PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Promoting Physical Activity in Regional and Remote Cancer Survivors (PPARCS) using Wearables and health-coaching: Randomised Controlled Trial protocol
AUTHORS	Hardcastle, Sarah; Hince, Dana; Jimenez-Castuera, Ruth; Boyle, Terry; Cavalheri, Vinicius; Makin, Greg; Tan, Patrick; Salfinger, Stuart; Tan, Jason; Mohan, Raj Ganendra; Levitt, Michael; Cohen, Paul; Saunders, Christobel; Platell, Cameron

VERSION 1 - REVIEW

REVIEWER	Ian Lahart University of Wolverhampton, UK
REVIEW RETURNED	04-Jan-2019

GENERAL COMMENTS	The protocol was well written and the experiment was well considered and planned. Please find my comments attached. My main concerns are the labelling of primary and secondary outcomes, and the appropriateness of the sample size calculation. Best wishes, Ian Consider use of word “significantly” to avoid confusion between “statistical” and “clinical” significance. (Abstract, pg 2 line 2) Define WA (Abstract, pg 2, line 8) What does “insufficiently active” mean? Insufficiently active to meet recommended guidelines, or insufficiently active to obtain benefits? (pg 2, line 4) I am assuming the objective is to increase PA and reduce SB to improve quality of life, rather than looking at the three independently (which is the way it is state here)? I think this is important, as I assume you want to link PA and SB to quality of life? Are these all primary outcomes, that is have all these been included in the power calculations? (pg 2, line 6-8) Pg 2, line 9, amend the grammar in this sentence; make clear that 94 cancer survivors will be randomised into either intervention or control (i.e., 47 in each group). Waist circumference, and psychological variables have also been assessed, are these not trial outcomes too? (Pg 2, line 11) Pg 3 line 17. Are these guidelines not for “moderate-to-vigorous PA”?

	Pg 3 line 24. Define what you mean by “insufficiently active”. Pg 4, line 7. Consider use of word “significantly” to avoid confusion between “statistical” and “clinical” significance. Given the nature of the intervention, I think the issues identified in this review should be acknowledged (e.g., the smaller increases in PA achieved in these interventions) https://www.researchgate.net/publication/326537416_Systematic_review_and_meta-analysis_of_broad-reach_physical_activity_interventions_for_cancer_survivors_2013-2018_We_still_haven%27t_found_what_we%27re_looking_for Pg 5 line 13. Please consider rewording: these are either your primary objectives—plural—or you are treating these three outcomes as one. Pg 5 line 20-pg 6 line 1. Sedentary behaviour appears to be missing from this list. Please consider the COMET guidelines for patient reported outcomes, including your choice of quality of life measure: http://www.comet-initiative.org/studies/details/856 Pg 8 line 14. Provide the week numbers that patients will wear the actigraph for assessments. Pg 12 line 7. Consider how you will monitor and report adverse events (see: http://www.consort-statement.org/extensions/overview/harms) Pg 12 line 12-19. This is the first mention of what the primary outcome is. This should be clear throughout the manuscript. If MVPA change is the primary outcome, then all other measures become secondary outcomes. The power calculation appears to be based on a t-test of change values; however, the proposed analysis is linear mixed model analysis. This means the trial will not be powered for the proposed statistical analysis. Therefore, you must power the trial specifically to the proposed analysis. Pg 16 line 15-17. The use of so many covariates will inflate the sample size needed (see above). Pg 16 line 18: sedentary behaviour, psychological variables, and (I assume) the other PA variables. Pg 17 line 3. Has the sedentary behaviour outcome been purposefully excluded from the mediation analysis? Pg 17 line 3. I have little experience of this analysis, but would using a Generalized Estimating Equations approach be beneficial when looking at the influence of the various components of the HAPA approach on MVPA?

REVIEWER	Jessica McNeil Department of Cancer Epidemiology and Prevention Research, Alberta Health Services, Canada
REVIEW RETURNED	23-Jan-2019

GENERAL COMMENTS	This protocol describes a randomized controlled trial aimed at comparing a physical activity intervention that combined the use of a commercially-available activity tracker (Fitbit) with behaviour change techniques in cancer survivors who live in rural areas of Australia. This is an interesting protocol that would certainly add to current literature on the use and efficacy of activity trackers to promote physical activity behaviour change, especially in individuals living in rural areas who may not have easy access to training facilities or resources. However, some sections of the methods could be moved to facilitate the flow of this paper and

