

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Structured supervised exercise training or motivational counselling during pregnancy on physical activity level and health of mother and offspring: FitMum Study Protocol
<b>AUTHORS</b>	Roland, Caroline; Knudsen, Signe; Alomairah, Saud; Andersen, Anne; Bendix, Jane; Clausen, Tine; Molsted, Stig; Jensen, AK; Teilmann, Grete; Jespersen, Astrid; Larsen, Jakob; Hall, Gerrit; Andersen, Emil; Barrès, Romain; Mortensen, Ole; Maindal, Helle; Tarnow, Lise; Løkkegaard, Ellen; Stallknecht, Bente

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Melanie Hayman CQUniversity
<b>REVIEW RETURNED</b>	21-Sep-2020

<b>GENERAL COMMENTS</b>	<p>Major Comments:</p> <p>The aims of this project are not supported by the data that will be included. There is no need to assess sleep or take blood samples for example if you are only interested in accessing the efficacy of a PA intervention on the level of PA as your main outcome. Further, there is also no need to assess partners if you are purely interested in looking at the efficacy of the intervention, which is not inclusive of partner. The secondary and additional outcomes do not add any value to answering the actual research question being "The FitMum study aims to explore strategies to increase PA during pregnancy among women with low PA. It will evaluate the efficacy of two separate exercise regimens."</p> <p>It is unclear what the two exercise regimens are? At present this protocol reads as a comparison of exercise v counselling</p> <p>To identify the true effect of the motivational counselling, you need to remove the technology, as evidence shows that this technology can motivate women to increase their activity. Thus, you will not know whether or not the counselling was effective at increasing the exercise behaviours of the participants in this group.</p> <p>If the guidelines recommend 30 mins of moderate intensity per week for associated health benefits, why are you asking women to participate in 180 (3 sessions x 60 minutes)?</p> <p>Also, if you are recruiting women who potentially participate in no PA into your intervention, it is unrealistic and unsafe to have them engage in 180 mins per week. There needs to be some sort of progression for these women if they will be considered eligible for this study.</p> <p>There is an assumption that all participants will have access to the internet in their home to complete the online sessions, yet this has not been recognised in the inclusion criteria.</p> <p>Minor comments:</p>
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	There are grammatical errors throughout. If accepted, these will need to be addressed.
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<b>REVIEWER</b>	Fernanda Surita University of Campinas, UNICAMP, Brazil
<b>REVIEW RETURNED</b>	27-Oct-2020

<b>GENERAL COMMENTS</b>	<p>Initially, I would like to thank you for the opportunity to review this manuscript. It is an interesting topic, in some points already much explored but there are new features that should be highlighted. The title is too long, I understand that this is because the name of the protocol, follow my suggestion below  “Structured supervised exercise training and motivational counselling during pregnancy on physical activity level and health of mother and offspring: FitMum Study Protocol”:</p> <p>Strengths and limitations of this study:</p> <ul style="list-style-type: none"> <li>• The efficacy of structured supervised exercise training and motivational counselling supported by health technology to improve physical activity and REDUCE weight gain of pregnant women is compared in a randomized controlled trial. - This is already well known, not a strength.</li> </ul> <p>As I read the summary, I wonder what this study will bring as a novelty, and I think that the primary and secondary results are already well studied and there is nothing new to be presented. However, “Additional outcomes: Complementary measures of PA; clinical and psychological health parameters in participant, partner, and offspring; analyses of blood, placenta and breast milk samples; process evaluation of interventions; personal understandings of PA” are the differential of this study. So I think that these results should be the most valued since the construction of the project.</p> <p>Another issue is that it is not easy to find 220 pregnant women within the inclusion criteria in a single center, in a country where the birth rate is low and that the participants do not miss follow-up until 1 year after birth.</p> <p>Thus, it is necessary to present data from the center on the number of new cases / month in the ANC, number of births / month and also an expected schedule of the study's feasibility and what will be its expected duration - I understand that this is a limitation of the study</p> <p>Introduction  “Insufficient PA during pregnancy is a global problem”- Only during pregnancy?  I think it is extremely important to point out that physical inactivity is not a problem of pregnancy, it is a worldwide problem. And bring the reflection that during pregnancy women are expected to be active, which should always be expected of the entire population. And be careful that the benefits of PA do not become an additional burden for women during a special phase of their life, which is pregnancy.</p> <p>Methods  They are very well described, with the whole quantitative and qualitative approach very well designed  I repeat that the additional results and also the related psychological aspects will be the great differential of this study.  I missed the criteria for discontinuing interventions, for example, premature rupture of the membranes, preeclampsia, restricted</p>
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	<p>fetal growth. This needs to be very well described in the study protocol.  These are my considerations.  Best</p>
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### VERSION 1 – AUTHOR RESPONSE

