Author's response to reviews

Title: Integrating Mobile health and Physical Activity to reduce the burden of Chronic low back pain Trial (IMPACT): a pilot trial protocol

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Author's response to reviews: see over
Dear Prof Ma. Luz De Guzman,

Please find the revised version of our article entitled “Integrating Mobile health and Physical Activity to reduce the burden of Chronic low back pain Trial (IMPACT): a pilot trial protocol” for publication at BMC Musculoskeletal Disorders.

The manuscript has been revised to address all comments received from the reviewers. We have provided a point by point response to each of the comments and have highlighted the changes to the original manuscript in yellow. We feel that these changes have strengthened the manuscript and we would like to thank you and the reviewers for the helpful comments.

Kind regards,

Anita Amorim

PhD candidate
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Comments by reviewer 1

Major Compulsory Revisions:

1. METHODS/Recruitment method, METHODS/Procedures, METHODS/Outcomes/Primary outcomes and Figure 1: Please correct discrepancies between these sections and Figure 1 to more clearly describe the study process. For instance, the Recruitment method text makes no reference to a phone call, as indicated in the figure. Also, there is no indication in the figure of when consent is obtained. Descriptions of weekly data collection for each of the groups are not clear in the text; and the Figure indicates SMS that is never mentioned in the text.

**Author’s response:** We thank the reviewer for raising this point. We have corrected the error in the figure as there will be no phone calls between the investigator and the potential participants before the baseline data collection. Treating physiotherapists will explain the study to their patients and the ones that show interest in participating in the study will receive the Participant Information Statement. A senior physiotherapist from Liverpool Hospital will be responsible for booking potential participants on their second last appointment to meet the investigator after discharge. We have deleted this information from the figure. To improve clarification we have changed this information in the text and now it reads:

Page 8, line 8: “Patients attending outpatient physiotherapy will be screened by their treating physiotherapists, who will determine eligibility, inform about the trial objectives and invite participation. The ones that manifest interest will be given the Participant Information Statement by their treating physiotherapist and decide if they want to participate in the study. A senior physiotherapist from Liverpool Hospital will be responsible for booking potential participants on their second to last appointment to meet the investigator after discharge. At discharge, patients that agree to participate will be asked to sign the consent form.”

Participants that agree in participating in the study will be asked to sign the consent form and complete the baseline questionnaires. We have included this information in the figure (see below):
Regarding the weekly data collection, we have included the following information in the manuscript to improve clarity:

Page 13, line 4: “The physical activity intervention group will receive a reminder every week through the web app with a brief questionnaire related to the primary outcomes. The standard care group will receive a SMS reminder every week with a link to the same questionnaire. Secondary outcomes will also be collected electronically at baseline, six and 12 months”.

2. METHODS/Interventions and Figure 1: Please update this section and/or Figure 1 to better align the summary of the Mobile Health Group intervention in Figure 1 with the description of the intervention components in the manuscript body. For example, the text describes “an individually tailored lifestyle modification plan developed with the advice of a health coach” that is not obvious in the figure. Also, while the 4 bulleted items are components of the intervention, they are not all components of the Home visit.

**Author’s response:** The authors agree with the reviewer’s comments and have now modified this section and figure 1. The Mobile Health Group is now described as the Physical Activity intervention group and we kept this term consistent in the text. We have also changed the figure to differentiate the components of the home visit and the follow up coaching phone calls.

*Figure (please see complete figure attached):*
Page 9, line 9: “The physical activity intervention group will also receive an individually patient-centred physical activity plan developed with the advice of a health coach. This new approach is based on a model of care used in a funded NHMRC trial combining physical activity promotion and fall prevention in older people (25) which is managed by co-investigator Tiedemann. The focus of the patient-centred physical activity will be on a gradual increase in physical activity where participants will be encouraged to devise fortnightly goals to suit and advance their physical activity levels.”

