Author’s response to reviews

Title: A novel behavioural INTERvention to REduce Sitting Time in older adults undergoing orthopaedic surgery (INTEREST): protocol for a randomised controlled feasibility study

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Author’s response to reviews:

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Professor Andrew Husband
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Dear Prof. Husband,

Thank you for response to the submission of our paper to the journal. We also thank the Reviewers for their time and insightful feedback, which has assisted us greatly in strengthening the quality of the manuscript. We have collated the Reviewers’ comments and our responses in the table available in the files of this re-submission.

Reviewer 1

TITLE: The title is appropriate but could be more informative. A Behavioural Intervention versus usual care to reduce sitting time in adults older than 65 undergoing elective hip or knee arthroplasty (INTEREST): study protocol for a feasibility study. I realize that the title is mean to reflect the acronym but it could still be used. RCT is also not mentioned.

Thank you for your suggestion, we agree the title should have included mention of the RCT design and as such have added this to the title.

Key words: these are interesting. Sitting and Sedentary behavior and sedentariness might be considered synonyms and the major intervention is not listed. Is behavior modification not a key word in the approved list, it should be. Some of the other key words could be redundant.

We agree that there was some redundancy in the keywords, so we have added the behaviour modification keyword and removed sedentariness.

Background: The background is well written. A number of good references are cited to support the need for the study and for the behavioral change intervention. Literature on prehabilitation has not been covered. A mention or two of the impact of prehabilitation in other surgical samples
would be helpful (Int J Surg 2017,39:156-162, Surgery 2016,160:189-1201) especially as this intervention is stated to be a prehabilitation one.

We agree that there could have been more information about prehabilitation in the background, so we have added a section about existing prehabilitation interventions in knee arthroplasty patients beginning at line 100.

The question to be addressed is well formulated, but there is no mention of a control group or usual care. The aim is to examine the feasibility of reducing sedentary time with a novel approach compared to usual care. It maybe usual care is more acceptable, I doubt it but it should be mentioned.

We agree and have clarified at lines 114 and 123 that this study will include a comparator group which is usual care, and that feasibility is being assessed in both arms.

Page 5 Line 106: the word elective could be added for precision before hip and knee.

We agree and have amended the manuscript as such at line 142 and in the methods section of the abstract.

Line 110 what are trial statistics? Are they different from ordinary statistical analyses? Do you mean intention to treat, on or off protocol analysis?

By trial statistics the authors meant statistics that are related to the running of the study, i.e. the recruitment rate, uptake rate, visit attendance, etc. This has been made more explicit (line 120).

Line: 112 efficacy measures is a vague term, especially after you have listed all the primary outcomes. A list of a few of the most relevant ones would be helpful.

Thank you, we have expanded this to include the most relevant measures.
The methods are well described with a few exceptions. The inclusion of persons capable of consent is from the chart review, it might be more efficacious to test their competency; e.g. the Folstein mini-mental test.

As the trial data collection is ongoing, unfortunately it is not possible to change this at this stage. However, in the manuscript it has been clarified under the Inclusion Criteria that capacity to consent is determined by the care team from medical records (line 143).

Page 6 lines 134-136 need to be rewritten there are typos here.

Thank you for pointing this out, this section has been rewritten.

Randomization: Why can the participants not be blinded? The researcher does not need to tell the participants which group they are in. You could add a small attention intervention of a telephone call, as in the intervention group, to ask a few simple not probative questions about their care to control for attention and outside influences. Such as when is your surgery, have you seen a doctor in the last week, have you seen a health care worker in the last week etc. Allocation can also be done electronically. There are a number of sites that will do this while you keep the records of the allocation confidential. It is a great weakness of the study not having a blinded data collector. The study is open to a great deal of bias.

We agree with the reviewer that the lack of blinding introduces bias. However, we did not have sufficient personnel working on the project to allow for multiple data collectors. Additionally, it was not possible to blind the participants to their group as we were informed by the research ethics committee that participants needed to know what each group would entail on the PIS documentation, and parts of the assessment of feasibility involves asking participants about how they felt to be randomised into their respective groups.

