Author’s response to reviews

Title: An evaluation of an intervention designed to help inactive adults become more active with a peer mentoring component: a protocol for a cluster randomised feasibility trial of the Move for Life Programme.

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Author’s response to reviews:

14th March 2019

Dear editor,

Thank you and your reviewers for your feedback on our paper. As authors, we are encouraged by your positive responses. The suggestions have been addressed below in a point-by-point format. Changes to the manuscript are indicated here in inverted commas.

Kind regards,

Andrew

Dr Andrew O’Regan

General Practitioner and Senior Lecturer in General Practice

Lines 149-153: Can justification be provided to the choice of the 2 counties? Especially when they already have good/very good health.

This has been explained in the manuscript. Lines 148-153 now read:

“The University of Limerick, where most of the academic team is based, has research links with the Local Sports Partnerships of counties Limerick and Clare. These counties cover one whole Health Service Executive Community Health Organisations (HSE CHO) area. These counties, both with distinctive urban dwelling and rural populations were selected both for convenience to the academic location and for their potential to replicate the national demographic.”

Line 154: There seems to be some discrepancy between the title and selected age-group (45+) i.e. interesting definition of "older" (also line 240)

The study protocol is to recruit participants aged 50+. It became apparent early in the recruitment that to attract people in this age range from local communities, a lower age threshold was
required. This was largely because participants attended in groups or pairs of mixed age, and rejecting the younger participants would lead to the loss of participants in the 50-60 age groups and break up already established supportive social groupings. All participants over the age of 45 who met the study criteria were invited to participate in the programmes but only those aged 50+ were included in the study. We estimate that approximately 7% of those that signed up are under 50 years.

The text has been amended in lines 239-243 as follows:

“Those who are aged over 45 and who report less than 150 minutes of MVPA will be invited to participate in the physical activity programme. The cut-off range of 45 years was chosen as it became apparent that few adults aged between 50-60 were registering an interest in participation when the study was advertised as only for “older adults”. The trial will only include data from those participants who were aged 50+.”

Also, the inclusion and exclusion criteria, on lines 265 and 268 have been corrected to read “aged 50 years and over” and “aged under 50 years”, respectively.

Line 177: Why the unequal number of hubs (2 true control & 3 for MFL and usual programme)?

The total number of hubs available from the Local Sports Partnerships was eight. Initially, randomisation was designed for two groups - control and intervention (4 hubs each). Subsequent to the identification of eight hubs, the funding body specified that the randomisation plan was revised to include a third group – ‘true control’, where the participants would receive no formal programme until after the trial had finished. Two hubs were assigned to this ‘true control’ group, leaving the intervention and usual programme groups with three hubs each.

Line 189: Should the second "programme" be "study"?

Yes, line 198 has been amended to read “study”.

Line 296: Some description of the behaviour change techniques would be useful here. Perhaps defined using the BCTT taxonomy. This would aid reporting and replication if the trial is demonstrated to be successful.

Lines 302 – 322 have been amended to read:

“Using the sources outlined, the MFL intervention was designed on a foundation of theoretical, empirical, and practical information. The Intervention Mapping approach was used to identify
theory-based determinants and matching them with appropriate methods for change [29]. A toolkit in the form of a training manual has been developed to train MFL professional instructors in key behaviour change techniques, involving social support and group dynamic strategies along with behavioural skills, aimed to facilitate change and maintenance of physical activity over time. The MFL toolkit contains strategies and outcomes identified in the intervention mapping process. The process will be described in more detail in a separate paper. Social cognitive theory (SCT) [30] was the primary conceptual framework of the intervention because of its emphasis on self-efficacy and social support. Behavioural skills strategies to address outcome expectancy and self-efficacy determinants of behaviour were derived from previous SCT-based intervention work [31-32] The Theory of Planned Behaviour [33], a second conceptual framework guided the intervention design in terms of influencing participants attitudes and beliefs around physical activity. Self-determination theory (SDT), [34] was a third conceptual framework, using its focus on basic psychological needs for autonomy and relatedness to others to having a positive impact on desired behavioural outcomes [35]. A fourth conceptual framework, the model of group cohesion in exercise and sport [36], was employed, with particular emphasis on task cohesion (i.e., how well participants work together toward a common goal) and social cohesion (i.e., how much participants enjoy working with each other toward the goal) to develop strategies for the group to achieve its outcomes.”

Line 299: How will the suitable non-professional volunteer be identified? What criteria will they need to fulfil? Line 300: How will the peer mentor be trained? By whom? For what duration? What content? Will they need to demonstrate competency? Line 302: What advice will they be given? How will they maintain the group? Line 307: What support will be provided?

Lines 323-341 have been added, as follows:

“It was initially envisaged that the Local Sports Partnerships (LSP) tutors would identify a suitable non-professional volunteer from existing programmes to act up as a peer mentor for this study. The desirable criteria were strong motivation and interpersonal skills and experience with group dynamics. However, because of challenges recruiting in this way and concerns about upsetting the group with an ‘outsider’ as a peer mentor, it was decided to recruit the peer mentor from the groups during the trial. Part of the role of the LSP tutor facilitating the programme would be to identify participants suitable for the peer mentor role.

