Author’s response to reviews

Title: 'Walk This Way': Results from a pilot randomised controlled trial of a health coaching intervention to reduce sedentary behaviour and increase physical activity in people with serious mental illness

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Author’s response to reviews:

Thank you to the reviewers and the editor for their helpful comments. Please find our responses below.

Editor Comments:

We thank the authors for submitting this manuscript to BMC Psychiatry. This manuscript has been reviewed by two independent reviewers. I have also thoroughly reviewed the manuscript. Although a pilot study, there are a number of inherent weaknesses in the manuscript.

Most notably the results, and to a greater extent, the discussion, does not address the stated aim of examining the acceptability of the intervention. Drop out rates alone are insufficient in this regard.
-compliance, dose, etc

In response to this comment and the comments from reviewer two, we have added details of how many coaching sessions participants attended, whether participants attended the optional walking group, satisfaction with the intervention, and whether participants were willing to wear the accelerometer and have blood tests. Please see the revised aims on page 6, primary outcome on page 8, and results on page 12-14. We have also commented and expanded on these details in the discussion on page 17.

Further, attention is given to the assessment of metabolic syndrome in the methods, and, although a protocol paper is referenced, there is insufficient detail regarding the analysis and timing of samples.

We had collected data for all of the criteria according to Alberti et al 2006 (Alberti K, Zimmet P, Shaw P. The metabolic syndrome, a new worldwide definition. A consensus statement from the International Diabetes Federation. Diabetic Medicine. 2006;23(5):12) and analysed these to determine whether the participants had metabolic syndrome or not. Samples were collected at the time points stated in the paper—at baseline prior to randomisation and at the end of the intervention.

Please also check the participant numbers in the text with those in the Figure as there seem to be disparities here.

Thank you. We have now stated that although we had follow up data for 33 participants (page 12), we have accelerometer data for 31 participants (page 14) hence the discrepancy.

Finally, the discussion itself is lacking. There are other studies reporting the challenges associated with recruiting via case managers that would be useful to include.

We have expanded our discussion to include other studies which have reported on the challenges of recruiting through case managers/care coordinators on page 16 and suggest other methods of recruitment on page 18.

Also more though needs to go into discussing the physical health outcomes, which are not addressed at all.

We have added more on physical health measures in the results (page 15-16) in the discussion (page 17). We note that due to the brevity of the intervention we had not expected to see change.

These limitations notwithstanding, I feel this paper has something to add to the literature, but much more work is required to fill these gaps, and those identified by the reviewers. I hope the authors agree to address these comments and I look forward to seeing a revision.
BMC Psychiatry operates a policy of open peer review, which means that you will be able to see the names of the reviewers who provided the reports via the online peer review system. We encourage you to also view the reports there, via the action links on the left-hand side of the page, to see the names of the reviewers.

Reviewer reports:

Magnus Lindwall (Reviewer 1): The topic of the paper is timely and highly relevant, dealing with the effect of a health coaching intervention on physical activity for individuals with severe mental illness. However, a number of problematic issues and uncertainties exist which makes the potential impact of this paper very unclear at the present stage.

Some major limitations are:

To start, I’m wondering about the scientific impact of the paper and its results.

What is the contribution to the field of this report of a pilot study?

Thank you for your comment. We have attempted to clarify this in the introduction. Briefly, we people with severe mental illness (SMI) have a premature mortality of 15-20 years predominantly due to physical disorders (Cardiovascular and cardiometabolic diseases). As the reviewer will be aware, there is an established link between low levels of physical activity / high levels of sedentary behaviour and poor physical health in the population. Our recent meta-analyses (Stubbs et al 2016, Vancampfort et al 2017) have demonstrated that people with SMI spend on average three hours a day being sedentary. Our recent systematic review (Ashdown-Franks et al 2018) demonstrated that no RCT or pre or post-test study has set out with the primary objective to lower sedentary behaviour and increasing physical activity using objective measure in people with SMI. Given this, we devised a ‘coaching’ intervention tailored to the SMI population but prior to seeking funding for a powered clinical trial we wished to establish the feasibility and acceptability of recruiting people who lead sedentary life styles and suffer from conditions that are known from other health-focused interventions to be a challenge for recruitment and retention as well as to examine the acceptability of the intervention and get an indication of it’s likely effectiveness. We have expanded on our use of a pilot study on page 5.

What are the lessons learned?