Interventions: Behavioural group: Behavioural change is well described and seems comprehensive. This section contains elements that might be better in the background. Although the elements are in the booklets in the additional information files, a SHORT description might help the reader clarify the elements without reading the entire additional section. The main
components in the intervention are very well described. The language level in some areas of the subject information and booklet needs to be checked for education level.

An "Intervention Materials" section has been added above the intervention components section (line 200) to give further detail on the booklet and pedometer used in the study. Unfortunately, the booklet text cannot be changed at this stage of the study, although we appreciate the language could have been better refined. We have also added a picture of the booklet in Figure 3 and placed it below this section.

Page 9 line 183 RCT not BCT

By BCTs the authors meant that the review found that studies which used a greater number of behaviour change techniques (BCTs) had greater efficacy.

Page9, LINES 203-211. The number of goals set out initially is a little confusing. Do the subjects list 6 to start and cover them one by one per week or do they make one goal and add to it once a week for 6 weeks?

We agree that this was not clear, this section has been clarified.

Page9 Line218 where is the pedometer recorded in the booklet. It was not obvious to this reviewer. How long do they wear it, when the same can be said of the accelerometer how long

The participants do not have space in the booklet to record their steps, they are encouraged to do so on their own piece of paper. This may be a limitation of the current iteration of the booklet, however, we are not using these step counts as a formal method of data collection. It is only for the participant to engage in self-monitoring. In the “individualised feedback” section, information has been added to state that the ActivPal accelerometer is worn for 3-7 days (line 228).

For Control group: there is no information on what constitutes usual care
We have added a section in the manuscript on line (line 274) that explains what usual care entails in this study.

How is the attention given to the behaviour group controlled for in the usual care group?

We have not built in any sort of control for attention effects as the planned RCT will be a pragmatic trial of the effectiveness of adding a new service to usual care (i.e. would using this service in the NHS be effective), not a test of the specific effects of a single intervention component, such as a drug (an efficacy trial). Please see Roland & Togerson (1998) for an overview of the pragmatic trial design, which is the design of choice for RCTs of health services interventions. We have clarified this on line 129.


For the interview and goal setting have the authors thought to use Goal Attainment Scaling (GAS) (Rockwood K. J. Clin.Epi 1993:46; 113-118). Seems similar to what you are doing. GAS has a numeric rating for achieving or not achieving goals.

We were not aware of this at the time of the design of the trial, but we thank the reviewer for their suggestion, and this may be considered if/when we move into a definitive trial.

Data Collection: Should be by a blind evaluator. The reviewer presumes that both groups data will be collected on relevant feasibility outcomes (lines 264,266,269,270,271,272,273,277) to help with both sides of the study and contrasts.

Unfortunately, we were not resourced to incorporate blind evaluations (see response above on blinding). Feasibility data will indeed be collected for both groups in the study.

Do the authors have some apriori idea of what would make a good functional outcome from all those they have suggested?
The authors expect that the SPPB would be the optimal outcome for assessing recovery of physical function at the post-surgery timepoint.

The feasibility questionnaire should be worded neutrally and not contain the word control or intervention and should contain questions about the invasiveness of the study i.e. blood collection and length of time the study took to complete.

We agree that the feasibility questionnaire could have contained more explicit questions about the invasiveness, however we intended for this to be covered in the questions about safety and risk. Additionally, we agree that it could have used more participant-friendly language, but unfortunately this cannot be changed at this point. However, we did want to assess whether participants were happy to be allocated to the usual care group, as some may have come into the study with the expectation of getting a plan to increase their activity.

The method of blood collection and storage should be stated.

A statement about this has been added under number 11 in the newly expanded “exploratory outcomes” section (lines 371-376).

The study lasts for at the longest 18 weeks. This time period may be insufficient to assess the quality of life of persons post-surgery.

The authors agree that an even longer follow-up would be ideal, however, it was not possible to do so within the project timeline given the rolling recruitment strategy. The length of follow up is acknowledged as an important issue (and design consideration for the full-scale trial) in the Strengths and Limitations section of the Discussion (line 460).

