Author’s response to reviews

Title: Investigating the effect of vitamin D vaginal suppository on sexual function among postmenopausal women: Study Protocol for a Randomized Controlled Trial

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Dear Editor

Thanks for comments. The revised version of manuscript is prepared as below:

1. Page 4, paragraph 3: “Vulvovaginal atrophy is characterized by vaginal changes, dyspareunia, itching, and asthma.” Please clarify and revise this sentence to remove the reference to asthma. Reply: Revised as commented

Vulvovaginal atrophy lead to vaginal dryness, irritation, soreness, and consequently dyspareunia

2. Please explain the blinding for the ‘no intervention group’ further, Reply: section is revised as below:

Blinding
Due to having a control group which receives no intervention, blinding cannot be performed for all groups. But in try to blind intervention and placebo controlled group, vitamin suppositories and placebo suppositories will have the same color and shape and will coded as A and B by a pharmacologist not involved in the research team. The researchers will receive the suppositories with codes and will not know what A and B stands for with respect to the suppositories. Finally, after collecting questionnaires and analyzing data using SPSS version 25 software, the codes that belong to the groups will be determined.

and provide more detail on the recruitment of participants for this study (how participants were contacted). Reply: some explanation is added as below:

Recruitment

To recruit the participants, eligible individuals will be selected on the basis of information in the health records of the comprehensive health centers in the city of Buin Zahra. A total of 105 eligible individuals will be invited to participate in the study. After screening the eligible individuals based on their health records, they will be called and invited for a visit in their comprehensive health care center. When they come for the screening visit, they will interviewed to assess eligibility criteria, introducing the project, its’ aim, their autonomy to participate in the study, confidentiality and anonymity of collected data. After signing the written consent, they will be randomized to study groups.

3. Please provide a list of participating centres for the study. Reply: some explanation is added as below:

Eligible participants from twenty five urban and rural comprehensive health center affiliated to abovementioned four districts of Buin Zahra will be included in this study.

4. Please include the expected effect size and power with the sample size calculation. Reply: some explanation is added as below:
According to previous study by Çayan et al. (32), considering $\alpha=0.05$, power=80%, moderate effect size of 0.6, the sample size for the research study was estimated to be 25 people for each group. Considering the attritional loss of 40% of the samples in the research process, the sample size for each group was calculated to be 35 people. The sample size calculation was performed according to primary outcome of study.

5. Please correct the city name ‘Boyin Zahra’ to ‘Buin Zahra’. Reply: Revised as commented