Author’s response to reviews

Title: Effectiveness of text messages for decreasing inactive behaviour in patients with knee osteoarthritis: a pilot randomised controlled study

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Author’s response to reviews:

REVIEWER 1

Main Comments

This trial is a small pilot RCT but the objectives and results do not include the feasibility of trial procedures. The results report 95% confidence intervals and p values, but the trial has insufficient power for these tests. It would be useful to set this pilot study in a framework such as the MRC framework for evaluating complex interventions.

AUTHOR RESPONSE

We thank the reviewer for this relevant comment. We agree that the study is underpowered, but we believe that the reporting of 95% confidence intervals are important in order to support the conclusion (that the text-messages were not effective, and a larger trial seems futile).

We agree that the MRC framework for evaluating complex interventions would have been relevant to use in the planning of this pilot study.

AUTHOR ACTION

We have added a discussion of the lack of feasibility assessment and that the MRC framework could have improved the quality of the intervention.

REVIEWER 1

Background
OA knee is an important clinical problem and increasing physical activity/exercise is a core treatment principle. Text messages have been used to encourage physical activity. Using text messages to discourage inactivity in people who have been through the GLA:D programme is novel and interesting.

AUTHOR RESPONSE

We thank the reviewer for this encouraging comment.

AUTHOR ACTION

No action performed.

REVIEWER 1

Objective

Clear objectives need to be stated to test the feasibility for a possible, future definitive RCT in terms of recruitment, retention, measurement of outcomes, etc.

AUTHOR RESPONSE

We agree that clear objective of a study is important. The objective of this study was to assess if there were any signs of the text-messages being effective at changing the patients’ time spent physically inactive. This was done to inform a decision about whether to design and conduct a large trial that would have the aim to reduce the risk factors for developing non-communicable diseases associated with physical inactivity. Such a trial would require a long intervention and there are ethical issues related to prolonged time under randomization if there is uncertainty about whether the intervention (text messages) work on the mediator (physical inactivity) of reduced risk (primary outcome). We realize that this important aspect of the study’s rationale was not clear enough and have revised the background section.

Hence, this study’s objective was to make an initial assessment of the effectiveness of the text messages on physical inactivity.

We agree that an assessment of the feasibility is also important, but this was not a part of the study’s purpose. Further, in retrospect it can be argued that the feasibility aspects of this study are of less importance as the results indicate that a larger trial of the current intervention with disease risk as outcome seems futile.

AUTHOR ACTION
We have elaborated on the underlying reason for doing this pilot efficacy assessment. Further, the lack of feasibility assessments has been added to the limitation section of the discussion.

REVIEWER 1

Methods

Power calculation is inappropriate for this pilot RCT. Sample size for a pilot RCT needs to be in terms of feasibility (Teare et al 2014).

AUTHOR RESPONSE

We agree. However, we cannot alter the sample size estimation at this point.

AUTHOR ACTION

We have changed the wording of the sample size estimation section to avoid inappropriate mentioning of statistical power considerations.

REVIEWER 1

Feasibility outcomes such as recruitment rate and retention rate would be more appropriate.

AUTHOR RESPONSE

We agree that these types of data would be appropriate to assess had it been the objective of the study.

AUTHOR ACTION

The lack of feasibility outcomes has been added to the discussion section.

REVIEWER 1

A mixed methods process evaluation would have been very useful.

AUTHOR RESPONSE

We agree that a mixed method process could have heighten the quality of this study.
 AUTHOR ACTION

The possible benefits of mixed methods has been added to the discussion section.

REVIEWER 1

Results

No feasibility results reported.

AUTHOR RESPONSE

For this pilot study the main objective was to assess of motivational texts would facility a change compared with no motivational text. We had no intentions to assess feasibility of study procedures.

AUTHOR ACTION

The lack of feasibility outcomes has been added to the discussion section.

REVIEWER 1

There is no statistical difference between the two groups but there is inadequate power for this statistical test. I would prefer the use of simple descriptive statistics such as means and SDs.

