Author’s response to reviews

Title: Protocol for a feasibility randomised controlled trial of the use of Physical ACtivity monitors in an Exercise Referral Setting: The PACERS study.

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Author’s response to reviews:

Dear Editor,

I am pleased to enclose the revised version of the manuscript “Protocol for a feasibility randomised controlled trial of the use of Physical ACtivity monitors in an Exercise Referral Setting: The PACERS study” (PAFS-D-17-00048).

We thank you and the reviewer for taking the time to review the manuscript and welcome your feedback. In this response letter, we have addressed each of the comments and suggested revisions in turn, broken down into numbered points. The response includes descriptions of changes made in the manuscript and where these can be found. Changes in the manuscript are highlighted in red.
We think the requested revisions have improved the quality of the manuscript.

We look forward to hearing from you.

Sincerely,

Jemma Hawkins

pp. co-authors

Reviewer #1:
This pilot is an important study. This article describes a protocol for a pilot randomised controlled trial with mixed-methods process evaluation and economic analyses. The intervention, an activity monitoring device and associated web platform is in addition to standard care to promote and sustain physical activity in an exercise referral population. The health benefits of increased activity and exercise are evident as outlined in the paper. The proposed study aims to evaluate the acceptability and feasibility of the intervention and of the process evaluation methodology. The results will inform the design of a full scale trial. The intervention is an additional component to standard care which is based on an existing effective programme of exercise referral. This is described and referred to in the background. The intervention aims to promote autonomous motivation and this process is described clearly and is innovative and takes advantage of current technologies. The paper acknowledges that engagement with technologies may not be acceptable to some populations. The objectives are outlined and refer to some of the principles of process evaluation objectives. Ethical approval was obtained in 2015 but it is not clear why there is a delay in submission. Patient recruitment is from patients referred to the NERS pathway opportunistically. Clear processes are described regarding invitation and consenting procedures. The intervention is described in detail in the text and illustrated further in box 2. Time-points for data collection are outlined and are clear. As well as describing the components of the intervention, mechanisms of action are outlined which provides a theoretical basis for the intervention. The logic model further illustrates components and intended outcomes of the intervention. The criteria have been agreed by the trial steering committee and adopts a traffic light system of assessment are outlined in detail in table 2 which is useful and provides clarity. The trial makes use of current data collected as part of standard care and refers to additional measures for the pilot trial all of which are validated measures with supporting references. I cannot comment on the methods and approaches of the economic analyses. Sample
size is adequately described and justified. Qualitative interviews will be conducted with sub-
sample of patients in the intervention group and telephone interviews with a sample of HCPs
both exploring acceptability and feasibility. However, no details are provided about how these
participants from both groups will be selected and recruited. Table 3 is extremely useful and
provides more detailed explanation of the process evaluation methods. Statistical methods and
qualitative methods of analysis are described. Other aspects of trial design are outlined with
reference to limited risk of adverse events and trial management. A well written paper describing
in detail the proposed study

We thank the reviewer for these positive comments about the manuscript. With regards the lack
of details about how interview participants will be selected/recruited, this information has now
been provided in the ‘recruitment’ sub-section of the Methods (Pages 9-10, lines 223-231).

Editorial comments:

This is a well-written paper on the feasibility of using an activity monitor, compared to usual
care on physical activity outcomes in clients enrolled in the Welsh National Exercise Referral
Scheme (NERS). I have the following comments:

1. Write NICE in full at first use in the abstract.

This has now been done (Page 2, lines 28-29).

2. The background provides interesting context for the current work, but could be shortened.
   Please aim for 2.5 pages max.

The background has now been shortened from 1010 words to 808 words so it is now 2.5 pages in
length with the existing font size and line spacing formatting (Pages 3-7).

3. The objectives are well described. It would help to define thresholds that would inform feas-
   ibility (briefly). For example what proportion of patients would you need to recruit/retain to
   claim that a larger trial is feasible? Do this for all the outcomes. This information is outlined
   in detail in table 2 and in the outcomes section but some more information in the objectives
   would make them clearer.

More information has now been added in the objectives section (Page 8, Lines 161-173).
4. Individual randomisation is usually the default trial design. It may not be necessary to mention it. If you absolutely need to, you can say: “this is an individually randomised pilot RCT.

We have now amended the text to refer to the study as ‘an individually randomised pilot RCT’ (Page 8, lines 178-179) and have removed the reference to allocation in the abstract (Page 2, line 40).

5. I am curious about the “embedded mixed methods process evaluation”. The pilot RCT is part of the mixed methods and not the other way around. The pilot RCT is one of the quantitative components of this mixed methods study. I will be helpful to outline the study processes (components) in an overarching flow diagram. Consider using this resource (Question 8):
http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1047&context=dberspeakers

We have amended the description of the study design to present it as a pilot RCT with additional data collected for the process evaluation and exploratory economic analyses (Page 8, line 179), and have also updated the abstract (Page 2, line 40).

6. Alternatively, you could present this as a pilot RCT and then mention additional (quantitative and qualitative) data that will be collected. As soon as you mention a mixed-methods approach, there are methodological expectations not covered here (sequence, priority, diagram, data integration, justification of approach, theoretical stance etc.)

We have amended the description of the study design to present it as a pilot RCT with additional data collected for the process evaluation and exploratory economic analyses (Page 8, line 179), and have also updated the abstract (Page 2, line 40).

7. Please shorten the sections on adverse events and project management.

The adverse events section has now been shortened by 61 words (Pages 18-19, lines 438-448); the project management section has been shortened by 50 words (Page 19, lines 451-462).

8. Table 3 doesn’t really describe how data will be analysed. Need to state how proportions will be presented: counts (%), and continuous data: mean (SD), etc.

This information has now been added to Table 3.

9. The sample size and economic analyses are well done.

Thank you.