There is no list of explanatory variables to be collected. It may be obvious but they still need to be stated e.g. age, sex, differential time taken for recovery in hip versus knee replacement, interventions outside the given intervention, readmission, infection, visit by home care or therapists etc.
We agree that some variables were omitted previously, and these have been added to a new section at line 339 onwards, and sociodemographic information added at line 330. Additionally, we agree that these variables put forward by the reviewer are very useful to have included in the study, however we do not have sufficient integration with the healthcare team to be accurately informed about all these occurrences. This is also a limitation of the present study and has been added to the limitations section at line 461.

Analysis: GAS will help with the goals. Have the authors thought of just counting the number of goals each person achieved out of the total number set per person, the percentage achieved? If 95% Confidence intervals are reported the reader can make their own between and within comparisons.

Unfortunately, this may not be possible due to the manner in which goal adherence is recorded. Goal adherence is recorded in the booklet as a single combined score for all goals that week. However, this is excellent feedback and something that would definitely be useful when designing the definitive trial.

Committees: Safety: despite the low risk assessment of this study a fall during the study would be classed a major adverse event. A list of possible adverse events or the definition of low and high risk events would help along with the statement that only high risks would be reported to the subject's physician or surgeon.

Unfortunately, we did not make a list of adverse events that were likely to occur and were not advised to do so by the ethical review board. Any events (i.e. falls) that resulted in injury or hospitalisation would be considered serious adverse events and would be reported to the medical expert on the study. We have added more details about what constitutes this on line 434.

Reviewer 2

The title would be more descriptive if it included that it is a 'randomised controlled feasibility trial/study'.
We have added the words “randomised controlled” to the title.

On page 6, the authors outline the inclusion/exclusion criteria for patients. Can they provide details as to how potential participants’ capability to provide informed consent will be assessed/judged and by whom? Likewise those with moderate/severe cognitive impairment will be excluded - again, how will this be determined (e.g. through MMSE score, what cut-offs will be used, etc.)

We have now added text to specify that this screening is based on medical records accessed prior to the participant information sheets being sent by the research nurses on the primary care team (line 143).

Some detail was missing from the recruitment process that would be helpful for the reader. For example, what patient lists will be screened? How will these be obtained? Will patients be sent the study material by post (I assume so)? Will the information sheet be accompanied by a cover letter?

Thank you for this suggestion, we have added further info regarding what is sent and how at line 155.

Regarding the behavioural intervention - I became a bit lost as to how the present intervention was developed; it may be useful to make reference to the MRC framework. Beyond the systematic review that was conducted, how did the research team decide upon the components to include and map these to BCTs? Have the intervention materials been piloted? A concise description of this should be provided. Has there been an external validity check conducted of the BCTs contained within the intervention? Have key stakeholders been involved in intervention development/design and in the design of the feasibility study?

The rationale for the development of the intervention is extensive and has been added as Additional File 8, as the required additional text would lengthen the manuscript considerably. One of the purposes of this study was to pilot and get feedback on the intervention tools, and there are questions relating to the tools used in the feasibility questionnaire. We have not yet had an independent expert classify intervention content against the BCT taxonomy, however, this
would be conducted prior to conducting a full clinical trial. Involved in the project design were clinicians working in orthopaedic care with considerable experience, however, patients were not directly involved in the intervention development. Piloting of updated tools resulting from the outcome of this feasibility study will be performed for the full trial.

There is a lack of detail about the qualitative interviews that will be conducted with healthcare staff. For example, what will the topic guides over? Where will interviews take place?

We have added the topic guide as Additional File 5.

Will any analytical software be used for quantitative or qualitative analyses?

We have added more detail about the software to be used for these analyses at lines 385 and 394.

There should be a greater description within the manuscript of the tools which have been chosen to measure each of the exploratory outcomes, and the rationale for their use. They are currently only mentioned in Table 2.

A description of the exploratory outcomes has been added to the manuscript in the new explanatory outcomes section at line 339, and the rationale for the selection of these tools has been added as Additional File 9, as it would otherwise lengthen the manuscript considerably.

There are no criteria specified which will determine whether succession to a main trial should be considered.

We have added a new section after the data analysis section, where the criteria for progression to a main trial are outlined.
I wondered if any local governance approvals were required, e.g. hospital trust and if this should be mentioned under 'ethical considerations'.

Thank you for your suggestion, this is correct and has been added at line 432.

