

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)	Effect of exercise on symptoms of premenstrual syndrome in low and middle-income countries: a protocol for systematic review and meta-analysis
AUTHORS	Pokharel, Pratik; Rana, Jewel; Moutchia, Jude; Uchai, Shreeshti; Kerri, Aldiona; Luna Gutiérrez, Patricia; Islam, Rakibul

VERSION 1 - REVIEW

REVIEWER	AHMED ASHOUR Department of Obstetrics and Gynecology, Faculty of Medicine, Cairo University, Cairo, Egypt.
REVIEW RETURNED	15-May-2020

GENERAL COMMENTS	<p>Dear editor Thank you for giving me the opportunity to review this protocol. I see that the protocol is well designed, organized, covers most of the aspects needed for the study question. However, I have some comments and queries listed below.</p> <p>INTRODUCTION</p> <ul style="list-style-type: none"> • Line 29: secretory phase instead of secretion phase • I would recommend more recent references regarding the incidence and prevalence of PMS • A recently published systematic review addressed the effect of exercise on PMS"reference; Saglam HY, Orsal O. Effect of exercise on premenstrual symptoms: A systematic review. Complementary Therapies in Medicine. 2020 Jan 1;48:102272. doi: 10.1016/j.ctim.2019.102272." What your study will add to the literature? <p>Methods</p> <p>Page 5 line 5; who meet either the screening or diagnosis criteria for PMS. Diagnostic instead of diagnosis. And could you detail the diagnostic or screening criteria for PMS?</p> <p>Page 5 line 8-11; you stated that PMS is related to menstruation in the introduction while you stated that you will exclude studies in postmenopausal and pregnant women where no menses normally occur. Could you explain this.</p> <p>Page 5 line 8-11; why you will exclude studies in women with psychiatric disorders and chronic diseases like breast cancer and diabetes.</p> <p>Page 5 line 15; on what basis will you categories countries as low, middle- or high-income countries. Please explain.</p> <p>Page 5 line 23; could you detail the types of exercises that you will</p>
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	<p>include in your systematic review? Page 5 line 55; what is meant by the accrued score for physical, behavioral, emotional or psychological symptom??? Will you consider the quality of life in your secondary outcomes?? Page 6, study design, why you will include non-randomized controlled trials in your review? Page 6 line 21; I would recommend that you also search in clinical trial registries as clinicaltrial.gov. Page 8; could you explain the I2 statistics in more detail.</p> <p>Thank you</p>
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REVIEWER	Lee P. Shulman Northwestern Medicine, Chicago, IL, USA
REVIEW RETURNED	25-Jun-2020

GENERAL COMMENTS	Having written and peer-reviewed review articles over the past 30 years, I do not see the need to publish a separate paper on HOW to perform a review of a clinical intervention WITHOUT providing any outcome data. The authors can provide a detailed overview of their approach to evaluating the clinical data on the effect of exercise on PMS symptoms when they present their findings.
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REVIEWER	Hava YESILDERE SAGLAM Eskisehir Omangaz University
REVIEW RETURNED	17-Jul-2020

GENERAL COMMENTS	I would like to thank the authors for addressing such a topic and their protocol. I would like to point out that the literature is not sufficient in this regard and is a field that needs to be filled in a lot. The impact of exercise on premenstrual symptoms should be assessed based on evidence, and guidance should be available for further studies. I wish you success in your work.
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1 comments:

Thank you for giving me the opportunity to review this protocol. I see that the protocol is well designed, organized, covers most of the aspects needed for the study question. However, I have some comments and queries listed below.

Authors Response: Thank you for your detailed and constructive comments.

INTRODUCTION

- Line 29: secretory phase instead of secretion phase

Authors Response: Line 29; we have changed “secretion phase” to “secretory phase”.

- I would recommend more recent references regarding the incidence and prevalence of PMS

Authors Response: Recent references on prevalence of PMS have been added and old references removed. Added references with appropriate reference number:

2. Chumpalova P, Iakimova R, Stoimenova-Popova M, Aptalidis D, Pandova M, Stoyanova M, Fountoulakis KN. Prevalence and clinical picture of premenstrual syndrome in females from Bulgaria. *Annals of general psychiatry*. 2020 Dec 1;19(1):3.
3. Ranjbaran M, Samani RO, Almasi-Hashiani A, Matourypour P, Moini A. Prevalence of premenstrual syndrome in Iran: A systematic review and meta-analysis. *International Journal of Reproductive BioMedicine*. 2017 Nov;15(11):679.

- A recently published systematic review addressed the effect of exercise on PMS"reference; Saglam HY, Orsal O. Effect of exercise on premenstrual symptoms: A systematic review. *Complementary Therapies in Medicine*. 2020 Jan 1;48:102272. doi: 10.1016/j.ctim.2019.102272." What your study will add to the literature?

