

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Can a sleep disorder intervention embedded self-management program contribute to improve management of diabetes? A pilot single-arm pre-and post-test study
AUTHORS	Sakamoto, Ritsuko; Kazawa, Kana; Jahan, Yasmin; Takeyama, Naoko; Moriyama, Michiko

VERSION 1 – REVIEW

REVIEWER	Reutrakul, Sirimon Mahidol University
REVIEW RETURNED	09-Jan-2021

GENERAL COMMENTS	<p>bmjopen-2020-045783</p> <p>The manuscript by Sakamoto et al addressed whether sleep disorder intervention program can contribute to improve management of diabetes. The paper employed a pre-post design in 24 people with diabetes. I applaud the effort of the authors in conducting this study, however, there are multiple concerns as below:</p> <ol style="list-style-type: none">1. Introduction is very long. There should be references in certain places (page 6 line 10, page 6 line 28). Line 34- sleep disorders need to be defined as there are multiple dimensions of sleep problems.2. Page 8 starting line 10, I do not believe that the detail description of the instruments belong here.3. I am not sure if the definition of the group “diabetic nephropathy” is appropriate, as there was nothing specific to target diabetic nephropathy (as diabetes education program should be incorporated for all people with diabetes). The authors simply excluded those with eGFR<30, which is reasonable- but to call the group “diabetic nephropathy” is somewhat misleading.4. Research questions are too many, and some would have not been able to be answered by this design. For example, to answer if “when the patients were divided into those with sleep disorders and those without sleep disorders, was diabetic nephropathy more markedly improved in those with sleep disorders”- will need a larger number of patients in each group. I don’t believe this project answered question #5 either (page 9 line 28).5. We need a reference of this “sleep meter”- what is it detecting? When the score is abnormal, what does that mean? This was also not given to all participants so you really cannot evaluate your research question#5. But the criteria of giving this out is also unclear (page 17, line 44). This will also affect the result and conclusion that you draw from question #5 (page 22 line 37).6. The authors used many questionnaires to assess sleep and also “sleep meter” but I’m not sure that they can conclude that
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	<p>PSQI is the best, given small subject number and that “sleep meter should be used before the questionnaires”.</p> <p>7. The detail of sleep intervention is lacking. I think there are too many interventions without a detail emphasis on sleep – which likely explained why the sleep score is not better (and possibly resulting in poor satisfaction from participants).</p> <p>I think the paper has some merit but it is very long and somewhat lacking good design to address each question (plus having too many questions).</p>
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REVIEWER	Martyn-Nemeth, P University of Illinois at Chicago
REVIEW RETURNED	10-Feb-2021

GENERAL COMMENTS	<p>Introduction The authors seek to evaluate the efficacy and feasibility of a self-management education program on sleep and activity in a population of T2D adults with nephropathy. This may be an important area to study however the background needs to be better focused on the current state of knowledge with regard to sleep and sleep disorders in those with nephropathy and the gaps that this study intends to fill. The research questions that follow should be logically linked to the gaps in knowledge and more clearly identify study outcomes.</p> <p>Methods A single group pretest/posttest design is utilized for this pilot study. Outcome measures incorporate both self-report and objective measures using sleep questionnaires and a “sleep meter”. The sleep meter (Nemuri scan) is described as polysomnography but from the description and a brief review of the device, it does not appear to use polysomnography technology. This needs to be clarified.</p> <p>Results The title of the study, “Does a Sleep Disorder Intervention Program Contribute to Improved Management of Diabetes?” implies that the program focuses on sleep disorders when it appears to be a more general self-management program that addresses sleep hygiene. The results confirm this assessment.</p>
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VERSION 1 – AUTHOR RESPONSE

Comments to reviewers

Reviewer: 1

1. Introduction is very long. There should be references in certain places (page 6 line 10, page 6 line 28). Line 34- sleep disorders need to be defined as there are multiple dimensions of sleep problems.

Response

We have revised and shorten the Introduction section as suggested. We also added the references accordingly. We defined the sleep disorder as below (p.4). We also defined the sleep disorder in the ‘Method’ section (p.8).

Regarding interventions for sleep disorders, several studies suggest that significant changes in sleep disorders of chronic primary insomnia are introduced by non-pharmacological approaches (p.8)

2. Page 8 starting line 10, I do not believe that the detail description of the instruments belong here.

Response

We removed the sentence accordingly.

