PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	KEPT-app trial- a pragmatic, single-blind, parallel, cluster-randomised effectiveness study of pelvic floor muscle training among incontinent pregnant women: study protocol
AUTHORS	Sidik, Dr. Sherina; Jaffar, Aida; Foo, Chai Nien; Muhammad, Noor Azimah; Abdul Manaf, Rosliza; Ismail, Siti Irma; Alagirisamy, Parwathi; Ahmad Fazlah, Amalina Farhi; Suli, Zailiza; Goodyear-Smith, Felicity

VERSION 1 – REVIEW

REVIEWER	Sahar Sobhgol Australia
REVIEW RETURNED	28-Aug-2020

GENERAL COMMENTS	Very interesting and timely research I have the following comments: Abstract 1. Please describe the primary and secondary outcomes in the abstract 2. Please clarify the aim of the study clearly. Is the aim of the study to measure the effectiveness of a newly designed app (mhealth or Kept-app) on urinary incontinence as a primary outcome? or the aim of study is to measure the adherence rate by using a PFME mobile-app? or the aim is only to develop a PFME app? or all of them? This needs to be described clearly in the abstract. 2. Please provide a brief discussion/or conclusion in the abstract (according to the journal format) to outline on how the results of this study can add to the current knowledge? Introduction 1. Please provide a brief literature review to justify the usage of an app method? Are there any similar study available on using an app? What are their results? It would be beneficial for the authors to justify why they want to use an app for PFME? Methods: 1. What method will be used for randomization? What is the ratio of treatment to control? Please describe the randomization and allocation process more thoroughly? 2. Please describe more about the intervention being delivered through the app? It is not clear to the readers as what kind of information is being delivered to women by mhealth app? can you please describe the intervention more clearly? 3. Can you explain about KEPT-app (line 41) ? You used two terms of mHealth app and KEPT-app? Are they the same? or different? Can you please provide a clear description about the various names and abbreviations are used throughout your study? 4. It would be beneficial for the readers if you provide a list of

	abbreviations with their definitions at the end of your papers 5. How long is the duration of intervention? Can you please describe it clearly? 6. How do you follow up women? This is not clear from the text. 7. Line 37. "Each primary care clinic will be randomized to either .....". This paragraph is not clear. Why 16 weeks? You start the intervention at 28 weeks. By 36 weeks gestation, there will be less than 10 weeks time. What do you mean by 16 weeks and 22 weeks? where is your start point? When exactly the recruitment will start and how long is the duration of study? 8. At which time points do you measure the several outcomes of the study? This is not well described in the text. 9. Line 28. table 2. What being Malaysian involve? what ethnicities are considered Malaysian? Will all pregnant women (Primiparous or multiparous) be included in the study? 10. The sample size estimation. You can add the formula you used for the estimation of sample size here. What baseline information on either the primary or secondary outcomes have you used to calculate the sample size?. What do you mean by secondary care/primary care in the estimation of sample size? 11. Line 55. Quantitative analysis: How do you assess the effect of time? How do you consider the intention to treat analysis?

VERSION 1 – AUTHOR RESPONSE

Reviewer's comments and responds

Abstract

1. Please describe the primary and secondary outcomes in the abstract

2. Please clarify the aim of the study clearly. Is the aim of the study to measure the effectiveness of a newly designed app (mhealth or Kept-app) on urinary incontinence as a primary outcome? or the aim of study is to measure the adherence rate by using a PFME mobile-app? or the aim is only to develop a PFME app? or all of them? This needs to be described clearly in the abstract.

2. Please provide a brief discussion/or conclusion in the abstract (according to the journal format) to outline on how the results of this study can add to the current knowledge?

- The abstract has been formatted as per suggested and conform with the CONSORT extension cluster trial abstract (Supplementary 3)

Introduction

1. Please provide a brief literature review to justify the usage of an app method? Are there any similar study available on using an app? What are their results? It would be beneficial for the authors to justify why they want to use an app for PFME?