#### Reviewer 1

Comment: The aims of this project are not supported by the data that will be included. There is no need to assess sleep or take blood samples for example if you are only interested in accessing the efficacy of a PA intervention on the level of PA as your main outcome. Further, there is also no need to assess partners if you are purely interested in looking at the efficacy of the intervention, which is not inclusive of partner. The secondary and additional outcomes do not add any value to answering the actual research question being "The FitMum study aims to explore strategies to increase PA during pregnancy among women with low PA. It will evaluate the efficacy of two separate exercise regimens."

It is unclear what the two exercise regimens are?

Response: Thank you for your comments. The FitMum study aims to explore strategies to increase physical activity (PA) during pregnancy among women with low PA and assess health effects of PA. The latter has now been added in the abstract (page 2, line 5&9). The primary and secondary outcomes are PA and gestational weight gain, respectively. In addition, the study has many exploratory outcomes, which we believe is a strength of the study. The new features of the exploratory outcomes are also mentioned by reviewer 2. The two exercise regimens are structured supervised exercise training (EXE) and motivational counselling supported by health technology (MOT).

Comment: At present this protocol reads as a comparison of exercise v counselling. To identify the true effect of the motivational counselling, you need to remove the technology, as evidence shows that this technology can motivate women to increase their activity. Thus, you will not know whether or not the counselling was effective at increasing the exercise behaviours of the participants in this group.

Response: We agree that technology tends to increase PA level as already mentioned in the discussion (page 14, line 15-16). We do not aim to identify the true effect of motivational counselling but rather to investigate the effect of counselling when supported by technology as described (page 8 line 1-3). Technology (Garmin Vivosport tracker) is used in all three groups to measure PA level, but the motivational counselling group extensively utilizes the tracker as part of the intervention. We have now mentioned your concern as a limitation of our study (page 14, line 12-14).

Comment: If the guidelines recommend 30 mins of moderate intensity per week for associated health benefits, why are you asking women to participate in 180 (3 sessions x 60 minutes)?

Response: The Danish Health Authorities recommend at least 30 minutes/day of moderate intensity PA for pregnant women, which sums up to at least 210 minutes/week. We advise the women in the two interventions groups to follow the authorities' recommendations. Therefore, women in both EXE and MOT are encouraged to be physically active on their own to reach the recommendations. This is now clarified on (page 7, line 12-13).

Comment: Also, if you are recruiting women who potentially participate in no PA into your intervention, it is unrealistic and unsafe to have them engage in 180 mins per week. There needs to be some sort of progression for these women if they will be considered eligible for this study.

Response: The interventions are based on the recommendations of the Danish Health Authorities for PA during pregnancy, which encourages all women to be physically active at least 30 minutes/day at moderate intensity when they become pregnant. In the structured supervised exercise intervention, the exercise is performed at moderate intensity and objective and subjective tools are used to monitor the intensity and that the women feel comfortable at all times. The health professionals ask the participants to slow down if they feel any pain and adjust the number of repetitions and the resistance of the exercise accordingly. Special attention is addressed at the newly recruited participants. We have now addressed this explicitly in the manuscript (page 7, line 24-26).

Comment: There is an assumption that all participants will have access to the internet in their home to complete the online sessions, yet this has not been recognised in the inclusion criteria.

Response: One of the inclusion criteria is to have a smartphone (page 5, line 28) and all smartphones have internet connection. Also, in Denmark the access to computer and internet by household is very high, more precisely 95% in 2020, according to the Danish Statistics Agency.

