Author’s response to reviews

Title: Efficacy of a multimodal physical activity intervention with supervised exercises, health coaching and an activity monitor on physical activity levels of patients with chronic nonspecific low back pain (Physical Activity for Back Pain (PAyBACK) Trial): study protocol for a randomised controlled trial

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We thank the reviewer for their comments. The responses to the comments made by the editor and reviewer are provided below.

1. What time point is considered primary outcome? 3 mo, 6 or 12 mo?

Response: In the revised version of the manuscript we have addressed this issue and adopted the short-term (i.e. 3-months post-randomisation) follow-up as the primary outcome for promoting physical activity as well as reducing pain intensity and disability. Please refer to Abstract, page 4 or refer to the revised paragraphs below.

“Outcome measures will be assessed at baseline, and at 3, 6 and 12-months post-randomisation. The primary outcomes will be physical activity, measured objectively with an accelerometer, as well as pain intensity and disability at 3-months post-randomisation. Secondary outcomes will be physical activity, pain intensity and disability at 6 and 12-months post-randomisation as well as
other self-report measures of physical activity and sedentary behavior, depression, quality of life, pain self-efficacy and weight-related outcomes at 3, 6, and 12-months post-randomisation.”

“Therefore, we will investigate the efficacy of a multimodal physical activity intervention consisting of supervised exercises, health coaching and provision of an activity monitor on physical activity levels, pain intensity and disability compared to supervised exercises plus sham coaching and sham activity monitor in patients with chronic nonspecific LBP. Our primary hypothesis is that the physical activity intervention will increase physical activity levels as well as reduce pain intensity and disability at 3-months post-randomisation. The secondary outcomes are physical activity, pain intensity and disability at 6-months and 12-months post-randomisation as well as other objective measures of physical activity (i.e. time spent in light and moderate-vigorous physical activity, number of steps), self-reported physical activity levels, depression, pain self-efficacy, perceived recovery, weight-related outcomes and quality of life measured at 3, 6 and 12-month follow-up.”

2. In sample size section, the authors quote both 30% and 15% followup rate? Which one is it?

Response: We have addressed this issue. Please refer to page 4 or refer to the revised paragraph below.

“A sample size calculation was performed based on an objective measure of physical activity level, i.e. counts per minute, derived from an accelerometer. A total of 160 participants (80 patients per group) will be required to detect a 20% between-group difference in physical activity levels (mean difference between groups of 59.2 counts per minute, a standard deviation of 111.6 counts per minute) with a power of 0.80, alpha of 0.05 allowing for up to 15% loss to follow-up. The counts per minute parameters used in the sample size calculation are from a previous study conducted with a similar population [22]. The total of 160 participants is enough to detect a between-group difference of 1 point (SD = 1.84) in the numerical pain rating scale and of 4 points (SD= 4.9) in the Roland Morris Disability Questionnaire (RMDQ) with a power of 80%, an alpha of 0.05 and 15% dropout as reported in a previous trial with this population [23].”

3. P. 10, line 47-51, since this is a randomized study no formal testing between groups is needed for baseline variables. You would simply report descriptive stats.

Response: In the revised version of the manuscript we have removed the tests to compare demographic and clinical characteristics of the groups at baseline. Please refer to page 10 and 11.

4. For mixed models, will both random intercepts and slopes be included in models?

Response: The point raised by the reviewer has been clarified. Please refer to page 10 and 11 or refer to the revised paragraph below.
“Continuous variables will be reported using mean (standard deviation) or median (interquartile range), depending on the data distribution, and dichotomous and categorical variables will be reported using frequencies (proportion). All data will be analysed following intention to treat principles. The difference between groups will be analysed with linear mixed models using fixed effects for group, time and group-versus-time interaction and random intercepts for individuals to account for the dependence of repeated measures. Statistical significance will be set at 0.05. We will report the number of participants with missing scores for each outcome. The statistical software SPSS V.20.0 (IBM corporation, Somers, NY, USA) will be used for data analysis. Planned subgroup analyses will investigate differences in effects of the intervention by physical activity levels at baseline assessment and pain self-efficacy. In addition, we will also conduct secondary analyses to investigate the treatment effects considering the adherence to treatment using a CACE approach.”

5. Given the high rate of loss to follow-up, how will missing data be handled? Isn't it likely that those that drop out are either more likely to be nonresponders or high responders? One way would be to make the 6 month time point the primary outcome so as to minimize loss to follow-up but still retain long term effect measurement. Another would be to consider imputation methods.

Response: We have used 3-month time point as the primary outcome to address the issue of potential loss to follow-up for longer time points. Please refer to page 4 or refer to the revised paragraphs in question 1.