# PEER REVIEW HISTORY

## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | Effect of music intervention on mental health in patients with diabetes mellitus: protocol for a systematic review and meta-analysis of randomized controlled trials |
| **AUTHORS** | Zhou, Lin-yue; Zhang, Yuan; Tian, Yuan; Fu, Xiaoxu; Wang, Li-zhen; Xie, Chun-guang |

## VERSION 1 – REVIEW

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| **REVIEWER** | Pilar Pérez-Ros<br>Faculty of Nursing. Universidad Católica de Valencia San Vicente Mártir |
| **REVIEW RETURNED** | 20-Dec-2019 |

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| **GENERAL COMMENTS** | This manuscript is a protocol for a systematic review and meta-analysis of randomized controlled trials, the aim is to know the Effect of music intervention on mental health in patients with diabetes mellitus.<br>The research question is clear and unifies two important aspects. The first is the possible relationship between diabetes and psychiatric disorders and the second is musical interventions to manage these pathologies.<br>It is a well written protocol, registered in PROSPERO and methodologically well designed to avoid bias and with a final prism checklist.<br>The authors have conducted a critical current review of the topic. I have only a few comments.<br><br>Will the authors include RCT in all areas? At community population, in nursing homes, in health centres, associations etc? After reading I understand that these are interventions based on music, so does music therapy? It is not well described. In this case, will the effects of both be analyzed separately? This aspect could be interesting since the economic cost and characteristics of music-based interventions are not equivalent to music therapy.<br>In the outcomes on the anxiety and depression rating scales, will only those indicated be assessed? Depending on the age of the population, and the area in which it is |

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| **REVIEWER** | Paula de Marchi Scarpin Hagemann<br>Sao Paulo State University - School of Sciences |
| **REVIEW RETURNED** | 24-Dec-2019 |

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| **GENERAL COMMENTS** | This is a protocol to perform a systematic review and meta-analysis about the effects of the music intervention on patients with diabetes mellitus. |

| | There isn't a systematic review about this issue on the Literature yet. Therefore, it is really new and relevant. It may enable the creation of standardized intervention practices for this population, even with the creation of guidelines. These guidelines would contribute to better practices and results.<br>The search strategy is adequate. I suggest only considering also searching in grey literature, such as academic documents, like PhD thesis.<br>The methodology is well defined, including the search for possible bias and take account the heterogeneity of the studies.<br>I recommend to accept the protocol study, however it is necessary to adequate the writing. I point out some suggestions, but I think the whole article needs a language adjustment:<br>p.3; L4: the word Abstract is writing incorrectly (Abstact)<br>p.3; L10: I suggest to change the word terrible for great, for example<br>p.3; L11: change there are no any to there are not<br>p.3;L18: I think you should change the word retrieve for search or some word like that<br>p.5;L19: change a few to few<br>p.5;L20: put diabetes or this disease in the end of the sentence<br>p.5;L23: change incident to incidence<br>p.5;L24: change suggested to suggests and change had to has<br>p.5;L33: put them at the end of the sentence<br>p.6;L10: rewrite this sentence. |
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**VERSION 1 – AUTHOR RESPONSE**

Responses to Reviewers
To Reviewer 1
Comment 1: Will the authors include RCT in all areas? At community population, in nursing homes, in health centres, associations etc.?
Response: Thank you for your question. In this systematic review, the major intervention is music intervention, including music therapy and music medicine, which can be implemented in areas like communities, nursing homes, health centres, etc. Data about the areas will come from the studies we included. In order to include studies that meet the inclusion criteria as far as possible, we intend to search not only the published articles in nine online databases, but also four sources of gray literatures. We will extract and tabulate all the data, including the areas where the RCTs were implemented. These areas may involve communities, nursing homes, health centers, associations, etc. When the data extraction is complete, we can determine whether all areas are included. We have added "area" into the data extraction items of participants, see LOA [11].

Comment 2: After reading I understand that these are interventions based on music, so does music therapy? It is not well described. In this case, will the effects of both be analyzed separately? This aspect could be interesting since the economic cost and characteristics of music-based interventions are not equivalent to music therapy.
Response: Thank you for pointing this out. In the process of revision, we searched a large number of relevant literatures about music intervention, music therapy and music medicine. Firstly, we found that the definition of "music intervention" is uncertain. Many literatures have used the word "music intervention" in their titles, most of which involve the content about both of "music therapy" and "music medicine", such as the article titled "Effectiveness of music interventions on dental anxiety in paediatric and adult patients: a systematic review" (PMID: 27819961); while others only describe the content about "music medicine", such as the article titled "Music intervention during daily weaning trials—a 6 day prospective randomized crossover trial" (PMID:27912960). Secondly, we also

searched for an article published by you entitled "Preferred Music Listening Intervention in Nursing Home Residents with Cognitive Impairment: A Randomized Intervention Study" (PMID: 31177232). After perusing this article, we found that the concept of "music medicine" in our paper is similar to the concept of "interventions based on music" you mentioned in the Comment 2. They both refer to the listening to music, which can be implemented independently by medical or healthcare professionals instead of music therapists. Therefore, we can better understand and respond to this comment. Thirdly, we have found at least four systematic reviews published in Cochrane Library, which use the word "music intervention" in their titles (PMID: 27524661, 25490233, 23740695, 28103638), include the content about both "music therapy" and "music medicine". Based on the above points, after discussion, we made a decision that the term "music intervention" will include both of "music therapy" and "music medicine" in this systematic review. We have added detailed description of music intervention, including music therapy and music medicine, in our paper, see LOA [1]. Additionally, according to your comment, we plan to compare the effects between music therapy and music medicine on depression and anxiety of diabetic patients, see LOA [2]. And we will also implement subgroup analysis according to the type of music intervention (music therapy or music medicine), see the part of subgroup analysis in LOA [12].

