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OPEN PEER REVIEW

The Effect of Vitamin D Cream on the Severity of Pregnancy Striae in the Thigh Region of First-Time Pregnant Women: A Triple Blind Randomized 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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Contents

1 **Original submission** Referee 1, Editor-in-Chief 3

2 **Revision 1** Referee 1 4

Authors' reply to reviewers 5

Reviewer and editor comments 8

3 **Revision 2** Referee 1 9

Authors' reply to reviewers 10

Reviewer and editor comments 13

4 **Revision 3** Referee 1 14

Authors' reply to reviewers 15

Reviewer and editor comments 16

5 **Revision 4** Referee 1 17

Authors' reply to reviewers 18

Reviewer and editor comments 20

6 **Revision 5** Referee 1, Associate Editor, Editor-in-Chief 21

Authors' reply to reviewers 22

Reviewer and editor comments 23

7 **Revision 6** 24

Authors' reply to reviewers 25

Reviewer and editor comments 26

1 Original submission

2 comments · 9 Jun 2024 – 10 Jun 2024

Referee 1 Reviewer

MAJOR REVISION 9 Jun 2024

This manuscript is about the prevention of striae gravidarum, a concern for pregnant women, with vitamin D cream, so the topic is important. However, it needs scientific revision as well as English editing by an expert. Unfortunately, there are many errors in English structure and grammar that make it difficult to understand the meaning of the sentences. I had to correct some sentences using Track Changes to make them easier to understand. Please confirm the corrections by clicking the Accept icon in the Word file. Moreover, there are some concerns about the methodology. For example, it is not clear why the researcher did not assess the striae at follow-up visits and asked the participants to do it. This might lead to bias. On the other hand, there is no control group, and the oil components of the placebo might affect the results. More comments are available in the attached file.

Editor-in-Chief

MAJOR REVISION 10 Jun 2024

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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 Reviewers,

Thank you for your valuable feedback on our paper submitted to the Journal of Nursing and Midwifery Sciences. We appreciate the time and effort you have taken to review our work.

We have carefully considered all of your comments and have made the necessary corrections to address each point raised. We have revised the manuscript accordingly to improve the clarity and quality of the content.

We believe that your constructive criticism has been instrumental in enhancing the overall quality of our paper. Thank you once again for your thorough review and we look forward to hearing your feedback on the revised version.

The followings are: the revision and answers to the reviewers:

Sincerely,

M.Kh.
[2024/07/25]

comment 1: (If it was a triple blind, so add it here). add it and was highlighted in line 2

comment 2: (There are various grammar errors in your manuscript Edit your manuscript by an English specialist). the text was revised due to your suggestion.

comment 3 & 4: (Methods is too long Summarize all parts of the abstract Follow the journal instruction for abstract regarding its word count / Add Iran). the text was revised due to your suggestion and was highlighted in the method section (line 14 – 23)

comment 5: (You can summarize this section as: At fourth, eighth, twelfth and sixteenth weeks, the incidence of striae was …, …, .., .. without striae and …, … .. … moderate erythema, respectively in the vitamin D group and …… and …… respectively in the placebo group). the text was revised due to your suggestion and was highlighted in the findings section (line 25-31)

comment 6: (Needs revision. It is not a relevant conclusion). the text was revised due to your suggestion and was highlighted in the conclusion section (line 33-36)

comment 7: (Revise according to MeSH). the text was revised due to your suggestion and was highlighted in the keywords section (line 39)

comment 8,9 & 10: (It is better put this part in the first paragraph /The references in the text are not according to this journal instruction.Moreover, definition of striae gravidarum needs to an original reference such as text books and the mentioned references are not proper / On development or prevention of development). the text was revised due to your suggestion in the background section (line 46-99)

comment 11: (The justification for conducting this study is not strongly written. Write the need to this study based on the lack or inconsistency of information). the text was revised due to your suggestion in the objectives section (line 101-102)

comment 12,13&14: (The titles were not written according to this journal. It is better to have subheadings and write this section structured/ It is not clear in the method section that who were blind/ Having stretch marks before the study was not considered). the text was revised due to your suggestion in the methods section (line 105-123)

comment 15, 16 & 17: (Do you have a reference?/ It is vague. How did you find s1 and s2? Are they equal? How much is d and what is it, the difference between the means?/ Explain drop of sample size at the beginning of the result section). the text was revised due to your suggestion in the sample size section and The standard deviation values were obtained based on the relevant article cited. (line 127-143)