Page 9, line 20: “The intervention will address the following factors:

Health coaching: This will involve an initial individual face-to-face coaching session. The session can take up to 2 hours and it will be held at the participants’ home. The health coach will be an experienced physiotherapist with a health coaching certification. The aim of health coaching will be to motivate and support the participants to increase their physical activity levels.”

Page 10, line 4: “The World Health Organisation (WHO) guidelines addressing healthy adults recommend at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate- and vigorous-intensity activity. These recommendations relate not only to sports, but also to other leisure activities, work and transport activity.”

Page 10, line 19: “Goal-Setting: Goals are more effective when they are important to the individual (e.g., self-set rather than assigned), realistic, can be monitored, and when the participant receives positive encouragement (28). The health coach will jointly work with each participant to set short-term physical activity goals to be achieved fortnightly.”

Page 11, line 8: “After the first individual face-to-face coaching session, the health coach will contact each participant fortnightly to assess progress (12 phone calls over a six month period), update the participants’ short-term goals and assist in overcoming barriers – e.g. how to get back to exercise after illness, and provide problem-solving strategies for maintaining physical activity.”
3. METHODS/Interventions/paragraph 8 (re IMPACT web app): As written, it is difficult to understand exactly what the web app actually does and what the user’s experience is within the app. Please clarify.

**Author’s response:** We have now modified this paragraph to improve clarity.

Page 12, line 1: “The IMPACT web app: A mobile web app will be built and hosted by the University of Sydney. The app will be customised specifically for the purposes of this project to allow participants to monitor their goals and their physical activities. Participants will be able to access the app at any time and write reports about their physical activity related goals to their health coach as well as receive coach-tailored feedback. In addition, each participant will receive a quick questionnaire every week to monitor their pain levels, based on the Numerical Rating Scale; disability, based on the Rolland-Morris disability questionnaire and care-seeking associated with LBP. This questionnaire was created specifically to this project. The health coach will have the ability to view the participant’s report and communicate with them by phone fortnightly to discuss their goals and update them according to their reports and feedback. Personalised messages constructed by the health coach will be sent every week to encourage participants to achieve their goals. In summary, the IMPACT web app will be designed to facilitate monitoring achievement and providing updates on participants’ goals, encouraging them to engage in physical activity and track potential adverse events.”

4. METHODS/Outcomes/Primary outcomes section: Throughout this section, please clarify whether the data collection methods (via the IMPACT web app?) are used for both the intervention and control groups. If the control group’s data collection process will be different (perhaps via SMS, as suggested in Figure 1?), these methods need to be described in the text.

**Author’s response:** As suggested by the reviews we have now modified this paragraph to improve clarity.
Page 13, line 2: “Primary outcomes will be collected at baseline and weekly over a period of six months of intervention through an electronic questionnaire, created by the research team. The physical activity intervention group will receive a reminder every week through the web app with a brief questionnaire related to the primary outcomes. The standard care group will receive a SMS reminder every week with a link to the same questionnaire related to the primary outcomes. Secondary outcomes will also be collected electronically at baseline, six and 12 months. Both groups will fill out the same questionnaire through the same system. The electronic version of the baseline questionnaires and the weekly questionnaire were created by the research group and will be hosted by the University of Sydney.”

5. METHODS/Sample size calculation: Please add a brief justification for the “2-point difference between groups.” Is this a clinically meaningful difference? A difference based on previous similar interventions?

**Author’s response:** According to a study conducted by J. T. Farrar et al. (34), in a randomized controlled trial a raw change of 1.74 and a percent change of 27.9% on a 0–10 pain intensity scale is a clinically important improvement (35).
To improve clarification, we have included this information, and related reference, in the manuscript on page 15, line 17.


6. METHODS/Sample size calculation: On an important related note, unless the team is confident that a 2-point difference in pain scale ratings can be achieved with this intervention, the sample size may be too small to truly test the hypotheses.

