Author’s response to reviews

Title: Promoting physical activity among community groups of older women in socio-economically disadvantaged areas: randomised feasibility study

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Author’s response to reviews:

Reviewer one

Comment

The paper read well and focusses on an area of important need.

Response

We would like to thank the reviewer for their positive comment.

Comment

One repeated issues throughout is the lack of clarity of what your feasibility questions are - these should be stated very clearly. A feasibility study should 1. have clearly stated objectives that directly address your uncertainties, 2. Data collection should match the described uncertainties 3. There should be clear criteria for progression to the planned substantive study (NIHR). I do not think this paper does this, but with some work could. Read more about feasibility studies and pilot studies Consort 2010 statement: extension to randomised pilot and feasibility trials BMJ 2016. Also Thabane et al 2010 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2824145/

Response

We have revised the manuscript throughout to increase the clarity of the feasibility questions and to clearly reflect the guidance stated in these suggested articles. We have attempted to add clarity by revising the last paragraph of the Background section (page 6 line 21) to make the specific objectives of the feasibility study clear. We have also added detail on how data collection
matches the described uncertainties on page 8 lines 10, and the criteria for progression on page 8 line 23.

Comment

One flaw key flaw in the paper is that you have randomised but have not stated why, and in your findings you have not mentioned findings from the control group at all. So what was the purpose of randomisation? What have you learnt from randomising? This should be linked to your feasibility questions. The text and table 3 (demographics of the sample) talks about people in 'immediate intervention', 'delayed intervention', but you have not reported demographics of the control. This is very confusing.

Response

Our purpose in randomising the community centres was to test the acceptability of this approach to participants and thus inform the design of a future trial to evaluate the intervention (see page 27 line 14). We have learned that simple randomisation was not acceptable to the community groups but randomisation to a delayed intervention design was acceptable. However, a consequence of randomisation to immediate and delayed groups was that one condition received the intervention under more favourable weather than did the other. We have added text to the Discussion section regarding the impact of weather on the study (page 27 line 18). Thus, when we refer to ‘control condition’, we refer to the initial 6 weeks of study time for the delayed intervention group, in which its participants had no contact with the research team. Demographic information is provided for the delayed intervention group. We have revised the manuscript to clarify our terminology and regret having caused confusion (see page 12 line 15).

Comment

Abstract Clear and well written. Conclusions are in line with the findings. You have not stated it was a feasibility study, and you have used the term primary outcome. This is not usual for a feasibility study (and if this was a trial only one 'outcome' should be listed under 'primary outcome' not two. I would suggest you change the phrase to 'main uncertainties' or similar.

Response

We thank the reviewer for their complimentary comment and as suggested, we have amended the text in our manuscript to state ‘key uncertainties’ instead of ‘primary outcomes’ on page 8 line 10.

Comment

Background Some opening statements were a bit vague 'large social and economic consequences' -like what? What specific issues does the target population face regarding their health?
Response

We appreciate the reviewer’s comment regarding the opening statements and have amended the text in the manuscript on page 4 line 4 to provide more detail.

Comment

Sentence starting 'Programmes that are context specific .. line 22 p, . 'can overcome' which of your listed barriers? I doubt all of them.

Response

This is an interesting point. We have therefore modified the text to take this into account stating on page 5 line 4 ‘Programmes that are context specific and delivered within the community may help overcome some of these barriers[22] such as accessibility, convenience and cost.’.

Comment

Your background sets up the potential usefulness of interventions within pre-existing social groups well.

Response

We thank the reviewer for this complimentary comment.

Comment

Line 5 p 6 you state you developed a feasibility study - should this read 'intervention'?

Response

We appreciate this comment and have changed the wording accordingly (page 6 line 12) to state: ‘…we developed a community-based intervention… and tested the feasibility of the intervention’s delivery and evaluation in a randomised trial’.

Comment

You have not specified what your feasibility questions are clearly enough line 11-14 p 6.

Response
We have revised the manuscript to ensure these are now clearly stated. The text on page 6 line 21 now states: ‘The objectives of this feasibility study were to (1) test the operational aspects of the trial design in terms of recruitment, retention, and outcome assessments; (2) ensure that the proposed methodological approach was feasible for a large scale trial[36–39]; and (3) gather participants’ views of the acceptability of the intervention and trial design[37].’