comment 18:(Usually, drug manufacturing is accompanied by control. Considering that your samples were human and pregnant women, was the drug controlled by the Food and Drug Organization after manufacturing? If the answer is yes, it is suggested that to mention this in the article by mentioning the documentation). add it and was highlighted in Intervention section (line 154-156)

comment 19: (Explain how informed consent was taken?) add it and was highlighted in Intervention section (line 164-167)

comment 20: (Did the researcher who investigated the effectiveness of the cream have the relevant expertise? Or passed a special course? If the answer is yes, it is recommended to mention it). add it and was highlighted in Intervention section (line 173-174)

comment 21: (It is vague. You visited women Four times, why you did not evaluate the severity of striae yourself? The first assessment was done by researcher, why follow-up assessments was done by women? How did you rule-out the bias between observers? How many times and when they were asked to record the severity of striae?) add it and was highlighted in measurement section.

comment 22 & 23: (How the consumption of creams was examined?/ By who?) add it and was highlighted in Intervention section (line 180-183) / add it (line 191)

comment 24: (Insert this part after sampling method. Moreover, explain demographic checklist or questionnaire and validity and reliability indexes, scoring and interpretation of it for stretch marks assessment tool and its Persian version). the text was revised due to your suggestion in the Outcome Measurement section. (line 205-217)

comment 25: (Use the latest format of consort for reporting). the consort was revised due to your suggestion in the figure 1

comment 26 to 33: (Integrate table1 & 2/ Needs to complete as: Demographic characteristics of pregnant women in vitamin D and placebo groups/ According to English format, you must report as Number (percentage)/ It is not according to English format. Correct all numbers in the tables./ It is not clear. You reported data as frequency and compared with t test. So, delete frequencies and only report as mean and SD/ Report also “t /It is better insert a symbol on p value and write the test at the footnote of the tables./ correct as the comment for age./ Write as super script: X^2). the table was revised due to your suggestion in the table 1.

Comment 34: (It is vague this is related to chi square test or Mann-Whitney. Compare the severity either by mean or frequency, but not with both of them). the table was revised due to your suggestion in the table 2.

Comment 35: (The discussion needs to a serious revision according to the comments.Delete all authors’ names in this section only write where the studies were done.Most of studies compared were done in Iranian population. Because of the effect of ethnicity on the results, it is recommended to compare with similar

studies in other populations. moreover, because the enlargement of the abdomen during pregnancy can be considered as an effective factor on striae, discussion about observing different results based on the treated area will be useful). There were very few studies regarding the severity of striae, and all studies examined the incidence and number of striae. Also, in all the published studies, the examined area was the abdomen, and there were no studies related to the thigh area in pregnant women. And the text was revised due to your suggestion in the Discussion section.

Comment 36 & 37: (In which area?/ Reference?). the text was revised due to your suggestion in the Discussion section. (line 299-300)

Comment 38: (It is vague. In which study sesame oil was used?) the text was revised due to your suggestion in the Discussion section. (line 303-304)

Comment 39 & 40: (In which area?/ How long after starting the intervention?) the text was revised due to your suggestion in the Discussion section. (line 305-312)

Comment 41: (The references should be written according to the journal instruction for authors Use reference manager softwares such as EndNote to insert the references Some references are old. Replace with the newest records. Use standard abbreviation for name of journals according to NLM). the references was revised due to your suggestion (line 376-459).

2 Revision 1

1 comment · 5 Aug 2024

Referee 1 Reviewer

MINOR REVISION 5 Aug 2024

Thanks for considering the comments. Some more corrections are needed, as well as English language revision.

3

Revision 2

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 Reviewers,

Thank you for your valuable feedback on our paper submitted to the Journal of Nursing and Midwifery Sciences. We appreciate the time and effort you have taken to review our work.

We have carefully considered all of your comments and have made the necessary corrections to address each point raised. We have revised the manuscript accordingly to improve the clarity and quality of the content.

We believe that your constructive criticism has been instrumental in enhancing the overall quality of our paper. Thank you once again for your thorough review and we look forward to hearing your feedback on the revised version.