**Author’s response:** As this is a pilot study, it will investigate the feasibility of conducting a randomized controlled trial (RCT) testing an innovative physical activity management strategy to prevent decline in clinical outcomes following conservative treatment for people with chronic LBP. Findings from this trial will inform on the feasibility, effect size and design of a large multi-centred RCT.

To improve clarity, we have included this information, and related reference, in the manuscript on page 15, line 23.

**Minor Essential Revisions**

1. **BACKGROUND, paragraph 5:** Two of the three parenthetic descriptors following “mHealth technology” are not technologies, but rather are behavior-change strategies that will be supported by the mobile technology. Consider dropping the parentheses and writing this sentence to more clearly distinguish between technologies that will be used and the strategies they aim to support.

**Author’s response:** The authors thank the reviewer for the suggestion and have re-written the paragraph:

Page 5, line 20: “Therefore, the primary aim of this RCT is to investigate the effect of a patient-centred physical activity intervention supported by health coaching and mHealth technology, including a mobile web app, tailored physical activity plan, goal setting, and feedback from affordable physical activity monitoring device (FitBit) in care-seeking pain and disability in people with chronic LBP.”

2. **ABSTRACT/Methods & Design and BACKGROUND, paragraph 5:** Please more carefully match the order, number and specific terms used to reference the primary outcomes throughout the manuscript to the details in the METHODS/Outcomes section. In the Abstract and paragraph 5 of Background, the text indicates that the primary outcomes are “incidence of flare up and
health care use” and “to reduce flare ups and health care use,” respectively. In the Outcomes section, the list of primary outcomes that are described in detail are: 1) Health care use associated with a flare up of LBP, 2) Pain levels, and 3) Disability.

**Author’s response:** We thank the reviewer for this comment. We have clarified that the primary outcomes are care-seeking associated with LBP, pain levels and disability. We kept this order and the terms consistent across the manuscript.

3. Please use consistent terminology throughout the manuscript to refer to the treatment intervention and its components. Currently there are a variety of phrases used in different sections, not all of which leave the same impression. (See the next item for one specific important instance.)

**Author’s response:** The authors agree with the reviewer and changed a few terms to keep the terminology consistent throughout the manuscript.

4. METHODS/Interventions: The subheading “Patient-centered physical activity plan” is inappropriate for the text that follows, which describes the health coaching component of the intervention, only one result of which may be an activity plan. On a related note, the first sentence in the 6th paragraph, beginning “This health coaching service…” could serve lead the description of the coaching component.

**Author’s response:** The authors agree with the reviewer and we have now changed the subheading “Patient-centred physical activity plan” to “Health coaching” on page 9, line 21. See answer 2 on major compulsory revisions.

5. METHODS/Interventions/paragraph 3. Goal-Setting: Consider rewording the sentence beginning, “Goals are more effective…” to more directly speak to how these elements are implemented in this intervention.
Author’s response: The authors thank the reviewer for the suggestion and we have now modified the paragraph accordingly on page 10, line 19. See answer 2 on major compulsory revisions.

6. METHODS/Interventions/paragraph 7 (re Fitbit): Suggest the following edit (or similar) to more accurately describe the limits of what the Fitbit tracker does: “The Fitbit is a personal accelerometer device designed to track physical activity and sleep.”

Author’s response: We have now included this sentence in paragraph 7.

Page 11, line 19: “The Fitbit is a personal accelerometer device designed to track physical activity and sleep.”

7. METHODS/Outcomes/1st paragraph: Is the “electronic survey” administered online? Is it also self-report?

Author’s response: The electronic survey is administered online and it is self-reported. We have now included this information:

Page 13, line 2: “Primary outcomes will be collected at baseline and weekly over a period of six months of intervention through an online, self-reported electronic questionnaire, created by the research team.”

8. METHODS/Procedures versus METHODS/Outcomes/Secondary outcomes/Physical activity: Please clarify the length of inactive period that will be used as a cut-point for “off time” or “non-wear time.” Procedures section indicates 60 minutes and Outcomes section indicates 90 minutes. It would also be helpful to standardize the terminology used across these two sections.

