

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol for a randomised controlled trial of interventions to promote adoption and maintenance of physical activity in adults with mental illness
AUTHORS	Chapman, Justin; Suetani, Shuichi; Siskind, Dan; Kisely, Steve; Breakspear, Michael; Byrne, Jacqueline; Patterson, Sue

VERSION 1 – REVIEW

REVIEWER	Brendon Stubbs Institute of Psychiatry, KCL, UK
REVIEW RETURNED	04-May-2018

GENERAL COMMENTS	<p>This is a timely, well thought out and much needed planned RCT from an author group with a track record in this area. I fully commend the paper, it is excellent to see a theoretically informed PA intervention in this population. The intervention and trial is very well thought out to the finest detail. I have a number of considerations for the authors which they may or may not be able to make changes to. My main comment is this – is there any treatment as usual group it may be possible to collect these measures on? Or at least baseline PA and follow up PA and some other routine measures? My slight concern is that both interventions may be equally effective and show no difference between each other. The authors will have to carefully present their data and interpretations in light of this.</p> <p>Second, the intervention is 16 weeks which is an appropriate length. Is there any scope for a long term follow up after 6 or 12 months to see if there is long term change in PA? This is the key issue we as clinicians all want to know, can the changes be meaningful in the longer term, particularly after the active intervention component ceases.</p> <p>Third, is there any way to try and acquire accelerometry after 16 weeks at least? This disruption in the strong point of your data collection (i.e. objective PA) seems unnecessary and will naturally affect the quality of data and inferences as we know the limitations of self report PA in general and in this population. I note the participants will wear the device continuously for 6 weeks, but also asking people to wear for 7 days at the end would be informative if possible.</p> <p>Finally, the authors do not seem to consider the issue of sedentary behaviour. We know from previous literature that people with mental illness engage in high levels of SB. Would it be worth also considering SB in your data and the impact of your intervention on this?</p> <p>I wish the authors the best in this timely, novel and important trial.</p>
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REVIEWER	Joseph Firth University of Manchester, UK
REVIEW RETURNED	15-May-2018

GENERAL COMMENTS	<p>This is an important, interesting and well-designed study, which, upon completion, will be a positive step-forward for the growing field of physical activity and mental health research. It is encouraging to see pre-publication of the protocol, which adds further scientific rigor to this impressive study.</p> <p>My suggestions are as follows:</p> <p>1) I feel the community-based approach is a major strength of the current study, which will produce more readily translatable results than interventions which demand the purchase of expensive equipment and/or onsite exercise provision. The authors may wish to note that a previous feasibility study conducted in Manchester, UK, (the IBEEP study) also made use of community leisure facilities, and found this to be a feasible and acceptable method for engaging young people with psychosis in regular physical activity (see: Firth et al. Exercise as an intervention for first-episode psychosis: a feasibility study. Early intervention in Psychiatry, 2017, doi: 10.1111/eip.12329).</p> <p>2) The authors should provide, if possible, more details on the cost-effectiveness analysis. For instance, pre-specifying how the cost of intervention delivery will be weighed against the outcomes will add further weight to this study, and ultimately increase its capacity to inform policy change.</p> <p>Beyond this, I have no improvements for this excellent protocol and believe that the authors should be commended on their work.</p>
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REVIEWER	Felipe Barreto Schuch Universidade La Salle, Brazil
REVIEW RETURNED	24-May-2018

GENERAL COMMENTS	<p>The authors describe a well designed and planned study that aims to increase PA in people with mental illness. The rationale is sound and well planned. The authors should be commended for the initiative for doing this very relevant trial. I have only minor suggestions.</p> <p>Page 5, lines 107-109 "The BCW identifies nine 'intervention functions' that potentially influence any given target behaviour, and explains behaviour change through the COM-B model"</p> <p>Please, briefly mention the nine "intervention function".</p> <p>Exclusion/Exclusion criteria Were patients with functional impairments that may limit (but not contraindicate PA practice, also included? what is the impact of the inclusion of patients on the outcomes?</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewers' Reports:

Reviewer: 1

This is a timely, well thought out and much needed planned RCT from an author group with a track record in this area. I fully commend the paper, it is excellent to see a theoretically informed PA intervention in this population. The intervention and trial is very well thought out to the finest detail.

