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OPEN PEER REVIEW

The Effect of *Pimpinella anisum* on Treatment and Recurrence of Menopausal Hot Flashes: A Randomized, Controlled, Multicenter, Double-Blind, Parallel-Group Clinical Trial

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About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

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1 Original submission

2 comments · 6 Nov 2021 – 23 Nov 2021

Referee 1 Reviewer

MINOR REVISION 6 Nov 2021

The authors performed a double-blind clinical comparison between Pimpinella anisum L. and placebo administered to menopausal patients with hot flashes for 2 weeks. They obtained significantly better results for the frequency and severity of menopausal hot flash symptoms with Pimpinella anisum L. than with placebo. However, some observations need to be made.
Minor comments:
1- As the aniseeds were purchased from herb shops in Tehran, the researchers should report the results of macroscopic and microscopic examinations conducted by a botanist, including authentication samples or a Herbarium Voucher Number.

2- Whereas patients had the opportunity to open the capsules and smell the contents, how did the researchers mask the smell of Anise extract to maintain blinding throughout the complete clinical trial?

3- Which randomization and allocation concealment method was used to divide 72 patients into two groups in this study?

Associate Editor

MAJOR REVISION 23 Nov 2021

Major Revision

2

Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Dear reviewer

Thanx for your valuable comments.

1- The intensity of hot flashes was measured by visual analog scale and the frequency and was recorded in a checklist. This scale was divided to 10 sections from 1 to 10 which demonstrate the intensity of pain or problem, 1 is for the the minimum and 10 shows the maximum intensity. The instrument was explain in line 109 in method section.
2- Written informed concept form was used in this study for participants and mentioned in line 91.
3- The researcher has used questionnaires (VAS and Demographic questionnaire) and check lists(for evaluation the activity which affect to hot flashes such as food, air temperature, physical activity ,… and a checklist for number of hot flashes). These instruments were well described in line 104-114.however i attach the files to journal website for more information.
4- The plant capsules and plcebo were coded by a fellow pharmacist such that neither the researcher nor the participants were aware of the capsule contents. Standardized was not done in this study. this process is costly and time consuming and should be done in separate project.
5- Statistical edition was done on line 142-145
6- I will attach the consort diagram in separate section. Because this large table change the form of my manuscript, beside many journals don't include this flow chart in main article. How ever if you insist on this, I will added the chart to main article.
7- I mention the citation (refrences) in line 162-177. I should say that citation was disappear in PDF format, not in word.

Dear reviewer 2

Thanx for your valuable comments.

1- I add the herbarium code of annisum in pharmacology department in the tex. The herbarium code is SBMU-8207
2- All medicines (anisum and placebo) were held together for two weeks in terms of not having distinctive odor. We mention women's not manipulate and open the capsules especially in hygienic consideration.
3- Sampling method was available and purposive so that from all household files in health centers under the auspices of selected health centers of Shahid Beheshti University of Medical Sciences, postmenopausal women were selected and invited to health centers. They were invited to participate in the research. Then according to inclusion and exclusion criteria's the participants were identified and allocated randomly(Table of random

numbers based on computer random sequence) in to two groups. This paragraph was added and highlighted in manuscript.

2 Revision 1

0 comments

No public comments in this round.