Authors Response: The study by Saglam HY, Orsal O, 2020, did a limited literature search, as they did not include Medline, Embase or CENTRAL, which most likely to miss some relevant studies. Secondly, the authors did not conduct meta-analyses rather they have summarised the effect of exercise on PMS separately what had been reported in each included study. Adding to the literature compared to Saglam HY, Orsal O, our study will provide an overall pooled estimate through meta-analysis (if not too heterogenous) and will try to explain the heterogeneity by subgroup and/or sensitivity analysis. Hence, our study will provide a plausible estimate of effect which is lacking in the literature. Also, our study will include recent studies published until March 2020.

Methods

Page 5 line 5; who meet either the screening or diagnosis criteria for PMS. Diagnostic instead of diagnosis. And could you detail the diagnostic or screening criteria for PMS?

Authors Response: Page 5 line 5; We edited "diagnosis criteria" to "diagnostic criteria". We also added "Validated symptom screening tool such as Premenstrual Symptoms Screening Tool (PSST) or established diagnostic tool such as DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition) should have been used for inclusion."

Page 5 line 8-11; you stated that PMS is related to menstruation in the introduction while you stated that you will exclude studies in postmenopausal and pregnant women where no menses normally occur. Could you explain this.

Authors Response: Page 5 line 8-11; We edited the statement to "We will exclude studies that included women who are either pregnant or of non-reproductive age." We omitted the statement regarding postmenopausal due to absence of menstruation course in them as PMS is entirely related to menstruating women.

Page 5 line 8-11; why you will exclude studies in women with psychiatric disorders and chronic diseases like breast cancer and diabetes.

Authors Response: Page 5 line 8-11; Statement of exclusion of women with psychiatric disorders and chronic diseases like breast cancer and diabetes is edited to "We will also exclude studies on

reproductive-aged women with psychiatric disorders and chronic diseases like breast cancer and diabetes to reduce misclassification of symptoms due to other causes except PMS.”

Page 5 line 15; on what basis will you categories countries as low, middle- or high-income countries. Please explain.

Authors Response: Page 5 line 15; We added country classification with reference as “Countries will be classified as low, middle- or high-income according to World Bank’s classification criteria.”

Page 5 line 23; could you detail the types of exercises that you will include in your systematic review?

Authors Response: Page 5 line 23; We will include all types of exercises. We added a line as “Hence, no limitation will be applied for exercise type.”

Page 5 line 55; what is meant by the accrued score for physical, behavioral, emotional or psychological symptom??? Will you consider the quality of life in your secondary outcomes??

Authors Response: Page 5 line 55; We have changed “accrued score” to “accumulated score”. This is the summed-up scores for PMS symptoms as measured by screening tool or questionnaire. We included “Quality of Life (QoL) score” as the secondary outcome.

Page 6, study design, why you will include non-randomized controlled trials in your review?

Authors Response: Page 6, The findings of non-randomized studies might differ from randomized ones. We want to use all the evidences and provide careful recommendations for clinicians as well as for future studies.

Page 6 line 21; I would recommend that you also search in clinical trial registries as clinicaltrials.gov.

Authors Response: Page 6 line 21; We added the database “ClinicalTrials.gov” in our search strategy. It is updated in abstract as well. As of now, we have already selected studies and have begun data extraction, we will embed the search from this database.

Page 8; could you explain the I2 statistics in more detail.

Authors Response: Page 8; We added explanation to I2 statistic as “Statistical heterogeneity will be tested using the I2 statistic, to quantify discrepancy across studies. I2 statistic of 75% and more indicates significant heterogeneity between studies.”

Reviewer 2 comments:

Having written and peer-reviewed review articles over the past 30 years, I do not see the need to publish a separate paper on HOW to perform a review of a clinical intervention WITHOUT providing any outcome data. The authors can provide a detailed overview of their approach to evaluating the clinical data on the effect of exercise on PMS symptoms when they present their findings.

Authors Response: Thank you for this comment but we respectfully disagree with the reviewer. Lack of reproducibility in medical research has become an important issue in recent years. One approach to deal with this issue is to require “open data”. This approach can increase data availability, re-use and

re-analyses; maximize reproducibility, transparency, and collaboration; and minimize duplication, bias, and waste in medical research¹.

Hence, we think that a published protocol enhances research transparency and helps prevent duplication. It also demonstrates that the methodology has been carefully developed and peer reviewed. It should help replicate reviews on similar subjects of relevance and need. We plan to provide a limited overview of our approach to evaluate the data in the final review and this will make the review paper less cumbersome.

1. Wallach JD, Boyack KW and Ioannidis JPA. Reproducible research practices, transparency, and open access data in the biomedical literature, 2015-2017. PLoS Biol. 2018;16:e2006930.

Reviewer 3 comments:

I would like to thank the authors for addressing such a topic and their protocol. I would like to point out that the literature is not sufficient in this regard and is a field that needs to be filled in a lot. The impact of exercise on premenstrual symptoms should be assessed based on evidence, and guidance should be available for further studies.

I wish you success in your work.

Authors Response: Thank you for the appreciation and vital suggestion. We plan to draw conclusion carefully based on our findings and hence guide possibilities for further studies on exercise and PMS.