	understanding the procedures of this trial. For instance, the procedures and description of the intervention should be presented prior to describing the outcome measurements, and patient and public involvement. In my opinion, it is important to understand how the trial will be conducted prior to describing the tools that will be used to conduct the various measurements. Additional comments are provided for your consideration. Abstract: Lines 3-4: Please indicate a proportion or percentage of breast cancer survivors who are insufficiently active. Line 8: Please define the acronym WA. Line 9: Please correct this statement by stating “ninety-four cancer survivors will be randomized to the intervention and control groups”. Lines 11-12: Please specify how these outcome variables will be measured. Line 12: What do the 12- and 24-week time points represent (e.g. end of intervention, end of follow-up?) Please specify. Introduction: Page 3, Line 15: If reference 3 refers to a study conducted in cancer survivors, then these individuals would be at an increased risk of developing second cancers. Please amend this statement accordingly. Also, please remove the term “both” since the authors mention more than two chronic conditions in this sentence. Page 4, Line 22: The design of an intervention that targets individuals living in rural areas is also a novel component in this study, especially as it relates to testing the efficacy of home-based interventions. Please mention this novel component of the study in this statement. Page 5, lines 13-15: Are these all primary study outcomes? If not, please specify which are primary and secondary study outcomes. Methods: Page 9, lines 1-2: Please specify whether or not participants will be asked to wear the accelerometer overnight/during sleep? Page 8 (primary outcomes): Will the accelerometer be mailed to the participants for data collection? If not, will they have to come to the testing facilities to obtain the accelerometer and return it)? If they have to go into the testing facilities, please specify how often and for what length of time, as this may impact the recruitment and time commitment of participants to this study, especially since it targets cancer survivors living in rural areas. The Procedure section should be placed prior to the description of study outcomes/after the section on recruitment. There is no mention of waist circumference measurements under the description of study outcomes (only in the Procedures section). Please amend. Page 12, line 6: please describe what is meant by “receive minimal intervention to mimic usual care”. The intervention section should be moved prior to the Procedures section/after the description of study participants and recruitment strategies. Will components of the intervention (either through the use of the Fitbit or behaviour change techniques) put emphasis on reducing sedentary behaviour? Page 13: Will data from the Fitbit device be used to track adherence and compliance with the intervention? Will compliance be verified during the 6 follow-up calls? If so, how will this be done? Tracking the objective physical activity and sedentary time data, as well as compliance with using the activity tracker, would provide novel and valuable information on the efficacy of using

	these types of activity tracker to promote physical activity behavior change. Page 13, lines 14-16: This is true, however, some of these activity tracker applications do offer “group chats and challenges” which could be optimized in a home-based intervention. Some of these platforms offered by the applications could be utilized in this type of trial. Page 13, lines 23-24: How will the need for additional health coaching sessions be determined? Will this be based on compliance data from the activity tracker or the participants may simply request additional sessions during a previous follow-up call? It would be interesting to look at how many participants do request additional sessions and whether this helped improve compliance and PA measures. This could also be used to inform the number of follow-up calls or coaching sessions that may be needed for this type of home-based intervention. Do participants have to return the Fitbit to the study team at the end of the 24-week period? Page 16, line 17: Please define the covariate “intervention dose”. Is this the amount of PA that is measured by the Fitbit during the intervention? Figure 1: Could you please add the number of letters that you would expect to mail given the targeted sample size?

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Ian Lahart

Institution and Country: University of Wolverhampton, UK Please state any competing interests or state ‘None declared’: None declared

The protocol was well written and the experiment was well considered and planned. Please find my comments attached. My main concerns are the labelling of primary and secondary outcomes, and the appropriateness of the sample size calculation.

Best wishes,

Ian

AUTHORS’ RESPONSE:

MANY THANKS IAN FOR YOUR HELPFUL FEEDBACK AND POSITIVE EVALUATION OF OUR TRIAL.

Consider use of word “significantly” to avoid confusion between “statistical” and “clinical”

significance. (Abstract, pg 2 line 2)

AUTHORS’ RESPONSE:

THANKS FOR THE SUGGESTION. WE HAVE REPLACED THE WORD ‘SIGNIFICANTLY’ WITH ‘SUBSTANTIALLY’ TO AVOID CONFUSION.

Define WA (Abstract, pg 2, line 8)

AUTHORS' RESPONSE:

WE APOLOGISE FOR THE OMISSION. WA REFERS TO WESTERN AUSTRALIA AND WE HAVE DEFINED AS SUCH IN THE REVISION.