3. Not sure if the definition of the group “diabetic nephropathy” is appropriate, as there was nothing specific to target diabetic nephropathy (as diabetes education program should be incorporated for all people with diabetes). The authors simply excluded those with eGFR<30, which is reasonable- but to call the group “diabetic nephropathy” is somewhat misleading.

Response

Since we aimed to prolong the progress of diabetic nephropathy patients moving onto stage 4, therefore, we chose patients stage 1 to 3. After stage 4, we cannot recommend fitness club level exercise. In case of nephropathy staging, we used ‘The Japan Diabetes Society’ guidelines. In the program, we explained the participants about their stages and did aware and educated them based on their staging. We added the explanation in the method section (p.12).

Regarding this statement we added the following citation in the text:

The Japan Diabetes Society. Chronic complications. 2 Diabetic nephropathy. Treatment guide for diabetes 2020.

We also did trial registration as “diabetic nephropathy”.

4. Research questions are too many, and some would have not been able to be answered by this design. For example, to answer if “when the patients were divided into those with sleep disorders and those without sleep disorders, was diabetic nephropathy more markedly improved in those with sleep disorders”- will need a larger number of patients in each group. I don’t believe this project answered question #5 either (page 9 line 28).

Response

We appreciate your comments. We deleted the research questions and also removed the comparison between with and without sleep disorders. We gave an explanation about the features with and without sleep disorders in the ‘Baseline characteristics of the participants’ in the result section (p.16).

5. We need a reference of this “sleep meter”- what is it detecting? When the score is abnormal, what does that mean? This was also not given to all participants so you really cannot evaluate your research question#5. But the criteria of giving this out is also unclear (page 17, line 44). This will also affect the result and conclusion that you draw from question #5 (page 22 line 37).

Response

We cited 2 references in the text and added ‘Supplemental file 1’ which clarified items and scores measured by the sleep meter. Additionally, we removed the question #5 and revised the result, discussion, and conclusion sections accordingly.

6. The authors used many questionnaires to assess sleep and also “sleep meter” but I’m not sure that they can conclude that PSQI is the best, given small subject number and that “sleep meter should be used before the questionnaires”.

Response

We added this part in our study limitation section with “Also, due to the small sample size, it cannot be possible to conclude which is better, subjective or objective measurements for sleep measurement” in the page 22.

7. The detail of sleep intervention is lacking. I think there are too many interventions without a detail emphasis on sleep – which likely explained why the sleep score is not better (and possibly

resulting in poor satisfaction from participants). I think the paper has some merit but it is very long and somewhat lacking good design to address each question (plus having too many questions).

Response

To provide more detail information regarding sleep intervention, we added 'Supplemental file 2', which is a part of our textbook. This section explained how we combined subjective and objective results together in the intervention.

To compensate the design, we revised and focused our purposes on evaluating feasibility and efficacy of the program.

Reviewer: 2

Introduction

The authors seek to evaluate the efficacy and feasibility of a self-management education program on sleep and activity in a population of T2D adults with nephropathy.

This may be an important area to study however the background needs to be better focused on the current state of knowledge with regard to sleep and sleep disorders in those with nephropathy and the gaps that this study intends to fill. The research questions that follow should be logically linked to the gaps in knowledge and more clearly identify study outcomes.

Response

We have revised the Introduction section accordingly. Please see the page 5-7.

We also omitted the specific research questions.

Methods

A single group pretest/posttest design is utilized for this pilot study. Outcome measures incorporate both self-report and objective measures using sleep questionnaires and a "sleep meter". The sleep meter (Nemuri scan) is described as polysomnography but from the description and a brief review of the device, it does not appear to use polysomnography technology. This needs to be clarified.

Response

We explained about the sleep meter in details and showed the validity and added references regarding this statement. Also, we added 'Supplemental file 1' for explanation of the evaluation items for sleep meter.

Results

The title of the study, "Does a Sleep Disorder Intervention Program Contribute to Improved Management of Diabetes?" implies that the program focuses on sleep disorders when it appears to be a more general self-management program that addresses sleep hygiene. The results confirm this assessment.

Response

We changed the title to "Can a sleep disorder intervention embedded self-management program contribute to improve management of diabetes? A pilot single-arm pre-and post-test study?"

We also revised the 'Result' section accordingly.

Thank you for your consideration. I look forward to hearing from you.