The followings are: the revision and answers to the reviewers:

Sincerely,

M.Kh.
[2024/16/08]

comment 1: (Delete.). the text deleted.

comment 2: (Striae Distensae ?). Its Striae gravidarum (line)

comment 3 & 4: (Delete). the text deleted.

comment 5 & 6: (Dear author, you must use the main references for each claim not the references which reported others' findings. It means the readers can find that result in the mentioned reference / As I said before, it is better refer to a text book such as Williams' obstetrics instead of reference 2for these two sentences). the text was revised due to your suggestion and was highlighted (line 42-44)

comment 7: (Delete reference 7). deleted

comment 8: (Insert main reference.). added it and was highlighted (line 52)

comment 9: (Reference 8 and 9 have the same title, authors and journal name, are they different? Moreover, reference 9 is not proper for this sentence.). the text was revised due to your suggestion in the background and refrences section.

comment 10 & 11: (Insert more references/ Needs references). Added (line 77 and 94)

comment 12,13&14: (Delete / Clinical trial/Delete. It was mentioned in another section.). the text deleted / edited line 107/ the text deleted.

comment 15: (It is vague, you referred to a cross-sectional study for choosing d and S indexes! I could not also find respond to previous comment, why are S1 & S2 equal? Please clarify). The standard deviation values were obtained based on the relevant article cited no 27.

comment 16:(put in the intervention section.). add it and was highlighted in Intervention section (line 156-157)

comment 17: (Omit here and explain in the beginning of the result section.) add it and was highlighted in result section (line 261-262)

comment 18: (Delete. It was repeated in the intervention section.). the text deleted

comment 19: (They were included in the personal questionnaire, so delete.) the text deleted

comment 20: (Put in the ethics section.) add it and was highlighted in ethics section (line 249-251)

comment 21: (Needs editing). the text was revised due to your suggestion. (line 177-178)

comment 22&23: (Having stretch marks before the intervention was an exclusion criterion, did not you exclude them?/ It is not clear. How much was the intervals of assessing severity of lesions by mothers? Every day, every week, or ….?) the text was revised due to your suggestion. (line 180-182)

comment 24: (Omit and change to “in these times”). the text was revised due to your suggestion. (line 186)

Comment 25&26: (What do you mean?/ mother's weight before and after the intervention). the text was changed (line 206-207)

Comment 27: (This paragraph needs revision it has not been written perfect. Each tools including Atwal scale and mothers’ checklist need to explain separately. Please mention clearly validity and reliability for Atwal striae gravidarum score. How did you report the severity of striae according to this tool (It seems, you did not consider scoring and just report its quality). the text was revised due to your suggestion in the outcome measurement section. (line 211-222)

Comment 28: (Mention in the ethics section.). the text was revised due to your suggestion in the ethics section. (line 249-251)

Comment 29: (All frequencies must be reported both absolute and relative.) the text was revised due to your suggestion. (line 239-241)

Comment 30,31&32: (Delete/It was shown in the diagram, so omit this sentence.) the texts deleted.

Comment 33: (It is vague). the text changed (line 267-268).

Comment 34: (Put scale). Added (line 270).

Comment 35: (In allocation stage, it is not clear why some mothers did not receive intervention. In this stage all participants must receive intervention and if they do not continue the study, you can report it in the follow-up stage.In the follow up section, show total number of mothers who continued and discontinued the study.) the diagram was changed. Figure 1.

Comment 36, 37, 38,39,40&41:(Change to Demographic and obstetrics characteristics of pregnant women in vitamin D and placebo groups/ And obstetrics/ All percentages must be written as number (percentage)/ You must type p values and related statistics for qualitative and quantitative variables for age in two separate rows/ Put its scale in parentheses / Divid to two rows according the comment for age). The table 1 was revised due to your suggestion.

Comment 42: (it needs explanation in the method section that how the skin color was determined.). Based on the Fitzpatrick scale to identify the skin type out of 6 categories, we chose three general categories of skin types: white, wheatish, and brown, with the opinion of a dermatologist.(added line 122-124).

Comment 43 & 44:(It is not a correct term for skin color/ It is not a correct term for skin color). Edited in table 1

Comment 45, 46 & 47: (Correct the order/ Correct as number (percentage)/ Divide this column to two rows and put these statistics in front of mean rows, because it is not right for frequency). The table 1 was revised due to your suggestion.