Minor comments: There are grammatical errors throughout. If accepted, these will need to be addressed.

Response: We are sorry and have now corrected errors throughout the manuscript.

Reviewer 2

Comment: Initially, I would like to thank you for the opportunity to review this manuscript. It is an interesting topic, in some points already much explored but there are new features that should be highlighted.

Response: Thank you for the encouraging comment.

Comment: The title is too long, I understand that this is because the name of the protocol, follow my suggestion below "Structured supervised exercise training and motivational counselling during pregnancy on physical activity level and health of mother and offspring: FitMum Study Protocol"

Response: We have now edited the title according to your valuable suggestion. We took the liberty of changing 'and' to 'or'.

Comment: Strengths and limitations of this study: The efficacy of structured supervised exercise training and motivational counselling supported by health technology to improve physical activity and REDUCE weight gain of pregnant women is compared in a randomized controlled trial. This is already well known, not a strength.

Response: We added "reduce" to the strength point (page 2, line 32). We agree that the effect of an exercise intervention on weight gain of pregnant women is already well known and not a strength of the present study. However, our aim, besides testing the efficacy of the two very different exercise interventions, is to directly COMPARE the interventions. Hence, we investigate how motivational counselling supported by health technology, which is still not well-explored, compares to structured supervised exercise training during pregnancy. It is now clarified that the two very different interventions are directly compared in a randomized controlled trial (page 2, line 33).

Comment: As I read the summary, I wonder what this study will bring as a novelty, and I think that the primary and secondary results are already well studied and there is nothing new to be presented.

However, “Additional outcomes: Complementary measures of PA; clinical and psychological health parameters in participant, partner, and offspring; analyses of blood, placenta and breast milk samples; process evaluation of interventions; personal understandings of PA” are the differential of this study. So I think that these results should be the most valued since the construction of the project.

Response: Thank you for this feedback and we tend to agree. However, we believe it to be novel that two very different exercise interventions for pregnant women are compared directly in a randomized controlled design. Also, few studies of pregnant women have measured physical activity level by objective methods and as extensively as in the present study (commercial activity trackers, doubly labelled water and questionnaire).

Comment: Another issue is that it is not easy to find 220 pregnant women within the inclusion criteria in a single center, in a country where the birth rate is low and that the participants do not miss follow-up until 1 year after birth. Thus, it is necessary to present data from the center on the number of new cases / month in the ANC, number of births / month and also an expected schedule of the study's feasibility and what will be its expected duration - I understand that this is a limitation of the study.”

Response: We acknowledge this point as recruitment of participants took longer than expected. However, we have now succeeded to recruit 220 pregnant women as the last participant was enrolled in October 2020. We have added this information on (page 12, line 32). We have also added that approximately 4,000 women per year give birth at the ANC (page 5, line 21-22).

Comment: Introduction: “Insufficient PA during pregnancy is a global problem”- Only during pregnancy? I think it is extremely important to point out that physical inactivity is not a problem of pregnancy, it is a worldwide problem. And bring the reflection that during pregnancy women are expected to be active, which should always be expected of the entire population. And be careful that the benefits of PA do not become an additional burden for women during a special phase of their life, which is pregnancy.

Response: We appreciate your comment and have edited the text in the introduction accordingly (page 4, line 13).

Comment: Methods: They are very well described, with the whole quantitative and qualitative approach very well designed. I repeat that the additional results and also the related psychological aspects will be the great differential of this study.

Response: Thank you.

Comment: I missed the criteria for discontinuing interventions, for example, premature rupture of the membranes, preeclampsia, restricted fetal growth. This needs to be very well described in the study protocol.

Response: We agree and have now clearly stated the discontinuation criteria (page 13, line 19-22).

#### VERSION 2 – REVIEW

<b>REVIEWER</b>	Fernanda Surita University of Campinas, Brazil
<b>REVIEW RETURNED</b>	17-Jan-2021
<b>GENERAL COMMENTS</b>	The study protocol is well written. All points under discussion by the reviewers were addressed.

	<p>My biggest concern was with the number of births at the study site, which I thought would make the proposal unfeasible, but the authors presented a number of births / year that surprised me, but it ends my doubts.</p>
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