Comment

I would like to see a clear link --with -the explicit feasibility questions in your background to the reported findings.

Response

We have amended the last paragraph of the background section (page 6 line 21) to highlight the objectives of our study. We have also revised the results and discussion sections of the manuscript to reflect these questions and strengthen the link.

Comment

Methods Line 2 p 7 - the sentence including 'one older…..'all four' is confusing, needs clarity.

Response

We have amended the text in the manuscript on page 7 line 13 to clarify the number of centres involved in the study.

Comment

Line 6 located in the 'top' 25%?

Response

We have clarified our text (page7 line 20), deleting 'top' and revising it to read: ‘….most socio-economically disadvantaged areas…’.

Comment

Line 17-18 p 7 'determine the feasibility' but you have not stated what the 'feasibility' would look like - consider changing to ..'information to answer the feasibility questions.'

Response
We have amended the text in the manuscript on page 8 lines 7 and 8 to read: ‘…information to meet our objectives.’ and have now included specific criteria by which we determined feasibility (see p8 line 23).

Comment

Outcomes - consider changing the heading. Outcomes are usually associated with outcome measures rather than recruitment and adherence or acceptability, and so could be misinterpreted.

Response

We appreciate this advice and have amended the heading to be ‘Data Collection’ to avoid misinterpretation (page 8 line 9).

Comment

You have not stated why you want to collect accelerometer data or HADS data. This should be clear in your aims/questions.

Response

We have revised the text in the Methods section on page 8 line 15 to clarify our reasons for collecting objective physical activity and valid mental health outcome measures. Page 8 lines 19 to 21 now reads: ‘These outcome assessments were chosen as the intervention is focused on increasing PA and providing social support which may be expected to impact on mental health’.

Comment

Line 20 p7 I am not sure talking about primary outcomes in this feasibility study is helpful. Perhaps reword to indicate your most important areas of uncertainty.

Response

We have revised the text in this manuscript on page 8 line 10 to state ‘key uncertainties to be examined…’.

Comment

Intervention development Is there any existing support for the use of this theory in physical Activity promotion interventions? Why did you choose this theory over others?

Response
We acknowledge that there is limited use of this theory in physical activity research but it has been successfully used by Spotswood et al. (2015) in a study of cycling. It has also been used to explain the results of the “Football Fans in Training” intervention (Bunn et al. 2016), which has received much acclaim for its appeal to types of participants who have been difficult to engage in research. The authors note that Social Practice Theory (SPT) ‘illuminated the social processes through which lifestyle change was achieved’, and concluded that SPT is useful to deepen and enrich design for interventions that are predicated on the interaction between social structures (in our case community groups) and behaviours (such as physical activity). Further information on its justification has been added to our manuscript (page 10 line 8).

Comment

P9 I would like to see more about the SPT such as definition of the three elements and perhaps examples of application from other interventions? And to point to Table 1 in the methods, also to say something about how you decided to use those particular components from Mitchies taxonomy. Then the diagram would also be clearer. For example I struggled to understand what Materials referred to before I looked carefully at Table 1. In Table 1 - There is no label for 'competencies.'

Response

We accept that Social Practice Theory is relatively new to this area of research and have added detail and definitions of the three elements (page 10 line 8), with reference to Table 1 in the methods section (page 11 line 4). We have also expanded the heading for Table 1, to further clarify its content and have omitted Figure 1, to avoid confusion.

We have also added explanation of the reasons why we chose the components of the behaviour change taxonomy to include in the intervention (see page 11 line 13).

We apologise that the label for ‘Competencies’ was missing from Table 1. This has been amended and we thank the reviewer for highlighting this.

Comment

Conclusions should state if you have enough information or not to move onto deliver the intervention in a trial, or if you would need to run a pilot to assess effect sizes.

Response

We have added in the ‘Recommendations for further study’ section that a pilot study is required to assess effect sizes and to test adaptations to the intervention and study design (see page 33 line 10). We now state in our conclusions that ‘…a pilot study of a refined intervention should be conducted…’ (page 34 line 3).
Comment

Table 2. 'Elaborate on responses' were these participants responses if so - this should not be here but in the findings section. Consider taking out the examples?