A team of educational experts with experience in physical activity and behavioural change will provide the peer mentor training through a series of interactive workshops. The peer mentors will be identified by the LSP sports development officer in the early stages of the Move for Life trial and will receive training during the course of the programme. They will be trained in motivational change techniques so that they will be able to develop rapport with their peers and
to support and encourage them in their journey to become more physically active. They will be trained on group dynamics, how to access local assets and facilities, to access funding by applying for grants and to promote their group by social and local media so as to secure the sustainability of the programme. During the trial, they will have the support of the sports development officer and, thereafter, peer mentors will be provided with leadership training courses and linked with local community-organisations, including the LSPs.”

Line 360: What year were the interviews conducted in?

Line 299 of the text has been amended as follows: “In 2018…”

Line 361: Has the trial already started or is this an a-priori protocol?

The protocol was submitted on 31st May 2018 and the trial began on 1st May 2018.

Outcomes & analysis: I would expect the feasibility outcomes to be the primary outcomes for this feasibility study and tests of effectiveness exploratory/to inform sample size calculation for full trial. This isn't clear from the manuscript at present.

Lines 358-361 of the text has been amended to read:

“The primary outcome of the study is to investigate the feasibility of measuring MVPA. The acceptability and safety of the intervention and measurement methods will be investigated. The data will provide reliable estimates for sample size calculation for a future definitive trial.”

Line 404: The minimum threshold is important - could it be defined and perhaps introduced earlier in the methods?

Lines 370-3721 now read: “At specific time-points, immediately post intervention and three months after the intervention ended follow-up testing sessions will take place. The authors define ‘minimum thresholds’ in the context of the three and six months follow up testing as the minimum proportion of participants that attend the testing sessions and provide reliable data.”

The Progression criteria subsection has been moved to line 374 to reflect this.

Line 413: Does this mean that you intend to recruit equally from the 3 age-groups? This should perhaps be introduced earlier also.

It is not planned to recruit equally from the three age-groups, but the recruitment strategy aims for a wide age distribution of participants.

Lines 458-460 have been amended to read:
“Further challenges envisaged regarding recruitment are that it may be difficult to attract older adults under the age of 60 years who may be working and who may not identify as being “older adults”.”

Reviewer #2:

1) It would be helpful to add two sections to the end of the "Background": firstly relating to the study "Hypothesis" (which could, for instance, relate to the proposed feasibility of the intervention) and secondly the "Aims and Objectives" of the study. There may be primary and secondary objectives, which would link to the primary and secondary outcomes of the study (see next point). The primary objectives of a pilot study should relate to the demonstration of feasibility/acceptability/deliverability/safety etc of the interventions/outcome assessments/recruitment/randomisation, etc or to provide reliable estimates for sample size calculation for a future definitive trial.

The following sentences have been added:

Lines 161-165 now read:

“The study hypothesis is that it is feasible to deliver the MFL intervention and measure the time spent in daily MVPA by participants. The aim of this study is to investigate the feasibility of the trial in terms of collecting data relating to the intervention and measurements. Specific objectives are to: record numbers recruited, retention and attrition rates, safety and acceptability of the intervention and measurements and follow-up testing attendances and participant compliance.”

The following sentence has been added to the outcomes section, line 358-361:

“The primary outcome of the study is to investigate the feasibility of measuring MVPA. The acceptability and safety of the intervention and measurement methods will be investigated. The data will provide reliable estimates for sample size calculation for a future definitive trial.”

The abstract has also been reworded to reflect this, lines 89-92:

“The primary objective of the study is to investigate if it is feasible to deliver the intervention and collect data on MVPA on all participants, thereby providing valuable information to guide sample size calculation for a future, more definitive trial.”
2) Please rephrase the sentence: "There is no sample size calculation as it is a feasibility study." to "There is no power calculation as it is a feasibility study, but the sample size has been estimated based on necessary group dynamics..." or some other justification for the sample size.

This has been changed as suggested, lines 225-227 read: “There is no power calculation as it is a feasibility study, but the sample size has been estimated based on minimum numbers required to sustain structured physical activity programmes and the necessary group dynamics.”

Analysis of a pilot study should focus on confidence interval estimation, rather than hypothesis testing or statistical modelling, as the limited sample sizes used in pilot studies mean that they are typically underpowered for statistical testing. Although it is interesting to explore possible outcomes, inferential statistics should be used with great caution. As such, please could you rephrase the statistical analysis section, clarifying that the analysis will focus on confidence interval estimation, and that any hypothesis testing or regression modelling will be considered entirely exploratory in nature.

The following sentences have been added to the Analysis Plan subsection of Methods, starting at line 429-431:

“As this is a feasibility study, the analysis will focus on confidence interval estimation. Accordingly, any hypothesis testing or regression modelling will be considered entirely exploratory in nature.”

4) Please add a SPIRIT checklist to the supplementary documentation.

This has been added.