What does "insufficiently active" mean? Insufficiently active to meet recommended guidelines, or insufficiently active to obtain benefits? (pg 2, line 4)

AUTHORS' RESPONSE:

INSUFFICIENTLY ACTIVE REFERS TO THOSE FAILING TO MEET THE RECOMMENDED GUIDELINES. WE HAVE REVISED TO IMPROVE CLARITY AS FOLLOWS: "not meeting the physical activity guidelines" (PAGE 2, LINE 4)

I am assuming the objective is to increase PA and reduce SB to improve quality of life, rather than looking at the three independently (which is the way it is state here)? I think this is important, as I assume you want to link PA and SB to quality of life? Are these all primary outcomes, that is have all these been included in the power calculations? (pg 2, line 6-8)

AUTHORS' RESPONSE:

MANY THANKS FOR NOTING THE INACCURATE WORDING OF THE OBJECTIVES. THE OBJECTIVE IS TO INCREASE PA AND REDUCE SEDENTARY BEHAVIOUR TO IMPROVE QUALITY OF LIFE. WE HAVE CLARIFIED THIS IN THE REVISION AS FOLLOWS:

"The primary objective of the trial is to increase moderate-to-vigorous PA (MVPA) among cancer survivors living in regional and remote Western Australia (WA). Secondary objectives are to reduce sedentary behaviour and in conjunction with increased PA, improve quality of life in non-metropolitan survivors. Tertiary objectives are to assess the effectiveness of the Health Action Process Approach Model (HAPA) variables, upon which the intervention is based, to predict change in MVPA" (PAGE 2, LINES 7-13)

Pg 2, line 9, amend the grammar in this sentence; make clear that 94 cancer survivors will be randomised into either intervention or control (i.e., 47 in each group).

AUTHORS' RESPONSE:

THANK YOU FOR PICKING UP ON THIS AWKWARDLY WORDED SENTENCE. WE HAVE AMENDED AS FOLLOWS: "Eighty-six cancer survivors will be randomized into either the intervention or control group" (PAGE 2, LINES 13-14).

Waist circumference, and psychological variables have also been assessed, are these not trial outcomes too? (Pg 2, line 11)

AUTHORS' RESPONSE:

WE HAVE REMOVED WAIST CIRCUMFERENCE FROM THE PAPER. ITS INCLUSION WAS A MISTAKE. WE AGREE THAT PSYCHOLOGICAL VARIABLES ARE TRIAL OUTCOMES RELATED TO OUR THIRD OBJECTIVE, TO ASSESS THE EFFECTIVENESS OF THE HEALTH ACTION PROCESS APPROACH MODEL, UPON WHICH THE INTERVENTION IS BASED, TO PREDICT

CHANGE IN PHYSICAL ACTIVITY. WE HAVE INCLUDED THIS TERTIARY OBJECTIVE IN THE REVISION:

“Tertiary objectives are to assess the effectiveness of the Health Action Process Approach Model (HAPA) variables, upon which the intervention is based, to predict change in physical activity” (PAGE 2, LINE 13)

Pg 3 line 17. Are these guidelines not for “moderate-to-vigorous PA”?

AUTHORS’ RESPONSE:

THE GUIDELINES ARE FOR MODERATE-TO-VIGOROUS PA. WE HAVE AMENDED ACCORDINGLY.

Pg 3 line 24. Define what you mean by “insufficiently active”.

AUTHORS’ RESPONSE:

OUR USE OF THE TERM ‘INSUFFICIENTLY ACTIVE’ REFERS TO THOSE WHO ARE NOT MEETING THE MODERATE-TO-VIGOROUS PA GUIDELINES. WE HAVE DEFINED THIS IN THE REVISED MANUSCRIPT AS FOLLOWS: “insufficiently active survivors (i.e., those not meeting the PA guidelines)” (page 4, line 2-3).

Pg 4, line 7. Consider use of word “significantly” to avoid confusion between “statistical” and

“clinical” significance.

AUTHORS’ RESPONSE:

THANKS FOR THE SUGGESTION. WE HAVE REPLACED THE WORD ‘SIGNIFICANTLY’ WITH ‘SUBSTANTIALLY’ TO AVOID CONFUSION.

Given the nature of the intervention, I think the issues identified in this review should be

acknowledged (e.g., the smaller increases in PA achieved in these interventions)

https://www.researchgate.net/publication/326537416_Systematic_review_and_metaanalysis_

of_broad-reach_physical_activity_interventions_for_cancer_survivors_2013-

2018_We_still_haven%27t_found_what_we%27re_looking_for

AUTHORS’ RESPONSE:

MANY THANKS FOR THE SUGGESTION. WE HAVE INCLUDED REFERENCE TO THE REVIEW IN OUR REVISION REGARDING THE SMALL EFFECT FOUND FOR MVPA IN DISTANCE-BASED INTERVENTIONS. IN SUPPORT OF OUR STUDY, WE HAVE ALSO HIGHLIGHTED THAT FEW STUDIES IN THE REVIEW (N=3) HAVE USED OBJECTIVE MEASURES OF MVPA (IE, ACCELEROMETERS) OR USED ELECTRONIC HEALTH PLATFORMS OR SMART TECHNOLOGY IN THEIR INTERVENTIONS, SUCH AS WEARABLES:

“Notwithstanding the obvious advantages of home-based interventions, a recent review and meta-analysis revealed only a small effect (standardized mean difference) 0.21 for distance-based PA interventions [18]. However, most of the studies included in the review relied on self-reported PA. Further, most interventions predominantly utilized print and telephone modes of delivery. Few interventions used electronic health platforms or smart technology such as wearables. Distance-based interventions in survivors that utilize wearables show promise with a recent trial revealing a

between group difference in MVPA of 103-minutes/week favoring the intervention group [19]" (PAGE 5, LINES 5-12).

