Author’s response to reviews

Title: Effects of individualized follow-up with a smartphone-application after cardiac rehabilitation: protocol of a randomized controlled trial.

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Author’s response to reviews:

Dear Editor,

Thank you for allowing us to submit a revised version of our paper to BMC Sports Science, Medicine and Rehabilitation. We have read the comments from the reviewers with interest, taking into consideration all of their constructive criticisms and suggestions and revised the manuscript accordingly.

All comments are responded to in consecutive order. Additionally, changes in the manuscript are indicated in the text by using track changes. We have also made some additional changes that are described after the response to the reviewers.

We do hope that our revision is satisfactory.

Reviewer 1, Marlien Varnfield:

General comment: This paper describes the protocol of a RCT to evaluate the effects of individualized follow-up with a smartphone-application after cardiac rehabilitation. It has previously been shown that an expanded cardiac rehabilitation after acute myocardial infarction or coronary artery bypass grafting reduces cardiovascular morbidity and days at hospital for cardiovascular reasons and this proposed research is therefore very relevant and needed. The paper is well written and I only have very minor suggestions (mainly grammatical) as indicated below.

Comment 1: p3 lines 26-29: Apps can in that respect function as long-term support, AS POINTED AS NEEDED (rephrase this) in the latest European guidelines on cardiovascular disease prevention in clinical practice for behavior change.
Our response: Thank you for your comment. We have rephrased it: “In that respect, apps may meet the need for long-term support, highlighted as necessary in the latest European guidelines on cardiovascular disease prevention in clinical practice for behavior”

Comment 2: p3 lines 29-33: Despite the clear need of such an intervention, to our knowledge, it doesn’t exist any research evaluating individualized follow up through an app after completing CR. Might be better to say ...to our knowledge, no other studies have previously evaluated individualized follow up...

Our response: We have revised the manuscript as suggested. In addition, we have specified the sentence by adding time: “To our knowledge, no other studies have previously evaluated individualized follow-up with an app for one year after completing CR.”

Comment 3: p4 line 26: Participants will be recruited from two CR centers in THE eastern part of Norway

Our response: We have revised the manuscript as suggested: “Participants will be recruited from two CR centers in the eastern part of Norway.”

Comment 4: p4 line 38-39: they will get an appointment for baseline assessment at the time they are finished at CR. Suggestion: they will get an appointment for baseline assessment at the time they completed there CR program

Our response: We have revised the manuscript as suggested: “they will get an appointment for baseline assessment at the time they complete the CR program.”

Comment 5: p6 lines 21-24: In this connection, motivational interviews can be used to help individuals ACQUIRE motivation to change a particular behavior through collaboration, evocation, autonomy and exploration

Our response: We have revised the manuscript as suggested: “In this connection, motivational interviews can be used to help individuals acquire motivation to change a particular behavior through collaboration, evocation, autonomy and exploration”

General comment: A concern for the study is the possibility of missing data at the 12 month collection, but this is fully acknowledged by the authors with mitigation plan.

Reviewer 2, JA Snoek:

General comment: The paper describes a relevant problem in CV disease. Consolidating lifestyle habits requires continued attention and appropriate guidance. Long-term CR programmes can
assist patients with CV disease to implement long-lasting lifestyle changes. Concern: according to the trial registration the inclusion of the study already ended. This makes it more difficult to write an unprejudiced design paper.

Comment 1: Page 2 line 35-41 The Telerehab III study and TeleCaRe study evaluated also the effect of a long term individualised follow-up programme after CR. However the follow-up programme was less than 12 months.

Our response: Thank you for your comment. We are aware of both the Telerehab III study and the TeleCaRe study. Nevertheless, we do not find them comparable as Telerehab III evaluate the addition of Telemonitoring during CR with traditional CR and since the programme in both studies was less than 12 months. Additionally, we have not been able to find any published results from the TeleCaRe study. With your comment as background we have specified a sentence in the introduction as well. See our response on comment 2 from reviewer 1.

Comment 2: Page 3 line 18-20 The sentence "The benefit... patients directly" is not specific enough. What does the app do more than other direct contact? (face to face or telephone) Or is it meant directly after training? Please explain.

Our response: This sentence is claim of the general benefit of using an app. Whether the feedback is automated (built in the app with algorithms), chat, e-mail or phone call depends on how the app has been built. The specific part of the app that will be used in our study is mentioned under the method section.

Comment 3: Page 3 line 27-28 as pointed as needed? Or pointed out....

Our response: The sentence has been rephrased according to comment 1 by reviewer 1: “In that respect, apps may meet the need for long-term support, highlighted as necessary in the latest European guidelines on cardiovascular disease prevention in clinical practice for behavior”

Comment 4: Page 3 line 29-33 The Telecare study (design paper published in BMC cardiovascular disease) evaluated individualised follow-up after CR with an app on a smartphone for 6 months.

Our response: This sentence has been rephrased and specified according to suggestion from reviewer 1 comment 2: “To our knowledge, no other studies have previously evaluated individualized follow-up with an app for one year after completing CR.”

Comment 5: Page 3 line 46-50 multiple references to 1 article in three sentences seems excessive
Our response: Thank you for your comment. We have revised it so that reference only appear after first and last sentence.