AUTHOR RESPONSE

The study is small, but based on the 95% confidence intervals of the group differences the study results suggest a possible (if any) benefit from being in the control group. We believe that this is important to convey. Descriptive statistics are not possible to generate on the group contrasts, but we respectfully insist on keeping the group differences.

AUTHOR ACTION

We have added SD to the within-group changes (table 2).

REVIEWER 1

There is baseline imbalance with the intervention group being 6 years older, less active with worse KOOS scores compared with the control group.
AUTHOR RESPONSE

Thank you for this comment. Yes, an imbalance exists between the two groups.

AUTHOR ACTION

A comment on the difference between the two groups and the potential influence on results have been added to the discussion section.

REVIEWER 1

I would prefer the reporting of means and SDs at follow-up too.

AUTHOR RESPONSE

We thank the reviewer for this comment and have added mean and SD to the follow-up scores.

AUTHOR ACTION

Mean and SD have been added to the follow-up scores.

REVIEWER 1

The results report that the time spent inactive increased in the intervention group and decreased in the control group; vice versa for the time spent moving. This is counter-intuitive and is not in agreement with the self-reported change. Is the sign in the results the wrong way round? Reporting the raw mean scores would be clearer.

AUTHOR RESPONSE

We thank the reviewer for this comment. The signs in the result section are the right way.

We agree that the results are not in agreement with the self-reported change, this is an issue that have previously been reported when assessing data on self-reported measurement of physical inactivity or physical activity versus accelerometer data.

AUTHOR ACTION

The result section has been checked for any potential error in sign.
REVIEWER 1

Figure 2 is unclear to me.

AUTHOR RESPONSE & ACTION

We thank the reviewer for this comment and have added information to the legend of figure 2 as well as in the results section.

REVIEWER 1

Discussion

This needs to be in terms of feasibility of a future RCT. The lack of statistical significance is not a good reason for not performing a definitive RCT. Clear stop/go criteria would help here.

AUTHOR RESPONSE

We thank the reviewer for this comment. A fundamental criterion for commencing a future main trial was that the intervention would reduce physical inactivity – or at least provide some indication of it. This was not the case and hence we do not think that planning a large trial with long term randomization is ethical. This has been added in response to a previous comment. We respectfully insist on keeping this line of argumentation and conclusion.

AUTHOR ACTION

No action performed.

REVIEWER 1

P12 line 21. This last sentence does not make sense. Please re-write.

AUTHOR RESPONSE

Thank you for noticing this.

AUTHOR ACTION

The sentence has been revised.
The lack of a mixed methods process evaluation is a weakness here. Qualitative interviews might have provided some reasons for the lack of effect.

Reference


AUTHOR RESPONSE

We agree. A qualitative element to this study could have been beneficial for this study.

AUTHOR ACTION

The limitations of the study set-up have been mentioned in the limitation section of the discussion.

REVIEWER 2

A well written clear and concise paper. It was a pleasure to read.

The background makes a compelling case for the need to conduct this pilot trail, citing seminal literature and justifying the population, intervention, primary outcome, the need to compare self report with objective data. 6 week intervention with text message on the importance of PA.

It was surprising that the authors did not consider the tailoring aspect in the intro or in the design of the intervention as they do mention/consider this in the discussion. It is well known that any such intervention could be more effective if there is a personalized element to it. Generic info transferred via text or any other electronic source is unlikely to yield any important change in behaviour. What was missing in the interpretation of the results is literature on behaviour change. AUTHOR RESPONSE

We thank the reviewer for this comment. We agree that the discussion could benefit from literature of behavior change theory.

AUTHOR ACTION

References to relevant literature on behaviour change theories have been added to the discussion section.
REVIEWER 2

The authors make a case for the smaller sample size but the study is still underpowered.

AUTHOR RESPONSE

We agree.

AUTHOR ACTION

As recommended by reviewer one, we have omitted the power calculations from the sample size estimation.

REVIEWER 2

With further mention of the behaviour change literature in light of the results, this pilot trial is additional evidence of the lack of effectiveness of passive information. It is worthy of publication.

AUTHOR RESPONSE

We thank the reviewer for this comment.

AUTHOR ACTION

We have added a section about the behavior change with references to the discussion.