and even cannot be used for meta-analysis. Therefore, this study cannot answer the questions about the psychological and behavioral effects of self-management, and more separate reviews are needed to determine these effects.'

Comment19

Reviewer: 3

Dr. Chaisiri Angkurawaranon, Faculty of Medicine, Chiang Mai University

Comments to the Author:

This is a nice protocol that addresses an important topic. I have no further comments and look forward to the results.

Response19

Thank you.

I also make some changes to manuscript:

Change1

In the study selection, I delete 'at least three times' because sometimes it makes no sense when we find a worry email or authors cannot receive emails from China. Thus, we delete this to increase the flexibility of author consulting.

Change2

In the data extraction, the form of cooperation is changed. We planned that two reviewers independently extract information from studies, but now one will conduct this and another one will check this to improve work efficiency. Because the research field of one reviewer is not diabetes self-management, it may take several months for him to finish data extraction, and it is unaffordable for him with respect to time cost. Therefore, we changed the form of cooperation. Let one reviewer with more experience of self-management extract the data to ensure the high quality of data extraction, and let another one check the result.

Change3

In the Outcomes of data extraction, I list the reason why we will collect death event.

Change4

In the data synthesis-paragraph 1, I change the content of summary table to make its structure more reasonable and its presentation more feasible. For example, I change the order of words to improve its structure. I add some words to make intervention more detailed. I had planned to present enrollment time and last follow-up time, but found most studies did not report the exact time, so I delete these words.

Change5

In the meta regression and subgroup analysis, I replace "region" with "country" because we will collect the information of country rather than region.

Change6

In the sensitivity analysis, I change follow-up rate from 20% to 10% because we think the low loss of follow-up rate can reduce the impact of attrition bias. Setting 10% as standard can get a higher quality result than 20%.

#### VERSION 2 – REVIEW

<b>REVIEWER</b>	Zimbudzi, Edward Monash University
<b>REVIEW RETURNED</b>	03-Jun-2021
<b>GENERAL COMMENTS</b>	The authors have addressed most of my comments adequately.