Author’s response: Thank you for identifying this discrepancy. We have now corrected the length of inactive period that will be used as a cut-point for “off time”, which will be 60 minutes. We have also standardized the terminology as “off-time” to improve clarification. See correction bellow:
Page 14, line 21: “Periods of 60-minutes or more of consecutive zeros (indicating non-use) will be considered as “off-time”.”

9. METHODS/Outcomes/Secondary outcomes/Physical activity: This section indicates that accelerometer data will be checked against “participant diaries/calendars,” which have not been mentioned previously in the manuscript. If this process is accurate, please indicate, where appropriate in the manuscript, when and how participants will be asked to keep diaries or calendars.

**Author’s response:** The authors agree with the reviewer’s comment. We have now included this information to improve clarification in the manuscript and it now reads:

*Page 14, line 22: “Participants will receive a diary to record all their activities on their waking hours during the seven days that they will be wearing the Actigraph.”*

10. METHODS/Outcomes/Secondary outcomes/Goal attainment: Please expand the description of this scale to better describe how a standardized scale will assess attainment of the 2 personal goals set by participants for this intervention.

**Author’s response:** The authors thank the reviewer for the suggestion and have included more details about the goal attainment scale.

*Page 15, line 04: “GAS is a method used to evaluate interventions according to the attainment of a number of participant-specific goals. In effect, each participant has his/her own outcome measure but this is scored in a standardised way to allow proper statistical analysis. Traditional standardised measures include a standard set of tasks (items) each rated on a standard level. In GAS, tasks are individually identified to suit the participant, and the levels are individually set around their current and expected levels of performance (33).”*
(33) Turner-Stokes PL. Goal Attainment Scaling (GAS) in Rehabilitation: A practical guide.

11.METHODS/Process evaluation: Clarify whether these interviews will be conducted with both treatment and control participants, which is currently implied, or just the treatment group participants.

Author’s response: The interviews will be conducted only with the physical activity intervention group (“treatment” group). We have now specifically stated this information in the manuscript.

Page 16, line 20: “Several face to face semi-structured interviews will be conducted with a minimum of 20 participants from the physical activity intervention group, at one and six months after study enrolment, in order to understand the experiences and attitudes of participants with regard to undertaking the intervention.”

Discretionary Revisions

12. BACKGROUND, paragraph 5: As written, the lead sentence indicates that “no studies have investigated the effectiveness of a physical activity intervention… on long-term outcomes in patients with chronic LBP,” which appears to be in conflict with the preceding paragraphs. It would be more accurate if rewritten to indicate that there are no studies of a post-treatment PA intervention consisting of mobile health and health coaching.

Author’s response: As suggested we have rewritten the sentence:

Page 5, line 18: “However, to the best of our knowledge, there are no studies of a post-treatment physical activity intervention consisting of mobile health and health coaching on long-term outcomes in patients with chronic LBP.”
13.METHODS/Recruitment method: Suggest reordering concepts in this paragraph to describe the linear process as potential recruits will follow it. For example, consider starting with “Treating physiotherapists from the outpatient…will screen (all) potential participants…”

**Author’s response:** As suggested we have rewritten the paragraph to improve clarification and it now reads:

Page 7, line 15: “Treating physiotherapists will screen (all) potential participants from the outpatient Physiotherapy Department of the Liverpool Hospital, South Western Sydney Local Health District, Australia, and inform them about the study. Potential participants interested in participating in the study will receive the Participant Information Statement and be referred to the research team. Patients with chronic LBP who have received any conservative physiotherapy treatment (e.g. exercises, spinal manipulative therapy) and meet the inclusion criteria will be invited to participate in the trial after treatment discharge. At treatment discharge, a research assistant will discuss the study and offer participation to those who meet the inclusion criteria. If they agree to participate a signed consent form will be recorded and baseline data will be collected.”

