Reviewer's report

Title: Does Physical Activity Change Predict Functional Recovery in Low Back Pain? Protocol for a Prospective Cohort Study

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Reviewer: Nadine Foster

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This protocol summarises the plans for a new cohort study of people with acute low back pain, in which the role of physical activity is to be specifically studied. This is an important area of research as previous studies have not included robust measurement of actual physical activity.

Minor Essential Revisions

1. In the methods section, given that the plan is to advertise for volunteers for the cohort, from the general public and the staff and student population of a University, it will be important to compare the sample with other cohort study samples from more clinically orientated settings (eg. consultation cohorts). It is possible that the sample for this cohort will be more motivated to improve, and/or perhaps more educated about the importance of physical activity for health benefits. In order to address concerns about generalisability of the results of this cohort, a planned comparison of the sample with other large scale consultation cohorts (perhaps those from primary care studies in Australia for example?) would be a useful addition to the plan.

Major Compulsory Revisions

2. In the methods section, it seems to suggest that everyone will see a physiotherapist but its not clear why. This might also influence the physical activity levels of participants, given that most physiotherapists will recommend physical activity as part of the patient’s management plan. The authors need to justify why these participants need to see physiotherapists, given the need for an observational study to assess the predictive role of physical activity on outcome.

3. The team need to consider adopting international recommendations about a core set of variables to include in prognostic cohort studies – see the work of Pincus T (the MIMICS study) and consider whether all of the key domains and measures have been included in the plan for this new cohort. Ref: Pincus T, Santos R, Breen A, Burton AK, Underwood M. A review and proposal for a core set of factors for prospective cohorts in low back pain: a consensus statement. Multinational Musculoskeletal Inception Cohort Study Collaboration. Arthritis Rheum. 2008 Jan 15;59(1):14-24.

4. The RMDQ change of 4 points as the smallest clinically important improvement is a topic of debate. Some authors suggest reduction of 30% of more (Jordan, Dunn), whilst others suggest 2.5 points. The team need to justify
their selection of 4 points more carefully and the approach to their sample size calculation overall, given this is a cohort study testing the predictive ability of physical activity on back related disability at 12 months. The sample size suggested of 120 at baseline seems low, as many may be lost at follow-up and the planned multivariate regression analysis needs to meet the usual ‘rules of thumb’ eg. 10 or more participants per variable in the model (Tabachnick B: Using Multivariate Statistics 2007).

5. Ultimately, although physical activity may predict outcome, the more important question which the team will be able to answer if they include the other key predictors of outcome, is ‘What further explanation of outcome (in terms of the extra percentage of the variance explained), over and above the already known predictors, does physical activity provide?’ This analysis would require several key predictors to be included in the model as well as physical activity, and thus the sample size would need to be sufficient for this.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Declaration of competing interests:**

- I have no conflicts of interest.