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.

Authors:
Andrew O'Regan (andrew.oregan@ul.ie)
Liam Glynn (Liam.Glynn@ul.ie)
Enrique Bengoechea (Enrique.Garcia@ul.ie)
Monica Casey (monica.casey@ul.ie)
Amanda Clifford (amanda.clifford@ul.ie)
Alan Donnelly (alan.donnelly@ul.ie)
Andrew Murphy (andrew.murphy@nuigalway.ie)
Stephen Gallagher (stephen.gallagher@ul.ie)
Paddy Gillespie (paddy.gillespie@nuigalway.ie)
John Newell (john.newell@nuigalway.ie)
Mary Harkin (info@ageandopportunity.ie)
Phelim Macken (pmacken@limericksports.ie)
John Sweeney (John@Claresports.ie)
Mo Foley-Walsh (Mo.foleywalsh@limerick.ie)
Geraldine Quinn (geraldinemary.quinn@hse.ie)
Kwok Ng (Kwok.Ng@ul.ie)
Nollaig O'Sullivan (nollaig.osullivan@ul.ie)
Gearoid Balfry (Gearoid.Balfry@ul.ie)
Catherine Woods (catherine.woods@ul.ie)
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Dear Lehana,

Thank you for the feedback on our revised paper. We are further encouraged by the positive reviewers’ comments. Each suggestion has been addressed below in a point-by-point format. Changes to the manuscript are indicated here in inverted commas and the corresponding line number in the manuscript is indicated. Changes to the manuscript are in red font.

Of note, a final review of the protocol paper was carried out recently by the extended research team and an error was noted in some of the figures provided. The error relates to the progression criteria, which were based on clinical pharmacoeconomic trials as opposed to community-based complex interventions of physical activity. The issue is addressed in the point by point responses below.

Kind regards,

Andrew

Dr Andrew O’Regan

General Practitioner and Senior Lecturer in General Practice, University of Limerick Graduate Entry Medical School

1) Please describe the control or comparator intervention.

Lines 285-299 now read:

“Description of comparator intervention”

“The physical activity programmes in the comparator intervention will be run by the LSPs at existing exercise hubs in community settings. The programmes were developed as part of Ireland’s national physical activity plan, ‘Get Ireland Active’ [28]. These programmes run
nationally and their purpose is to encourage and support physical activity by facilitating access to a wide range of physical activity opportunities in local communities. For Move for Life, four existing LSP programmes were identified as suitable for inactive adults aged 45+ years. Two programmes are gender segregated: ‘Men on the Move’ and ‘Women on Wheels’; both are 12-week structured exercise classes involving general sport, physical activities and cycling. ‘Get Ireland Walking’ is an eight-week walking initiative for inactive men and women; ‘Go For Life’ is an eight week structured exercise class that typically recruits older adults aged 65 years plus. For the purposes of the comparator intervention in this trial, these programmes will run in the usual way so that participants are exposed to a community-based structured physical activity programme. Participants in the intervention arm of the trial will have these programmes augmented by the Move for Life intervention.”

2) Please state the secondary PICOT (Population; Intervention; Comparator; Outcomes; Time-frame) objectives corresponding the resource utilization, costs and QoL outcomes, clearly. These outcomes have been described in the Outcomes section, but there are no clearly framed objectives corresponding to them.

Lines 162-165 now read:

“The secondary aim is to obtain preliminary information on the economic impact of the trial on participants. Accordingly, secondary objectives are to collect data on health costs and quality of life for participants in each arm of the study for the duration of the trial.”

3) Consider replacing "Sample size and power calculation" with "Sample Size Justification". Also, the sample size justification needs to be based on the primary feasibility objective/outcome. Please see CONSORT extension to pilot trials and BMC Medical Research Methodology 2010;10:1.

Lines 224-227 now read:

“Sample size justification”

“As this is a feasibility study, a formal sample size calculation has not been used but the sample size was estimated based on the primary outcome of interest, which is the feasibility of measuring MVPA.”

4) The analyses of the secondary efficacy outcomes need to present the preliminary estimates of the effect along with their 95% CIs. In addition, please state the software that will be used for these analyses.
Lines now 372-37 read:

“For each secondary outcome, the point estimate of effect will be reported, and precision will be presented with 95% confidence intervals. SPSS version 25 will be used for the statistical analyses.”

5) The research team noted an error in the progression criteria. The criteria were incorrectly based on criteria used for clinical trials. For this trial, criteria should be based on published literature on community-based complex interventions of physical activity.

In a systematic review of supervised physical activity programmes for patients post pulmonary rehabilitation, Beauchamp and colleagues (2013) reported a mean adherence of 60%. Another recent review of adherence to physical activity programmes stated that approximately 50% of participants dropped out of programmes within six months before the benefits could be observed (Herring, 2014). A mixed-methods review of group physical activity programmes in community settings reported a mean adherence rate of 69.1% (Farrance, 2016). Based on this summary of the most recent evidence, we have adjusted the progression criteria to read:

· Failure by more than 40% of participants to provide reliable data for daily determination of time spent in moderate to vigorous exercise
· Failure by more than 40% of participants to maintain engagement with the intervention.
· Failure to identify less than 80% of the required number of peer mentors by the LSP tutors in a timely fashion.

References