14.METHODS/Procedures: There are several seemingly gratuitous mentions of a blinded assessor prior to subjects having been assigned to a group. Perhaps the intent is to say that this person will remain blind to condition after group assignment?

**Author’s response:** We thank the reviewer for the comment. Yes, we intended to say that the assessor will remain blinded after group assignment. To improve clarification we have changed this information in the manuscript.

Page 9, line 5: “Data will be extracted by a research assistant who will remain blinded to group assignment throughout the trial.”
15. DISCUSSION, paragraph 1: The information in the sentence beginning “This new model of care is based…” also would be valuable earlier in the manuscript, perhaps in the section describing the intervention.

Author’s response: The authors thank the reviewer for the suggestion. We have now included this information in the METHODS/Intervention section and it now reads:

Page 9, line 11: “This new approach is based on a model of care used in a funded Australia-NHMRC trial combining physical activity promotion and fall prevention in older people (37) which is managed by co-investigator Tiedemann.”

Minor Issues Not for Publication

1. METHODS/Participants: Missing the term “booklet” after “advice” in the intervention description.

Author’s response: We have now added the missing term in the text.

Page 6, line 20: “Consenting participants will be randomly allocated to either the physical activity intervention group (n=34) and receive a patient-centred physical activity promotion program involving health coaching, mHealth tools and advice booklet, or to a standard care group (n=34) who will receive an advice booklet only.”

2. METHODS/Interventions/paragraph 3. Goal-Setting: Suggest “to set short-term physical activity goals to be achieved fortnightly.” Physical activity should not be relegated to a parenthetic comment.

Author’s response: The authors thank the reviewer for the suggestion. We have rewritten the sentence and it can be found on page 10, line 22. Please see answer 2 on major compulsory revisions.

3. METHODS/Interventions/paragraph 7 (re Fitbit): Suggest adding “during the initial visit” after “…by the health coach”. 
**Author’s response:** We have modified the sentence accordingly.

Page 11, line 15: “The Fitbit activity monitor and feedback device: The activity monitoring device will be provided to the participant by the health coach during the initial visit who will also demonstrate its use.”

4. METHODS/Interventions/paragraph 8 (re IMPACT web app): Unless the text in this section is referring to a proprietary or trademarked name, the capitalization and spacing conventions on “WebApp” are unusual. The term “web app” appears to be more appropriate.

**Author’s response:** We have now corrected the term “WebApp” to “web app” in the manuscript.

5. METHODS/Interventions/paragraph 8 (re IMPACT web app): May want to add the term “coach-tailored” before the phrase “…feedback on their physical activity goals.”

**Author’s response:** We have now included this information in the sentence and it now reads:

Page 12, line 9: “Participants will be able to access the app at any time and write reports about their physical activity related goals to their health coach as well as receive coach-tailored feedback.”

6. DISCUSSION, paragraph 1: Suggest changing “translated to a broader general population” to “translated to a younger population”

**Author’s response:** Thank you for rising this point. As the translation will be mainly to a different population (LBP) instead of an “at-risk for falls” population we changed this sentence to reflect this and it now reads:
Page 18, line 6: “This is an innovative approach of translating knowledge from other health fields and a successful model will be translated to a population recovering from LBP that seeks care through public and health private systems.”

Comments by reviewer 2

Major compulsory revisions:

1. Background: There is a lack of information concerning the normal clinical course of LBP. In fact, we know that most LBP runs a recurrent or persistent course through life, and that full recovery is unlikely. See the work of Dunn, Kongsted, Macedo, Downie, and Chen. The problem is rather that patients and clinicians may not be aware of this, and work according to the hypothesis that the pain will be cured. This results in the following questions:

   - Will your booklet also contain information regarding the nature of LBP?
   - Will your subjects’ individual goals be set with this in mind?