The authors acknowledge that the single site design is a limitation. Given this, it would be helpful if they could provide an explanation as to why this study design was chosen.

An explanation of the rationale has been added to the limitations section at line 458.

Referencing needs attention. For example, references 7 and 15 are duplicates. Some of the references appear to be incomplete.

Thank you for noticing these issues and we apologise for including these mistakes. We have amended the references accordingly.

Reviewer 3

The background work up included rationale for addressing sedentary behaviour in older adults with mobility limitations but I wonder if the link as to why this intervention is to be delivered in those awaiting joint replacement for OA could be strengthened.

We agree that this link could have been more clear; it has now been strengthened by including new references to prior prehabilitation studies in individuals undergoing arthroplasties at line 100.
The prehab context and rationale for potential post-operative outcome improvements is mentioned in the abstract (lines 36-38), however this is not justified within the background (line 103).

Thank you for your suggestion, we agree the link with prehabilitation could be stronger and as such have added some text and references to support this at line 100.

Given the specific focus of this study on sedentary behaviour could the sentence (lines 94-96) be rephrased slightly for clarity? You refer to the more general term "activity" and it is not clear to if this reference relates to sedentary behaviour, moderate-vigorous activity or any other type of activity.

This has been amended to make it clearer to the reader.

Please add citations to support the sentence ending on line 79.

We have added additional citations to support these points at line 81.

This paper aimed to "assess the feasibility of reducing sedentary time using a novel behaviour change intervention in a population of adults >60 years waiting hip and knee replacements" and also "assess the feasibility and acceptability of conducting procedures required to conduct a full-scale RCT, etc". The authors then go on to give additional "primary and secondary aims". Do the authors think that it would be more appropriate to speak of the first aim in terms of assessing the feasibility of delivering the sedentary "behavioural intervention" rather than the feasibility of reducing sedentary behaviour per se? I also suggest that rather than reporting multiple aims it may help the reader to have one or two aims and then subsequent objectives relating to how these overarching aims would be met (covering content in lines 110 to 113).

We agree that the phrasing the reviewer suggested is better and have amended the manuscript accordingly in the aims section. Thank you.
It may be clearer to say that the research nurses will screen for patients matching "all required study eligibility criteria" (this implies both inclusion and exclusion criteria are satisfied) (line 141-142). Please briefly explain your rationale for the 2:1 randomisation (line 162).

Rationale for 2:1 randomisation has been added to the randomisation section at line 179, and the section regarding screening by research nurses has been updated for clarity at lines 137 and 155.

If the potential future main trial would be delivered at multiple centres by different clinicians then there may have been benefit in assessing feasibility across more than one site and with more than one individual delivering the intervention. It is not possible to address this at this stage of the feasibility trial but this is a limitation to consider as mentioned later in the discussion. We agree with the reviewer and this was considered during study inception, however, it was decided against due to resource limitations and advice from clinicians and have added information about this to the limitations section in the discussion at line 458.

Please add further detail/rationale around the sentence that study procedures and intervention/assessment visits will take place either at participants' own homes, at the hospital, or at Birmingham university (lines 120-122).

We have added rationale for this comment at line 134.

Do you have any existing hospital data that you could link to your that justifies your 12-month recruitment period?

We did not receive any written advice but we were verbally told by clinicians the number of participants to expect with those criteria over a 12-month period. This is reflected in the new “progression to a definitive trial” section at line 401.

Please provide a model consent form in the appendices (line 158).
This has been added as supplementary file 6, and the PIS has been added as supplementary file 7.

Please provide detail on the third party who will carry out the randomisation (line 162).

This has been added to line 178.

In my ignorance I found the language within the sentence on line 176-178 slightly unclear. Given that the readers of pilot and feasibility studies will not necessarily have a psychology background please can you rephrase this for clarity for a non-specialist readership.

We have amended the text with some more background information to clarify for a broader readership.

I think that the order you describe your intervention in could be altered to help orientate the reader. For example, I believe a brief overview summary of the intervention at line 165 (sessions/ mode of delivery/ brief content etc) prior to talking about the underpinning theoretical framework etc.

We agree that this could have been clearer and as such have moved the TIDieR table to this position (line 182), which should give a good overview to the reader in the final version. Thank you for the suggestion.