Comment 48: (All percentiles are vague. It needs two number to show 25th and 75th percentiles). Since the dispersion of the data is low, the values of the first and third quartiles are obtained as follows.

Comment 49: (Correct as (table 2)). Corrected line 316.

Comment 50 & 51 : (If there are not other scores according to Atwal scale, please mention it./ omit) the text was revised due to your suggestion. (line 317-318) / omitted.

Comment 52: (it is not usual to write the title, so it is better to write a study compared the effect of ……). the text was revised due to your suggestion. (line 330-334).

Comment 53: (Furthermore, they did not compare with placebo.). They compare with placebo.(Edited. Line 330-334)

Comment 54: (delete). the text deleted.

Comment 55: (if they had not a placebo group, it is another difference with this study. Because control group is different with placebo. Placebo in your study included an oil component that could be effective on striae and leads to no significant difference between the groups.) They had placebo group and added in the text (line 350-354).

Comment 56: (the affected area). the text was revised due to your suggestion. (line 355)

Comment 57: (As I explain before, you cannot conclude this. It is better to say adding vit D to oil base cream can not increase its effect on striae.). the text was revised due to your suggestion. (line 368-369).

Comment 58: (Delete. it is not relevant.). the text deleted.

3 Revision 2

1 comment · 20 Aug 2024

Referee 1 Reviewer

MAJOR REVISION 20 Aug 2024

Unfortunately, the comment about revising references was not considered carefully. Many of the references, especially in the background section, were not used properly. For example, many sentences about the definition of the problem, its symptoms, prevalence, and pathology need references to descriptive studies or textbooks that directly support those claims. However, many of the references used are interventional or qualitative studies whose findings do not support the claims. So, further review will be done after all the requested corrections have been made.

4

Revision 3

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 Reviewers,

Thank you for your valuable feedback on our paper submitted to the Journal of Nursing and Midwifery Sciences. We appreciate the time and effort you have taken to review our work.

We have carefully considered all of your comments and have made the necessary corrections to address each point raised. We have revised the manuscript accordingly to improve the clarity and quality of the content.

We believe that your constructive criticism has been instrumental in enhancing the overall quality of our paper. Thank you once again for your thorough review and we look forward to hearing your feedback on the revised version.

The followings are: the revision and answers to the reviewers:

Sincerely,

M.Kh.
[2024/08/25]

Comment 1: (Unfortunately, the comment about revising references was not considered carefully. Many of references, especially in the background section were not used properly. For example, many sentences about definition of problem, its symptoms, prevalence and pathology need to references among descriptive studies or textbooks that directly found those claims. However, many references used are interventional or qualitative studies that the readers cannot find the claims in their findings. So, further review will be done after doing all the requested corrections.). References Edited.

4 Revision 3

1 comment · 1 Sep 2024

Referee 1 Reviewer

MAJOR REVISION 1 Sep 2024

Thanks for making some of the requested corrections; however, some of them were not adequately addressed. Furthermore, if this manuscript is not edited by an English expert, it will not be acceptable for publication in this journal.

5

Revision 4

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

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Dear Reviewers,

Thank you for your valuable feedback on our paper submitted to the Journal of Nursing and Midwifery Sciences. We appreciate the time and effort you have taken to review our work.

We have carefully considered all of your comments and have made the necessary corrections to address each point raised. We have revised the manuscript accordingly to improve the clarity and quality of the content.

We believe that your constructive criticism has been instrumental in enhancing the overall quality of our paper. Thank you once again for your thorough review and we look forward to hearing your feedback on the revised version.

The followings are: the revision and answers to the reviewers:

Sincerely,

M.Kh.
[2024/09/06]

Comment 1: (Insert references for this claim in front of it). Edited.

Comment 2: (d=6). Edited

Comment 3,4: (It is vague. How did mothers determine the severity of striae? Final analyze of striae severity was done based on the mothers' report or measurements by the researcher or both of them? / So make clear why did you want mothers also report the severity?!!!!). The analysis of striae severity was done based on the researcher's measurement, and the mothers only recorded the number of times they used the cream. It was edited in the text.

Comment 5: (This explanation must be insert in the following paragraph that Atwal tool was explained). Edited

Comment 6: (What do you mean by examination? Is it the gestational age when participant were enrolled in the study?). It means the gestational age at the times of examining the severity of striae.