   **Author’s response:** The authors agree with the reviewer’s comments regarding the poor awareness of patients and clinicians of the normal clinical course of LBP. In fact, research has shown that many LBP patients still have high levels of pain and/or disability up to 12 months after one episode. To improve clarity, we have included this information:

   Page 4, line 9: “The clinical course of LBP is intricate. Over a 1-year after discharge from treatment, most patients will still have pain for a sustained period, and a small proportion will still have persistent severe pain (4, 5).”

The main focus of our study is to investigate how physical activity can prevent clinical decline in patients who have received the benefits of conservative treatment for chronic LBP, empowering them to self-manage their LBP as well as to prevent back pain recurrence and reduce care seeking. Although the booklet will not contain information regarding the nature of LBP, but only information regarding the importance and benefits of physical activity, the health coaching session will involve education regarding the nature of LBP and its normal clinical course. Participants’ individual goals will be set taking this into consideration.

To improve clarification we have included this information in the manuscript on page 11, line 3: “The participants’ individual goals will be set taking into consideration the nature of LBP and its normal clinical course.”

2. I am not sure about your statement that patient disappointment with LBP flare-ups leads to costly, invasive procedures. The reference you provide to support that statement (reference 5) is not a study designed to test that. Rather, the main economic burden from chronic LBP stems from sickness absence and productivity loss. There are numerous research articles that have studied costs, see for instance Woolf, Gustavsson, Juniper and Dagenais.

**Author’s response:** We acknowledge that the reference provided is not a study design to test costs related to LBP reoccurrence. As suggested by the reviewer, we have excluded the information about invasive procedures in the paragraph and we have provided a new reference to support our statement. The paragraph now reads:

Page 4, line 11: “Although randomised controlled trials (RCT) investigating the efficacy of conservative interventions for chronic LBP have found improvements in pain and disability, patients usually exhibit a rapid decline in clinical outcomes, 3 months after treatment discharge (6, 7). These patients are likely to have a new episode of LBP or continual pain and therefore seek additional health care (8).”

3. Methods: I am not clear on who your target group of patients is. You state that they have been discharged from physiotherapy. Does that mean that they are considered well or that they are “hopeless” cases? Further, as the economic burden of LBP is associated with sickness absence, are these patients sick-listed or working? Are you going to measure this variable in the study?

Author’s response: For this study, our target group is chronic low back pain patients, which means patients with pain that persists for 12 weeks or longer, with no spinal pathology who have had recurrent episodes and are being discharged from a hospital program. Discharges are based on clinicians’ judgement of recovery and clinical status. This targeted group are likely to return to the health care system requiring additional physiotherapy several times. Those patients usually have additional psychosocial components, such as poor quality of life, low activity levels and deficient sleep quality. We will not include patients who will be referred to other treatment centres or specialized clinics after being discharged by their physiotherapists. Although the economic burden of LBP is associated with sickness absence, we are not measuring this variable in our study. The patients included in our study can be either sick-listed or working. To improve clarity, the statement below has been added to the manuscript:

Page 7, line 1: “Inclusion criteria: Adults over 18 years of age with chronic LBP persisting for over 12 weeks but without radicular symptoms; who have been discharged from a hospital-based, LBP physiotherapy program but still have consistent pain (at least 3 in the Numerical Rating Scale).”

4. I welcome a clearer description of the IMPACT WebApp. Apparently, it is not yet built, and it is important to have users’ input into the design and user-friendliness of such a product. It is not clear to me if participants access the App at their own leisure, or if the App has a system of
reminding and asking for information. (For instance, the weekly NRS and RDQ measures). The difference in compliance and the success of the intervention could rely heavily on the amount of data entered via the App, and the ability of the system to respond, prompt and remind. Please describe how the outcomes will be collected. Weekly measurements will be collected electronically, but through what system? Secondary outcomes are not mentioned concerning mode (paper, interview, electronically) nor system. You also mention diaries/calendars – is this in paper form to be filled in also, aside from the App information? Finally, are the interviews individual or group interviews?