Please describe what "usual care" is for this patient group. It is important to report this in sufficient detail for the study to be reproducible.

This has been added in a “usual care” section after “intervention structure and delivery” at line 275. We agree that this needed to be clearer and thank the reviewer for their comment.
Please can you add information about concomitant care and interventions that are permitted/prohibited during the interventions.

As this is a pragmatic trial, we intended to reflect the ‘real’ population that such a programme could be rolled out to as realistically as possible; thus, our exclusion criteria are based only on co-morbidities that would affect their ability to reduce their sedentary behaviour. We do not have restrictions on what medications, etc., that patients could be taking and the patients will not be enrolled in any other intervention during this study. We have made it clear that this is a pragmatic RCT at line 129.

Please can you report how will you capture data on fidelity of intervention delivery (line 246-249). Will this be on case report forms?

Details of this has been added in the “intervention fidelity assessment” section at line 287.

Would it be stronger and possible to have a separate independent assessor assessing intervention fidelity rather than the same author delivering the intervention?

Motivational interviews are being recorded and assessed by a third party, so that aspect is independently assessed. However, for pragmatic reasons we did not include a similar assessment of the phone-delivered elements of the study. This is a limitation of the study and has been added to the limitations section at line 460/461.

Can you concisely offer details on how many qualitative interviews you plan to carry out with the recruiting research nurses and what elements of feasibility you are looking to understand within these interviews (line 286-288/302).

Further description of these interviews has been added and a topic guide has been added as Additional File 5.
You mention that data will be analysed thematically—please provide additional information about this process, will it be deductive based on existing theory, inductive or a combination of the two?

We have added more detail on the range of qualitative data that is to be collected; it is likely that certain types will be deductively coded and others inductively. The participant goals are likely to be deductively coded, for example, but open-ended feasibility questionnaire answers will be coded inductively. We have clarified this at line 393.

For your exploratory outcomes it would aid the reader to know how these are captured, validity of measures where appropriate and scale ranges etc.

We have added further details regarding these in the “exploratory outcomes” section and rationale for these measures are available in the new Additional File 9.

Do you have any "stop-go" criteria for a main trial? How will you collate and triangulate your feasibility findings in order to make a decision about whether you can progress to a main trial?

Information and rationale regarding this process has been added to the “progression to a definitive trial” section below the data analysis section.

Please add information about your rationale for how you will choose your primary outcome measure for the main trial.

This has been added to the “Progression to a Definitive Trial” section at line 401.

References: Please use consistent formatting with your references. For example, references 3 and 12 do not require both web address and journal reference.
We agree that the references were not consistently reported and apologise for including these errors. This has been amended.

Please add discussion about the limitations linked to lack of blinding and the clinical importance of this trial.

These have been added to the limitations and discussions sections.

Please add the research nurse "one week post PIS form phone call" to figure 1.

Thanks for the suggestion, this has been added to the figure.

I found the logic model for Figure 2 slightly disorientating. Is it possible to keep all blue "intervention components" at the top of the page (eg reposition "self-monitoring") to help the reader follow the logic flow?

Thanks for the recommendation, we have adjusted the figure as suggested to enhance readability.

Overall major revisions

1. Please add rationale for why you are looking to deliver your intervention in people with OA specifically at the time point prior to joint replacement (line 103).

Extensive rationale for this has been added towards the end of the background section (line 100 onwards).

2. Please describe what "usual care" is for this study (around line 242)
A section describing usual care has been added at line 275.

3. Please add information regarding concomitant treatments (intervention description)

The trial has been specified as a pragmatic trial (see above responses), as such there are no limitations on what medications patients are taking.

It has also been clarified on line 138 that patients will not be taking part in other interventions during participation in this study.

4. Please provide additional description regarding qualitative interviews as suggested above.

The interview topic guide has been added as an additional file and further description of analysis has been added in the data analysis section.

5. Please describe your criteria for continuing to a main trial.

A new section has been added describing these at line 402.

We hope these responses are to the satisfaction of the reviewers and editor, and we have taken the time to also improve other aspects of the manuscript to enhance readability and be more descriptive. We look forward to your decision.

Yours sincerely,

The authors.