Response

We have altered the Table heading, hopefully to clarify its content. ‘Elaborate on responses’ refers to the researcher’s instructions regarding the format of intervention delivery. The task was to create interactive sessions. We have revised some wording in Table 2 to ensure that this is clear.

Comment

Is table 2 a reflection of the intended intervention or what was actually delivered? Perhaps comment in the discussion strengths and weaknesses. Eg how do you know it was delivered as intended?

Response

Table 2 is a table of what was intended and delivered: ERL delivered the intervention and can confirm that the intervention content was delivered as intended except that, as reported, one group had two sessions combined due to scheduling of other activities. We have added text in the manuscript on page 32 line 1.

Comment

Was there any justification for including social support in the 3rd session? Social support seems to be a key component of the intervention/theory/setting so it is surprising it is introduced later on.

Response

The first two sessions provided a general overview and background to physical activity and social support was an integral component by virtue of the group engaging in the intervention in an interactive manner. We agree that social support is a key component of the intervention: we considered it appropriate to formally acknowledge this in the third session.

Comment

Randomisation and blinding Please justify why the study was randomised. Please also clearly state the numbers in each group with breakdown of those who had both intervention and control, those who only had the intervention.
Response

As explained above, we wished to test the feasibility of randomisation in order to inform planning of the design of a definitive study to evaluate the effectiveness of the intervention. All participants experienced both the intervention and control conditions but at different times and order, as noted in our responses above. We have added a sentence in the section on Participant demographics on page 15 line 22 stating ‘with group sizes ranging from nine to twelve participants’. Table 3 specifies the numbers of participants in each group.

Comment

Qualitative method Please state which qualitative method you used and more explanation of the processes (or reference it). I could not replicate what you did and come up with the same results with the little information provided. What processes did you use to ensure rigor, and validity of findings?

Response

We acknowledge that the section describing the qualitative methods requires further detail to enable replication. We have added to the text that we used framework analysis and how our method ensured rigour on page 15 line 6.

Comment

What questions were asked in the focus group and how were these questions decided? What feasibility questions did the qualitative component address? What was the purpose of the qualitative component? Please state clearly.

Response

We have now included the semi-structured interview schedule as a supplementary file and included (page 15 line 12) a reference to this and indicated that we chose our questions in order to address our study’s aims. We have added to the text of the manuscript on page 15 line 8 the aim of the focus groups and how the findings will be used.

Comment

Participant demographics There is no description of demographics for the different groups: intervention/control group/immediate/delayed groups.

Response
Table 3 contains baseline participant demographic information for each of the four different community groups, indicating the immediate and delayed intervention groups. As explained above, due to the study design there is no control group.

Comment

Acceptability of the intervention  Line 13 what does the 'information about the study' refer to? Patient information sheet/letter? Or something more general. Please specify.

Response

This refers to the information letter and verbal explanation of the study provided to the participants at recruitment. We have clarified this in the text (page 19 line 4).

Comment

Table 5 Please present the findings from the different groups. There is a lot of missing data. What efforts did the team make to collect this on other occasions (add to Discussion : strengths and weaknesses)

Response

We have updated this table and now provide data separately for each group. We recognise that there was missing data for this questionnaire. However, this was distributed at the last session and we did not have ethics approval for further contact with our participants. We have acknowledged this in our text (page 30 line 20).

Comment

Qualitative results. An interesting section and provides some important findings to help design a better future intervention.

Response

We thank the reviewer for this complimentary comment.

Comment

Without understanding the reason for doing the focus group it is difficult to judge who took part and what you wanted to find out as you have only reported the findings. It seems to just be about the intervention itself (see earlier comment).
Response

We have now addressed this issue as we have included the aim and purpose of the focus group on page 15 line 8, and we have also included the interview schedule as a supplementary file.

Comment

Please state what groups the people in the focus group, any comments about important demographic characteristics. Were there any differences in findings between the different groups? (if this is what you set out to do by randomising?)

Response

In the manuscript (page 16 line 13) we have stated that the focus group participant characteristics reflect those of the total sample and Table 4 presents the demographics of the participants; we feel that further comment is not required.

Comment

It would be good to know how long the group lasted, and how many of the participants were there/how they were selected, and the number that contributed/spoke.