Author’s response: The Impact App is at the final stage of its development. The participants will be able to access the App at anytime they want, but they will also receive a weekly reminder asking about their LBP status based on the NRS and RDQ measures. The weekly measures will be collected electronically through a survey linked to the University of Sydney. At the end of every week, each participant will receive a link in their smartphone with the questions related to the outcomes. Secondary outcomes will also be collected electronically through the same system created specifically to this project, however those outcomes will be collected in the presence of an investigator using a study tablet (Ipad). An interactive calendar will be part of the app. Participants will be able to include day and time of the activities and goals that they have set with the health coach. Each participant will have one individual face-to-face session with the health coach and 12 follow-up individual phone calls over the study. To improve clarity, the statement below has been added to the manuscript:

Page 12, line 11: “In addition, each participant will receive a quick questionnaire every week to monitor their pain levels, based on the Numerical Rating Scale; disability, based on the Rolland-Morris disability questionnaire and care-seeking associated with LBP. This questionnaire was created specifically to this project”

Page 13, line 6: “Primary outcomes will be collected at baseline and weekly over a period of six months of intervention through an online, self-reported electronic questionnaire, created by the research team. The physical activity intervention group will receive a reminder every week through the web app with a brief questionnaire related to
the primary outcomes. The standard care group will receive a SMS reminder every week with a link to the same questionnaire. Secondary outcomes will also be collected electronically at baseline, six and 12 months. Both groups will fill out the same questionnaire through the same system. The electronic version of the baseline questionnaires and the weekly questionnaire were created by the research group and will be hosted by the University of Sydney.”

Page 10, line 1: “This will involve an initial individual face-to-face coaching session. The session can take up to 2 hours and it will be held at the participants’ home.”

Page 11, line 11: “After the first individual face-to-face coaching session, the health coach will contact each participant fortnightly (12 phone calls over a six month period each participant) to assess progress, update the participants’ short-term goals and assist in overcoming barriers – e.g. how to get back to exercise after illness, and provide problem-solving strategies for maintaining physical activity”

5. Discussion: You use some terms that I think should be introduced already in the background: first, you mention “prevention of clinical decline and recurrence”. I think this is really your aim, to minimise deterioration (tertiary prevention) and recurrence (secondary prevention). These fit well with my suggestion above to talk about the persistent and recurrent clinical course of LBP. Second, you state that the aim is to empower patients, which you did not mention in the background. I think this is also a consequence of learning to deal with a condition that is life-long.

Author’s response: The authors agree with the reviewer’s comments and have now included the suggestions above in the background.

Page 6, line 2: “We hypothesise that the use of a patient-centred physical activity intervention will prevent clinical decline in patients who have received the benefits of conservative treatment
for chronic LBP, empowering them to self-manage their LBP as well as to prevent worsening of LBP and reduce care seeking.”

Minor essential revisions:

4. Title: I think it is unfortunate to use the abbreviation IMPACT, as this may easily be confused with that of the IMMPACT recommendations of reporting outcomes from clinical trials.

   **Author’s response:** Yes, we acknowledge that the abbreviation IMPACT could be confused with the IMMPACT recommendations, however, our trial has been funded with this abbreviation.

5. Background: I think there is an implicit (as you are gathering information about BMI) as well as an explicit association (reference 6) between obesity and LBP in the text, which I am not sure is evidence-based. In the referenced report by the WHO, they are not connecting the two. A reference should thus be provided to support this association.

   **Author’s response:** We agree with the reviewer that there is not an evidence-based association between obesity and low back pain. Our research group has recently published a systematic review supporting the idea that although obesity is commonly reported to be a risk factor for LBP, a direct causal relationship between obesity and LBP cannot be confirmed (9). However, the authors aim to gather as much information as they can to further investigate possible association between different cofounders and low back pain, such as BMI. However, we are not implicating an association between obesity and LBP.

6. Methods: The patient-centred physical activity plan is somewhat confused with “healthier lifestyle”, these are not the same. You also state that you will encourage a gradual increase in physical activity. This presumes that the level is already low, or that it is always possible to increase. There should be a target level (evidence-based) incorporated into the individual goals.