In general, the paper bring about very little new relevant information. The authors claim that the primary aim of the study is to establish the feasibility and acceptability of the intervention by evaluating if participants could be recruited, randomized to and complete the intervention. As a
primary aim of the paper, this seems not so relevant. Examining if one is able to recruit participants and randomize them to an intervention study is not of any large scientific interest and does not contribute to the literature. The answer to this question should be self-evident, of course the authors will be able to recruit and randomize participants. A question that could be of interest, in a different paper, is to what extent the authors manage to recruit enough participants, given some standards.

Thank you for the reviewer’s comments. We hope that our response to the above point has helped highlight the importance of our paper and first establishing the feasibility and acceptability before undertaking a larger RCT. We would respectfully argue that it is not self-evident that we would be able to recruit and randomize the appropriate participants for this intervention given the focus on physical exercise and with this client group based on other studies which is why we undertook an initial pilot study rather than a fully powered RCT.

Overall, the primary purpose of the study does not seem relevant enough to highlight in a paper such like this, the effect of the intervention is of much higher interest. I can understand why the authors would like to describe not only the effects of the intervention, but also the feasibility of it, but the rationale for highlighting this issue is simply not provided.

If the authors still like to focus mainly on the intervention study set-up, its feasibility, I suggest they focus only on this issue and rebuild the paper accordingly, building a strong case for the need of this information in the introduction and only highlighting results linked to this in the Results part.

The main lesson learned from the results seem to be that it is very hard to recruit enough participants to intervention studies such as this one, and to keep them in the study. This information is not new to the community, and therefore the results does not provide any new information to the field.

We disagree of course. Both the data on feasibility and the preliminary estimates of effectiveness are important and we think of interest to other researchers pursuing this field. No prior intervention has specifically set out to see if it is possible to recruit and undertake a trial to change objective sedentary behaviour and PA. In accordance with the MRC design of complex interventions, it is necessary to evaluate the feasibility and acceptability of an intervention first and publish this so that we (and others) learn from these issues and can 1) produce more effective larger trials, 2) do not waste research money and delay people with SMI knowing if such interventions can help them. It is true that we have identified some problems with recruitment that are common to most clinical trials but also identified particular issues related to exercise interventions. We note that wearable accelerometer devices that provide very accurate assessments of activity are acceptable to the majority of patients and are tolerated at least for the established minimal period for data collection, as we state on page 17. Our coaching intervention
was also acceptable, and this preliminary data suggests it leads to the desired reduction in sedentary behaviour. Any future study will need to address patient concerns about whether these devices can be used to ‘snoop’ on wider behaviour and more attention needs to be given to the interactive walking group. We included this as an optional extra to the core coaching intervention. In future we would increase attention to the importance of this component.

The study seem unpowered, in particular to examine effects of the intervention. If one wants to examine if the intervention could reduce SB and increase PA (as in the second aim), aiming for 20 persons in each group seem not very realistic. The argument that the number of 40 was based on recruiting an adequate sample to assess feasibility of the study with the resources available is very unclear. What resources what available?

Our aim in accordance with best practice (e.g. MRC guidelines is to test the feasibility and acceptability of our intervention and not to undertake an adequately powered study to test if our intervention works. We do not contest the fact that the study is underpowered – at least in terms of what would be necessary to establish efficacy with certainty and explore mechanism. These are the goals for a larger definitive trial. Here we follow guidelines for pilot studies. We are aware that there are different views on the purpose of pilot studies. We had limited resources—a part time PI and two part-time researchers. We therefore followed the line of Eldridge and colleagues (page 6) and Leon and colleagues (page 7) to use the pilot study to understand the issues with recruitment and randomisation, and whether participants would engage with the intervention. We felt that that was the most helpful approach given that we are aware of large scale intervention studies with this client group that have had difficulties in these areas. We have added more rationale for a pilot study on page 5/6

A key aspect of any intervention study is the nature of the intervention itself and not least the hypothesized mechanisms therein. Very little information is provided about this in the paper. For example, what is the theoretical rationale that the health coaching program would help the participants change behaviour?

Thank you for this comment. We agree that this could be much improved and have added further details on the rationale for the intervention including health coaching on page 9

What are the hypothesized theoretical mechanisms of this program?

We have added a paragraph on possible mechanisms on page 9 but are careful to note that these are entirely hypothetical at this point as the study does not allow formal testing of mechanisms.

If the authors would have addressed the aspect of mediation effects, the paper would be of much higher interest. In light of this, the lack of information on the health coaching program is problematic.

What is the scientific backbone of this program?
What theoretical foundations does it stand on?

Has it been tested before?

Given the reference, I wonder about the evidence-base of this program. I assume that the authors have chosen a program with sound evidence-base, given its importance in the intervention and the study, but this cannot be evaluated given the present information given in the paper.