Comment 3: In the outcomes on the anxiety and depression rating scales, will only those indicated be assessed? Depending on the age of the population, and the area in which it is?
Response: Thank you for your question again. In our initial manuscript, only four scales (SDS, HAMD, SAS, HAMA) were selected to measure the primary outcomes. The reason why we chose the four scales is that they are the most widely used scales in our country. However, after we searched and read many related literatures of protocols for systematic review about anxiety and depression, we have found that, in most of the literatures, all validated scales for anxiety or depression are included to measure the outcomes. After serious discussion, we decided to use not only the scales indicated in our initial manuscript, but also other validated scales as well, see LOA [6] and LOA [7].
Besides, considering the heterogeneity that may arise due to different scales, we also plan to implement subgroup analysis according to the type of scales, see the part of subgroup analysis in LOA [12].


To Reviewer 2
Comment 1: The search strategy is adequate. I suggest only considering also searching in grey literature, such as academic documents, like PhD thesis.
Response: We agree your good suggestion. And according to your suggestion, we intend to search not only the published articles in nine online databases, but also four sources of gray literatures as following: OpenGrey (www.opengrey.eu/), CNKI (www.cnki.net), Open Access Theses and Dissertations (oatd.org) and British Library EThOS (ethos.bl.uk/), see LOA [8].
As for the search strategy, thanks for your recognition. But we have also revised it in the Table 1. Because after revision, the term "music intervention" will include both of "music therapy" and "music medicine" in this systematic review, but we only covered the MeSH term for music therapy in initial search strategy. In order to search the relevant literature as comprehensively as possible, we have added the MeSH terms for music and singing, combined with their respective free-text terms, see LOA [10].

Comment 2: I recommend to accept the protocol study, however it is necessary to adequate the writing. I point out some suggestions, but I think the whole article needs a language adjustment:
p.3; L4: the word Abstract is writing incorrectly (Abstact)
p.3; L10: I suggest to change the word terrible for great, for example
p.3; L11: change there are no any to there are not
p.3; L18: I think you should change the word retrieve for search or some word like that
p.5; L19: change a few to few

p.5; L20: put diabetes or this disease in the end of the sentence
p.5; L23: change incident to incidence
p.5; L24: change suggested to suggests and change had to has
p.5; L33: put them at the end of the sentence
p.6; L10: rewrite this sentence.
Response: Thank you for your good instruction on language revision for this article. Firstly, according to the suggestions you pointed out, we have made corresponding modifications. But for the suggestion "p.5; L19: change a few to few", we are sorry for that we actually changed "a few" to "some". And we did that for the following reasons. In the Oxford dictionary, "few" means "not many" or "hardly any". In fact, in recent years, there have been at least ten literatures, which have indicated that depression is more prevalent in diabetic patients compared to those without this disease. Therefore, we didn't change "a few" to "few". We sincerely hope that you can accept this modification. Moreover, we have revised the whole manuscript carefully to avoid any grammatical or syntactic errors, see LOA [22]. We hope that the revised language can meet the publication standard.

List of Actions (LOA)
[1] p.6; L47: "although the distinction between them are often neglected" has been deleted, and a detailed description of music intervention, including music therapy and music medicine, has been added as following:
The official definition of music therapy is the "…clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program".[16] A trained music therapist leads the treatment process, choosing the type of music, the form of music presentation (pre-recorded or live), and the treatment setting (singing, playing instruments, composing, etc.) based on the patient's condition, ultimately resulting in a therapeutic scheme that is best for the patient. By comparison, music medicine is defined as the passive listening to pre-recorded music, which can be implemented independently by medical or healthcare professionals instead of music therapists.[17] In brief, music therapy focuses on active music therapy and personalized treatments while music medicine belongs to passive music listening and non-personalized therapy. It is significant to emphasize the distinction between music therapy and music medicine because some literatures suggest that the effect of the former is better than the latter in a great many outcomes.[18-19]
References from 16 to 19 were newly added, so the reference numbers of the subsequent references were increased in turn.
[2] p.7; L54: a new objective has been added, that is "compare the effects between music therapy and music medicine".
[3] p.8; L19: "PRISMA" has been changed into "PRISMA-P", and the PRISMA Statement we have to comply with when conducting this systematic review has been added as following:
The results will be reported in conformity to the PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Healthcare Interventions.[41]
References 41 were newly added.
[4] p.9; L6: the interventions have been revised as following:
"music" has been changed into "music intervention (music therapy or music medicine)".
[5] p.9; L10: "lifestyle management" has been changed into "diabetes self-management education and support (DSMES)" according to the newest guideline of American Diabetes Association (ADA).
[6] p.9; L33: "or other validated scales for depression" has been added after the "Hamilton depression scale (HAMD)".
[7] p.9; L35: "or other validated scales for anxiety" has been added after the "Hamilton anxiety scale (HAMA)".
[8] p.9; L50: the time "August 2019" has been changed into "the present"; and sources of grey literatures have been added as following:
OpenGrey (www.opengrey.eu/), CNKI (www.cnki.net), Open Access Theses and Dissertations (oatd.org) and British Library EThOS (ethos.bl.uk/)