- The introduction has addressed all the suggestions by the reviewer.

Methods:

1. What method will be used for randomization? What is the ratio of treatment to control? Please describe the randomization and allocation process more thoroughly?

2. Please describe more about the intervention being delivered through the app? It is not clear to the readers as what kind of information is being delivered to women by mhealth app? can you please describe the intervention more clearly?

3. Can you explain about KEPT-app (line 41) ? You used two terms of mHealth app and KEPT-app? Are they the same? or different? Can you please provide a clear description about the various names

and abbreviations are used throughout your study?
4. It would be beneficial for the readers if you provide a list of abbreviations with their definitions at the end of your papers
5. How long is the duration of intervention? Can you please describe it clearly?
6. How do you follow up women? This is not clear from the text.
7. Line 37. "Each primary care clinic will be randomized to either .....". This paragraph is not clear. Why 16 weeks? You start the intervention at 28 weeks. By 36 weeks gestation, there will be less than 10 weeks time. What do you mean by 16 weeks and 22 weeks? where is your start point? When exactly the recruitment will start and how long is the duration of study?
8. At which time points do you measure the several outcomes of the study? This is not well described in the text.
9. Line 28. table 2. What being Malaysian involve? what ethnicities are considered Malaysian? Will all pregnant women (Primiparous or multiparous) be included in the study?

10. The sample size estimation. You can add the formula you used for the estimation of sample size here. What baseline information on either the primary or secondary outcomes have you used to calculate the sample size?. What do you mean by secondary care/primary care in the estimation of sample size?

11. Line 55. Quantitative analysis: How do you assess the effect of time? How do you consider the intention to treat analysis?

- The methodology section has addressed all the enquiries and suggestions by the reviewer. The information has been followed according to the CONSORT 2010, extension pragmatic and extension cluster trials (Supplementary 1)

VERSION 2 – REVIEW

REVIEWER	Sahar Sobhgol Western Sydney University Australia
REVIEW RETURNED	03-Nov-2020

GENERAL COMMENTS	Thank you for your effort to address the previous comments. I think the total describtion of the study has been improved. This study is mainly looking at the efficacy of an online application to promot pelvic exercise training. About the seondary objective of your study which is the measurement of adherence rate, do you have any plan to measure adherence during pregnancy as well? How do you measure self-efficacy? You already mentioned that you use a questionnaire. However, dose it give you accurate information? You can describe these as two limitations of your study since they are the secondary objectives of the study.

VERSION 2 – AUTHOR RESPONSE

Thank you for allowing us to submit a revised draft of the manuscript "KEPT-app trial- a pragmatic, single-blind, parallel, cluster-randomised effectiveness study of pelvic floor muscle training among incontinent pregnant women: study protocol" for publication in the BMJ Open Journal.

We appreciate your time and effort dedicated to providing feedback and are thankful for the insightful comments on our manuscript to improve the quality of our paper. We have included all the suggestions, and the changes are highlighted within the manuscript.

1. About the secondary objective of your study which is the measurement of adherence rate, do you have any plan to measure adherence during pregnancy as well?

Yes, Prof. Thank you for this comment.

KEPT-app will record the exercise activities during the study period to capture the actual adherence rate with a reminder occurring on the screen if no activities are recorded. Page 16, Second paragraph, Line 3-5.

2. How do you measure self-efficacy? You already mentioned that you use a questionnaire. However, does it give you accurate information?

Thank you, Prof, for this suggestion. We add this as the study limitation.

The self-efficacy assessment will be done via a validated questionnaire without any objective assessment, which may not provide accurate results. Page 5, last line

3. We added one statement to highlight the reminder will be given to study participants a week before data collection to improve the response rate during data collections.

All data will be collected digitally via mobile apps and google documents *(with a reminder a week before the data collection's date)* and will be kept in data storage.
Page 21, First paragraph, Line 1-2.