- Thank you for these comments

I have a number of considerations for the authors which they may or may not be able to make changes to.

My main comment is this – is there any treatment as usual group it may be possible to collect these measures on? Or at least baseline PA and follow up PA and some other routine measures? My slight concern is that both interventions may be equally effective and show no difference between each other. The authors will have to carefully present their data and interpretations in light of this.

- Thank you for this suggestion. Although we do not have a treatment as usual group, participants wear the accelerometer for one week prior to engaging in the intervention so we will be able to assess the intervention impact within groups by comparing with baseline. To assess intervention impact, we also intend to compare participants who complete a high proportion of intervention sessions with those who withdraw or participate in a low proportion of sessions.

Second, the intervention is 16 weeks which is an appropriate length. Is there any scope for a long term follow up after 6 or 12 months to see if there is long term change in PA? This is the key issue we as clinicians all want to know, can the changes be meaningful in the longer term, particularly after the active intervention component ceases.

- Thank you for this suggestion. We won't make any immediate change to the protocol; however, we will discuss with the ethics committee about the potential of re-contacting participants at 6-months for self-report measures. Any subsequent changes to protocol will be updated on the trial registry and outlined in future publications.

Third, is there any way to try and acquire accelerometry after 16 weeks at least? This disruption in the strong point of your data collection (i.e. objective PA) seems unnecessary and will naturally affect the quality of data and inferences as we know the limitations of self report PA in general and in this population. I note the participants will wear the device continuously for 6 weeks, but also asking people to wear for 7 days at the end would be informative if possible.

- We are currently asking participants to wear the GENEActiv monitor for a total of 9 weeks – one week at baseline and continual monitor wear for 8 weeks during the intervention. An additional week at follow-up would benefit data quality; however, based on our initial pilot round, we believe asking participants to wear the monitor for any longer amount to excessive study burden. We initially asked participants to wear the GENEActiv for the entire 16-week study duration; however, some participants withdrew after the group sessions specifically because they didn't want to wear the monitor, and other feedback was that it was disrupting their sleep. Some participants were willing to wear the monitor for longer periods; however, we would also be concerned about the selection bias this may present. We are drafting a manuscript describing observations from pilot work that led to development of this protocol in its current form.

Finally, the authors do not seem to consider the issue of sedentary behaviour. We know from previous literature that people with mental illness engage in high levels of SB. Would it be worth also considering SB in your data and the impact of your intervention on this?

- We will do exploratory analyses of self-reported sedentary behaviour from the SIMPAQ questionnaire. Sedentary behaviour wasn't a focus of analyses because we're using GENEActivs to measure activity, which have questionable validity for measuring sedentary behaviour using standard threshold methods. Should more robust analytical methods for defining sedentary behaviour with GENEActiv data become known we will factor this into analyses.

I wish the authors the best in this timely, novel and important trial.

- Thanks again!

Reviewer: 2

This is an important, interesting and well-designed study, which, upon completion, will be a positive step-forward for the growing field of physical activity and mental health research. It is encouraging to see pre-publication of the protocol, which adds further scientific rigor to this impressive study.

- Thank you for these comments.

My suggestions are as follows:

1) I feel the community-based approach is a major strength of the current study, which will produce more readily translatable results than interventions which demand the purchase of expensive equipment and/or onsite exercise provision. The authors may wish to note that a previous feasibility study conducted in Manchester, UK, (the IBEEP study) also made use of community leisure facilities, and found this to be a feasible and acceptable method for engaging young people with psychosis in regular physical activity (see: Firth et al. Exercise as an intervention for first-episode psychosis: a feasibility study. *Early intervention in Psychiatry*, 2017, doi: 10.1111/eip.12329).