[9] p.10; L8: two MeSH terms, including "music and singing", has been added.

[10] p.10; L37: the Table 1 has been revised. Three steps have been added as following:

#6 "Music"[Mesh] OR music intervention[Title/Abstract] OR music medicine[Title/Abstract] OR music listening[Title/Abstract] OR audio recording[Title/Abstract] OR mp3 hearing[Title/Abstract]

#7 "Singing"[Mesh] OR sing[Title/Abstract] OR sings[Title/Abstract] OR song[Title/Abstract] OR compose[Title/Abstract] OR composing[Title/Abstract]

#8 #5 OR #6 OR #7

[11] p.11; L19: "area" has been added into the data extraction items of participants.

[12] p.11; L49: three new paragraphs (unit of analysis issues, subgroup analysis and sensitivity analysis) and some sentences have been added to elaborate the content of data analysis. According to the Cochrane Handbook, the content of data analysis of a systematic review often consists of the following parts: measures of treatment effect, unit of analysis issues, dealing with missing data, assessment of heterogeneity, assessment of reporting bias, data synthesis, subgroup analysis and sensitivity analysis. Therefore, we reorganized the original content of data analysis and supplemented new content.

[13] p.13; L6: "based on verbal communication" has been added after psychotherapy.

[14] p.13; L17: "based on verbal communication" has been added after psychotherapy.

[15] p.13; L55: the part of "Figure legend" has been added.

[16] p.16; L17: four new references [16-19] has been added as following:

16.American Music Therapy Association. What is music therapy?, 2013.Available: https://www.musictherapy.org/about/musictherapy/. Accessed January 9, 2020.

17.Dileo C. A classification model for music and medicine. National Association of Music Therapy, Washington, DC, 1999: 1-6.

18.Raglio A, Bellelli G, Mazzola P, et al. Music, music therapy and dementia: a review of literature and the recommendations of the Italian Psychogeriatric Association. Maturitas 2012;72(4):305–310.doi:10.1016/j.maturitas.2012.05.016

19.Dileo C. Effects of music and music therapy on medical patients: a meta-analysis of the research and implications for the future. J Soc Integr Oncol 2006;4(2):67–70. doi:10.2310/7200.2006.002

[17] p.17; L19: the original reference has been replaced by a latest reference—"Gómez Gallego M, Gómez García J. Music therapy and Alzheimer's disease: Cognitive, psychological, and behavioural effects. Neurologia 2017;32(5):300–308. doi:10.1016/j.nrl.2015.12.003"

[18] p.17; L39: the original reference has been replaced by a latest reference—"Bieleninik L, Geretsegger M, Mössler K, et al. Effects of Improvisational Music Therapy vs Enhanced Standard Care on Symptom Severity Among Children With Autism Spectrum Disorder: The TIME-A Randomized Clinical Trial. JAMA 2017;318(6):525–535. doi:10.1001/jama.2017.9478"

[19] p.18; L28: one new reference has been added—"Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. BMJ 2009;339:b2700.doi:10.1136/bmj.b2700"

[20] p.18; L29: the guideline of the 2019 version has been changed into the 2020 version—" American Diabetes Association. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes-2020. Diabetes Care 2020;43(Suppl 1):S98–S110. doi:10.2337/dc20-S009"

[21] p.18; L35: the guideline of the 2019 version has been changed into the 2020 version—" American Diabetes Association. 5. Facilitating Behavior Change and Well-being to Improve Health Outcomes: Standards of Medical Care in Diabetes-2020. Diabetes Care 2020;43(Suppl 1):S48–S65. doi:10.2337/dc20-S005"

[22] Other changes: All errors about grammar, spelling and formatting have been corrected.

## VERSION 2 – REVIEW

| REVIEWER | Pilar Pérez-Ros<br>Universidad Católica Valencia SanVicente Mártir, Spain |
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| REVIEW RETURNED | Spain |

| | 05-Feb-2020 |
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| GENERAL COMMENTS | After reviewing the changes made by the authors, the manuscript is suitable for publication. |
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| REVIEWER | Paula de Marchi Scarpin Hagemann<br>Sao Paulo State University |
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| REVIEW RETURNED | 07-Feb-2020 |

| GENERAL COMMENTS | I think you accepted my suggestions and made the necessary adjustments, so the article is ready for publication. |
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