Comment 6: Page 5 line 2 fixed or variable blocks?

Our response: The randomization was done by variable blocks. The sentence is revised as suggested: “Participants will be randomly assigned at a 1:1 ratio in variable blocks to the intervention group and the control group.”

Comment 7: Page 5 line 51-52 "The participant will decide when and how often reminders of the tasks should appear on their smartphone." What would be the minimum amount of reminders?

Our response: Thank you for your comment. We have added two short sentences to precisely explain this: “The participant will decide when and how often reminders of the tasks should appear on their smartphone. The lower limit of amount of reminders will be one reminder each week for each task. There will not be any upper limit.”

Comment 8: Page 7 paragraph with peak oxygen uptake: Will the test and re-test have the same protocol? It's not mentioned. Will the absolute (ml/min) or relative (ml/min/kg) oxygen uptake be used?

Our response: We appreciate your comment. The same protocol will be used at test and re-test. This was only mentioned under the paragraph about Endurance capacity. Now, we have added a sentence in the paragraph with peak oxygen uptake as well. “Two standardized protocols are drafted on a treadmill. The same treadmill protocol will be used at test and re-test.” Regarding absolute or relative VO2peak: We have tried to clarify in the paragraph with peak oxygen uptake, as a second sentence: “Relative VO2peak (ml/kg/min) will be the primary outcome and the absolute VO2peak (L/min) will be a secondary outcome.” Relative VO2peak will be used as primary outcome as this measure is established as an independent predictor for both risk of CVD and CVD mortality as well as all cause mortality.

Comment 9: Endurance capacity is, as described on page 7, a surrogate for peak oxygen uptake. Time to exhaustion, inclination and speed are directly related to oxygen uptake. Time to exhaustion at a submaximal level may say something about endurance capacity. Suggest to change.

Our response: Thank you for your valuable comment. We have discussed the term within the research group as well as with two sports physiologists. We totally agree that endurance capacity may appear as a surrogate for peak oxygen uptake. To be clearer about the physiological terms, we have changed the term to exercise performance. Additionally, we have specified the description of the term: “Exercise performance will be evaluated as time to exhaustion, peak
incline (%) and peak velocity (km/h) on the treadmill.” Based on this change, we have changed the rest of the manuscript where it was needed.

Comment 10: Page 8 line 36 “The same weight will be used at both measurement times’ It’s not clear for me what is meant. The same scale at both times? Or actually the weight of the first measurement during the second visit? This would not make sense to me.

Our response: Thank you for your comment which helped us to clarify. We have rephrased the whole paragraph: “Body weight will be measured prior to the CPET at both baseline and follow-up. The same equipment will be used to measure weight of the participants at pre and post-test. Participants will be weighed without shoes, wearing exercise clothes.”

Comment 11: Page 8 line 38 weighted or weighed?

Our response: We have rephrased the whole paragraph. See response to comment 10.

Comment 12: paragraph blood pressure This is quite brief. How many minutes did the patient sit before measurement was started? How many measurements? Both or one arm? Which protocol is used? ESC? Norwegian?

Our response: We have rephrased the paragraph: “The assessor of the primary outcome (blinded for group allocation) will also measure blood pressure prior to the CPET. Measurement will be done manually, preferably on the left arm. Participants will be sitting on a chair relaxing for 3-5 minutes before measurements will be done. Three measurements will be performed, of which the lowest measured value will be used.” This according to procedures at the CR centers involved.

Comment 13: page 9 sample size. The additional effect size in increase in VO2peak after CR is lower than during CR. Between group differences will probably be lower than expected. A sample size of 47 seems to be to low to detect differences between both groups.

Our response: We totally agree that using 1MET as the clinically meaningful difference in the sample size calculation may be a bit ambitious. However, as 1MET is the established value as mention under our response to comment 8, we found that this value was the most correct to use. Additionally, based on previous research, it would not be surprising if a difference of 1MET is reached as most of the literature shows that without intervention, post-CR patients’ VO2peak drops with 1-2.5 ml/kg/min.

Comment 14: Page 10 line 5-7 The sentence “According to our knowledge, there are no studies that evaluate the effect of long-term individualized follow-up through an app after completed CR on patient centered outcomes like the described study.” seems to be a iteration of the first sentence of the discussion.
Our response: Thank you for your response. We have deleted the sentence as we agree that it was an iteration of the first sentence. In order to connect the sentence in front and the sentence behind the deleted sentence, we have merged them to the following: “Additionally, by evaluating the impact of the intervention, we hope to contribute to fill the knowledge gap that has been addressed by previous research in the field 3, 6, 9, 12, 34, and it is reasonable to assume that the study may be groundbreaking.”

Additional corrections:

- The address of one of the authors affiliations has changed the last month. The affiliation is now updated according to this change. Can be seen on page 1 (title page) in track change document.

- Based on the change of the term “endurance capacity” pointed by reviewer 2, we have done corrections throughout the manuscript.

- Some language editing throughout the manuscript. Can best be seen in the revised manuscript with track changes.

All authors have participated in the work and have reviewed and agreed with the content of the manuscript. We appreciate your time and look forward to your response.

Yours sincerely,

Pernille Lunde