- Thank you for this suggestion. The suggested study as well as Raine P, Truman C, Southerst A. The development of a community gym for people with mental health problems: Influences on psychological accessibility. *J Ment Health* 2002 were added to the discussion to embed this point within the broader literature:

- o “Interventions will also be delivered at community facilities, likely the most practical way to implement PA interventions given accessibility and absence of gym facilities in many mental health services[45, 46]”

2) The authors should provide, if possible, more details on the cost-effectiveness analysis. For instance, pre-specifying how the cost of intervention delivery will be weighed against the outcomes will add further weight to this study, and ultimately increase its capacity to inform policy change.

- Please note we are not undertaking a cost-effectiveness analysis. We are looking at the feasibility of the interventions by comparing intervention costs with procedural statistics. To add clarity, we have amended Line 321 page 14: “Feasibility of the interventions will be assessed using by comparing intervention costs (intervention equipment, staff time), with referral and uptake rates, adherence (attendance at group sessions assessed by the researcher; attendance at unsupervised sessions assessed using self-report), completion rate, and reasons for non-completion”. It may be possible to compare intervention costs with change in physical activity; however, we will not know until we can assess the quality of data and intervention impact.

Beyond this, I have no improvements for this excellent protocol and believe that the authors should be commended on their work.

- Thank you for these commendations.

Reviewer: 3

The authors describe a well designed and planned study that aims to increase PA in people with mental illness. The rationale is sound and well planned. The authors should be commended for the initiative for doing this very relevant trial. I have only minor suggestions.

- Thank you for these commendations.

Page 5, lines 107-109 "The BCW identifies nine 'intervention functions' that potentially influence any given target behaviour, and explains behaviour change through the COM-B model"

Please, briefly mention the nine "intervention function".

- Thank you for this suggestion. To maintain clarity and flow in the introduction, we have added the possible intervention functions from the Behaviour Change Wheel in the footnote of Table 1 and made reference to the table footnote in the introduction:

- “The BCW identifies nine 'intervention functions' that potentially influence any given target behaviour (Table 1, footnote (a)), and explains behaviour change through the COM-B model, in which capability (C), opportunity (O), and motivation (M) interact to generate behaviour (B).[23]”

- Table 1, footnote a: “a Nine possible intervention functions are specified in the Behaviour Change

Wheel framework: Education, Persuasion, Incentivisation, Coercion, Training, Restriction, Environmental restructuring, Modelling, Enablement.[23]”

Exclusion/Exclusion criteria

Were patients with functional impairments that may limit (but not contraindicate PA practice, also included? what is the impact of the inclusion of patients on the outcomes?

- Functional impairments (e.g. mobility issues, cognitive impairment) are not being used as exclusion criteria. It's likely that participants of this study will have diverse presentations in terms of physical and mental capacity representative of the broader sample of adult outpatients of the mental health service. We are not formally assessing functional impairments; however, the presence of physical conditions is being assessed as part of the baseline screening, so there will be potential to comment on the impact of physical conditions on adherence.

FORMATTING AMENDMENTS

Authors must include a statement in the Methods section of the manuscript under the sub-heading 'Patient and Public Involvement'. This should provide a brief response to the following questions:

- How was the development of the research question and outcome measures informed by patients' priorities, experience, and preferences?

- How did you involve patients in the design of this study?

- Were patients involved in the recruitment to and conduct of the study?

- How will the results be disseminated to study participants?

- For randomised controlled trials, was the burden of the intervention assessed by patients themselves?

- Patient advisers should also be thanked in the contributorship statement/acknowledgements.

If patients and or public were not involved please state this.

- The following was added to the Methods section:

- o “Participant burden of the intervention and research measures was assessed using focus group interviews and informal feedback from patients participating in two pilot rounds. Development of the research question and the intervention content was based on existing community programs developed collaboratively with people recovering from mental health issues. These programs that have been implemented and iteratively improved based on participant feedback since 2015. Patients weren't directly involved in recruitment of participants or conduct of the study. Results of this study will be disseminated to participants through presentation at consumer and community forums.”

- The following was added to the Contributions section:

- o “The authors would like to thank participants of pilot rounds of this study, and of the community program Healthy Bodies, Healthy Minds, for contributing to the study design by providing feedback about their experiences, preferences, and perceived burden of completing research measures.”