Comment 7: (What about severity of striae that you mentioned previously?). It was corrected.

Comment 8: (All frequencies must be reported both absolute and relative). Edited

Comment 9: (From participants. English language of this manuscript is too weak). Edited

Comment 10: (Delete. the reasons were shown in the diagram). Deleted.

Comment 11: (At the last boxes (analyze}, make clear why some participants were excluded. Boxes in follow up stage also are not standard according to CONSORT diagram). It is specified in follow up section and This section has been edited based on the referee's opinion in the previous review.

Comment 12,13: (You reported t test for comparing the age, so delete the groups for age and only report the means). Edited.

Comment 14: (it needs explanation in the method section that how the skin color was determined). Added in Methods.

Comment 15: (It is not a correct term). Wheatish complexion is characterized by light brown skin, almost like the color of wheat.

Comment 16: (All of the p values must be placed in the below rows in front of mean ranks. This row must show comparison of severity based on chi-square or Fisher test not mann-Whitney). Since the severity was not normally distributed based on the Kolmogorov-Smirnov test, the non-parametric Mann-Whitney test was used for comparison.

Comment 17: (Since all percentiles are the same, and are not practical, it is suggested to omit all of them in the table). This section has been added based on the referee's opinion in the previous review.

Comment 18: (Why did you report this finding here?? It is not related to this sentence!!!!!). Deleted.

Comment 19: (if they had not a placebo group, it is another difference with this study. Because control group is different with placebo). They had placebo group.

5 Revision 4

1 comment · 4 Oct 2024

Referee 1 Reviewer

MINOR REVISION 4 Oct 2024

Thanks for responding to the comments. Some minor revision is needed.

6

Revision 5

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 Reviewers,

Thank you for your valuable feedback on our paper submitted to the Journal of Nursing and Midwifery Sciences. We appreciate the time and effort you have taken to review our work.

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We believe that your constructive criticism has been instrumental in enhancing the overall quality of our paper. Thank you once again for your thorough review and we look forward to hearing your feedback on the revised version.

The followings are: the revision and answers to the reviewers:

Sincerely,

M.Kh.
[2024/09/06]

Comment 1: (It is better to use a reference manager software, because the sequence of references numbers was not considered! I could not find reference 42!). Edited

Comment 2: (Make clear, to record what thing? Daily use of cream?). Edited

Comment 3: (Please Delete). Deleted.

Comment 4: (Do you mean Atwal tool was modified? Explain which items were modified and why). Demographic questionnaire and daily checklist were modified.

Comment 5: (Please report accuracy or validity indexes.). Edited

Comment 6: (There is no need to this explanation). Deleted.

Comment 7: (There are some vague points in this diagram. Since putting comments for the boxes is not possible, I had to changes some items, please confirm and delete or add red words.). Edited

Comment 8: (I could not find explanation in the method section about how you determined skin type). Based on the Fitzpatrick scale, in Section “Method” in page 3.

6 Revision 5

3 comments · 16 Oct 2024 – 19 Oct 2024

Referee 1 Reviewer

ACCEPT 16 Oct 2024

Thanks for responding to the comments. The Fitzpatrick scale needs a reference. The manuscript is acceptable after English language revision.

Associate Editor

MINOR REVISION 19 Oct 2024

Thanks for responding to the comments. The Fitzpatrick scale needs a reference. The manuscript is acceptable after English language revision.

Editor-in-Chief

MINOR REVISION 19 Oct 2024

Thanks for responding to the comments. The Fitzpatrick scale needs a reference. The manuscript is acceptable after English language revision.

7

Revision 6

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 Reviewers,

Thank you for your valuable feedback on our paper submitted to the Journal of Nursing and Midwifery Sciences. We appreciate the time and effort you have taken to review our work.

We have carefully considered all of your comments and have made the necessary corrections to address each point raised. We have revised the manuscript accordingly to improve the clarity and quality of the content.

We believe that your constructive criticism has been instrumental in enhancing the overall quality of our paper. Thank you once again for your thorough review and we look forward to hearing your feedback on the revised version.

The followings are: the revision and answers to the reviewers:

Sincerely,

M.Kh.
[2024/10/21]

Comment 1: (Fitzpatrick scale needs a reference). added

7 Revision 6

0 comments

No public comments in this round.