**Author’s response:** The authors agree that the patient-centred physical activity plan is somewhat confused with “healthier lifestyle”. To clarify we have maintained the same term “patient-centred physical activity plan” instead of using “lifestyle modification. In addition, we have included information about recommended physical activity levels as showed below:

Page 9, line 12: “The physical activity intervention group will also receive an individualised patient-centred physical activity plan developed with the advice of a health coach. The focus of the patient-centred physical activity will be on a gradual increase in physical activity where participants will be encouraged to devise fortnightly goals to suit and advance their physical activity levels. This intervention will be supported by the use of mHealth, which will include a specifically designed mobile web application (web app) and a physical activity monitoring device (FitBit).”

It is well described in the literature that LBP is a very common problem that most people experience at some point in their life. Most people with chronic LBP will have some level of disability or activity limitation and therefore low levels of physical activity.

The individuals’ goals will be set following the World Health Organisation (WHO) guidelines which recommends at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate- and vigorous-intensity activity. These recommendations relate not only to sports, but also to other leisure activities, work and transport activity [7]. The plan will be tailored to each participant’s physical activity level that will be objectively measured with the Actigraph at baseline.

To improve clarity we have included this information in the manuscript:
Page 10, line 4: “The World Health Organisation (WHO) guidelines addressing healthy adults recommend at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate- and vigorous-intensity activity. These recommendations relate not only to sports, but also to other leisure activities, work and transport activity (11).”


7. The manpower needed to run the system is not well described. If participants are to receive feedback and even contact their coach, it is not clear to me what their level of engagement will be. Will it be possible to communicate during normal working hours only? Will the coaches be able to make contact with a participant that is clearly “off course”? Will this require manual surveillance or will features like this be built into the system?

Author’s response: The health coach will be responsible for creating feedback responses related to the participants’ goals. The aim is to create feedback messages that are personalised for each participant. Those messages will be built into the system and sent every week to encourage participants towards achieving their goals. The health coach will contact participants by phone every two weeks in the time that they have arranged in the first session, which will be within the coach working hours. During the follow-up phone calls the coach will be able to discuss with participants how they are progressing in relation to their goals. Although the focus of the interaction between the coach and participants is not on symptom monitoring, if significant clinical decline (e.g. participants’ reports of nerve root compromise) is observed, coaches will advise participants to seek appropriate treatment. If participants do not answer the weekly survey they will receive a reminder after that week asking for completion of the survey. If they do not answer they will receive a message asking when the coach can get in touch with them again.

To improve clarification we have included this information in the manuscript:
Page 11, line 1: “The participants’ individual goals will be set taking into consideration the nature of LBP and its normal clinical course. Although the focus of the interaction between the coach and participants is not on symptom monitoring, if significant clinical decline (e.g. participants’ reports of nerve root compromise) is observed, coaches will advise participants to seek appropriate treatment.”

Page 12, line 12: “The health coach will have the ability to view the participant’s report and communicate with them by phone calls fortnightly to discuss their goals and update them according to their reports and feedback.”

Discussion: Finally, I wonder if you are going to look at costs. It would be interesting to look at development costs for the App (and later: costs for updating), and the costs of coaches previously mentioned.

Author’s response: The authors thank the reviewer for raising this point. The economic evaluation would take the perspective of the health care funder, and would include benefits measured in terms of health care prevented. Data will be collected on the cost to deliver the intervention program (staff costs, training, capital costs and consumables). Detailed supplementary data on costs of health care use will be collected by the investigators to assist accurate costing of different types of health care use.

We are using the funding from the Medibank grant to develop the web app system and will not require further funding to use the system. So if proven to be effective, this web app can be used in larger trials and extended to a broader population without further costs. Furthermore, as mentioned in the manuscript “This health coaching service will be modelled after the successful (19) NSW Ministry of Health initiative Get Healthy service”, which is a free service provided by the Australian government.