I suggest the authors develop the rationale for the health coaching program and the mechanisms of the intervention and make this a bigger part of their paper. This will also open up for examining not only main effects of the intervention, but also mediating effects and mechanisms of the intervention, which would be of large interest to the field, answering questions such as why, through which mechanisms, does the intervention work (or not work). In light of what we know in the field, such information will be of much more interest and relevance compared to what is now highlighted in the paper as the primary aim.

We have added more details on the components of the intervention and hypothesised mechanisms on page 9. Due to the small sample size we were unable to undertake any formal mediation analysis. However, we would want to do this when we undertake a full trial.

More minor limitations:

The tables are not in line with normal standards in scientific journals.

We have made a number of changes to the tables and hope these changes meet approval. We changed Table 2 to two tables (Table 3 and 4).

Bonnie Furzer, PhD (Reviewer 2): Overall, this manuscript is well written and a worthwhile read. The focus on a coaching intervention within the community has significant merit given the high possibility of translation into practice in future. The strengths and limitations are well balanced and provide direction for future work in this field, with just a few minor comments that I think could improve the manuscript.

INTRODUCTION

Succinctly written.

METHODS - AIMS - DATA COLLECTION

The authors state the primary aim to establish the feasibility and acceptability of the WTW intervention (P5 L58), however based on the data collection information (P7 L48-56) and results (P11) it appears that the recruitment aspect of feasibility has been assessed (and well discussed
throughout the piece) but limited other aspects of feasibility or acceptability of the trial have been included. For example ...

- compliance of participants with intervention,

- dose delivered (Amount or number of intended units of each intervention)

- dose received such as exposure (Extents to which participants actively engage with, interact with, are receptive to, and/or use materials or recommended resources) or satisfaction (Satisfaction with program + Implementation)

Thank you to the reviewer for these helpful comments and suggestions. We have now added further results of measures of feasibility including compliance with the intervention, the number of sessions attended, and dose received. Please see the revised aims on page 6, primary outcome on page 8, and results on page 12-14. We have also commented and expanded on these details in the discussion on pages 16-17.


Thank you to the reviewer for these helpful comments and suggestions. We have cited the reference provided in the introduction, we agree it is very helpful approach to pilot studies.

The manuscript would benefit from the addition of some further information around acceptability and feasibility more broadly(if possible), and if not consideration or comment around how and whether acceptability and/or feasibility were sufficiently assessed based on recruitment data alone. Or what additional aspects may need to be considered in future to inform RCTs?

We have added more details of acceptability and feasibility in the aims and in the results-please aims on page 6 and in results on pages 12-14.

RESULTS

Primary Aim - see above comment regarding 'acceptability and feasibility' results

Secondary Aim

P12 L38-43 - Accelerometry data was collected for 4 days however due to missing data the final analysis was based on only 3 days. There is no mention of if/how the authors believe this may have impacted the results and/or whether this is considered methodologically appropriate.
Thank you for this comment. As we note in the discussion, subsequent data from general population samples suggest 3 days are adequate. Future studies might benefit from the use of less cumbersome devices and certainly greater prior discussion of the limitations of the data collected to reassure readers that these are not used for purposes other than to monitor activity levels. We have added more discussion of this on page 17.

Table 2 P12

Following on from the activity data above, in table 2 the follow up data is presented on n=21. However I am unable to determine (apologies if I have missed it) why only n=21 analysed for the activity and the number in control/intervention?

We have added a sentence on page 14 to state that we were able to follow up 21 participants at six months follow up, with 8 from the intervention group and 13 from the control group.

P11 L27 reports follow up data for 33 participants and this is matched in Figure 1, and there is mention of 2 not wearing accelerometers. If n=21 with only 3 days of data and depending on group allocation, it would be worth considering whether the follow up data is sufficiently robust to draw any solid conclusions.

Thank you for this comment. We are aware of the limitations of our small sample size and being cautious of our findings. We have made it clearer on page 17 that we are aware of these limitations but that this data gives us some initial indications of the possible effect of the intervention.

P13 L32 - Authors note that intervention group had significantly higher light PA, and they also had higher TOTAL PA (approaching significance) ... what impact (if any) did this potentially have any impact on outcomes?

There was an error in the reporting of the analysis – the corrected table shows that the intervention group did not have significantly higher light PA. However, it is the case that although not statistically significant, the intervention group did appear to be more active at baseline. We have therefore added a comment to this effect on page 17.

DISCUSSION

Well written with regards to results presented and also well considered future considerations around clinical and research implications.

Thank you