Response

We have added to page 16 line 10 this extra detail requested:

‘In total, 26 participants (65.0%) were interviewed within four focus groups, ranging in size from five to eight participants. All participants present at the third intervention session were invited to participate; no participants declined and all contributed their views. Focus group discussions lasted approximately 30 minutes and participants’ characteristics reflected those of the total sample (Table 4).’

Comment

Discussion The headings here should relate directly to the feasibility questions and the findings linked to these.

Response

We appreciate this comment and have reviewed the text of the manuscript to reflect this.
More work is needed to discuss the findings with the direct implications for the design of a future study methods (recruitment, retention, outcome measures, randomisation, and components of the intervention).

Response

We have taken this advice on board and added further discussion regarding these details.

Comment

Strengths and limitations Line 15 p 27 The issue of measurement bias is not relevant as you did not report outcome measures (not an objective to test effectiveness).

Response

We thank the reviewer for this comment and have deleted this sentence.

Comment

Recommendations for a further study This section seems too short considering that this is a feasibility study (to inform a future study). What would you do differently to overcome the issues highlighted or to ensure the successes are present again?

Response

Please refer to our responses above regarding added discussion of implications for future study design (page 32 line 15).

Comment

There should also be more links from the findings to the theory - was it supported or not? Is the theory useful for a future trial?

Response

We appreciate this comment and in response have added a paragraph in the Discussion section on page 28 line 5.

Comment

EG How would you involve patients and or the public and stakeholders in a future design?
Response

We have now added to the text on page 33 line 12. Some examples could include possibly creating and consulting with a patient user group panel, and/or including a community centre leader in the research team in a future study.

Comment

How could you resolve the phone call support issue?

Response

We have added to the text on page 33 line 6 that further exploration of alternative follow-up support models would be sought in a pilot study; email may be potentially utilised but more exploration is required to identify an acceptable method.

Comment

How could you address the lack of friends and family social support?

Response

We stated in the text that the focus group participants suggested using organised group activities, which would generate social support for physical activity. We have now also added that we will present the task of identifying a physical activity buddy in the first session to give participants more time to do this, and remind them of this at later sessions (see page 32 line 24).

Comment

The consort diagram need to have number of participants at each step. Please see guidance

Response

We now have included a CONSORT diagram as a supplementary file.

Comment

Conclusions are clear and do not overstate the findings. I have not checked the references.

Response
We would like to thank the reviewer for the constructive comments on this manuscript.

Reviewer two

Comment

On page 1, under "Methods," HADS should be defined on the first mention of it in the article.

Response

The manuscript has been updated with the full title of ‘Hospital Anxiety and Depression Scale’ being added to the text on page 2 line 21.

Comment

On page 7, MRC is spelled out, but it should have been spelled out at the first mention in the article: in the abstract and on page 3.

Response

The manuscript has been updated and now includes the full title of Medical Research Council in the abstract (page 2 line 12) and page 6 line 11.

Comment

On page 9, you mention the "secondary prevention of cardiovascular disease." Why isn't this mentioned in the abstract and sooner in the article? I think it would add to the importance of the study to identify this secondary benefit.

Response

We appreciate this suggestion. However, whilst our systematic review was of community-based interventions for secondary prevention it was not the focus of the work presented in this article. Our review identified gaps in provision for women and socio-economically disadvantaged populations and our subsequent interviews confirmed these needs but community group leaders considered that our proposed intervention may bring health benefits to all of their attendees, amongst whom there was a high prevalence of cardiovascular disease. We did not ask any questions about health conditions because we were aware of the potential sensitivity of such questions for group attendees but would explore collection of such data within a future pilot study. However, we thank the reviewer for highlighting this point and have added some specific examples of the conditions that physical activity helps prevent to the first paragraph of the background section (page 4 line 7) and made reference to this in the abstract (page 2 line 1).
Comment

Overall, I found this to be an informative article and enjoyable to read. This is valuable information that was obtained from your study. Once it is published, I look forward to sharing it with colleagues and others interested in socio-economic impacts on health, prevention and wellness. The use of pre-existing groups for your intervention was a brilliant approach. I believe this approach could be utilized for other interventions seeking to overcome barriers to individuals engaging in their own health and wellness and further encourage them to take personal ownership.

Response

We would like to thank the reviewer for their complimentary appraisal and encouraging comments.