Pg 5 line 13. Please consider rewording: these are either your primary objectives—plural—or you are

treating these three outcomes as one.

AUTHORS' RESPONSE:

MANY THANKS FOR THE SUGGESTION. THE PRIMARY AIM IS TO INCREASE PA. WE HAVE AMENDED THE AIMS ACCORDINGLY:

"The primary aim of the study is to increase PA in adult cancer survivors residing in regional and remote areas in Australia. Secondary objectives are to reduce sedentary behavior and in conjunction with increased PA, improve quality of life in non-metropolitan survivors. Tertiary objectives are to assess the effectiveness of the Health Action Process Approach Model (HAPA) variables, upon which the intervention is based, to predict change in physical activity" (page 6, lines 1-6)

Pg 5 line 20-pg 6 line 1. Sedentary behaviour appears to be missing from this list.

AUTHORS' RESPONSE:

THANK YOU FOR NOTING THE OMISSION. WE HAVE INCLUDED SEDENTARY BEHAVIOUR IN THE LIST (PAGE 6, LINE 12).

Please consider the COMET guidelines for patient reported outcomes, including your choice of

quality of life measure: http://www.comet-initiative.org/studies/details/856

AUTHORS' RESPONSE:

MANY THANKS FOR SHARING THE COMET GUIDELINES FOR PATIENT REPORTED OUTCOMES. IN ORDER TO FACILITATE COMPARISON WITH OTHER STUDIES, WE AGREE WITH THE PRINCIPLE OF ADOPTING A STANDARDISED SET OF OUTCOMES IN CLINICAL TRIALS. THEREFORE, WE WILL ASSESS COMBORDITIES USING THE VALIDATED SELF-ADMINISTERED COMBORDITY QUESTIONNAIRE (SCQ): "Comorbidity will be assessed using the self-administered comorbidity questionnaire [Sangha et al 2003]" (Page 14, line 18-19). IN LIGHT OF COMET AND THE EORTC GUIDELINES, WE WILL ALSO USE THE QLQ-C30 CANCER HEALTH-RELATED QUALITY-OF-LIFE QUESTIONNAIRE TO ASSESS QUALITY OF LIFE RATHER THAN THE SF-12. WE HAVE REVISED THE TEXT IN RELATION TO QUALITY OF LIFE AS FOLLOWS:

"Quality of life will be measured using the European Organization for Research and Treatment of Cancer, QoL Core Questionnaire (EORTC QLQ-C30) [38] The QLQ-C30 is a feasible, reliable and a valid questionnaire and is used in clinical trials of cancer worldwide [38-40]. It includes five function domains (physical, emotional, social, role, cognitive), eight symptoms (e.g., fatigue, pain) in addition to global health/quality of life" (PAGE 13, LINES 7-11).

Pg 8 line 14. Provide the week numbers that patients will wear the actigraph for assessments.

AUTHORS' RESPONSE:

WE HAVE INCLUDED THE WEEK NUMBERS THAT PATIENTS WILL WEAR THE ACTIGRAPHS FOR ASSESSMENTS: "Participants will wear the accelerometer on their right hip for all waking hours for one week at baseline, 12-weeks and 24-weeks" (PAGE 12, LINE 17).

Pg 12 line 7. Consider how you will monitor and report adverse events (see: http://www.consortstatement.org/extensions/overview/harms)

AUTHORS' RESPONSE:

THANKS FOR RAISING THIS POINT. WE WILL SET UP A TRIAL MANAGEMENT GROUP TO OVERSEE, MONITOR AND REPORT ADVERSE EVENTS. WE HAVE INCLUDED THE FOLLOWING TEXT IN THE REVISION TO EXPLAIN SUCH MONITORING AND REPORTING:

"The trial will be overseen by the trial management group, consisting the principal investigator, the trial-coordinator and health coach. The trial management group will oversee all aspects of the conduct of the trial including performing safety oversight activities and will meet every 4-weeks. Any significant adverse events will be reported to the HREC within 72-hours, and managed by the HREC alongside the principal investigator (SH). The principal investigator will keep an audit trail and maintain responsibility for the trial including conduct and management of the trial" (PAGE 16, LINES 7-13)

Pg 12 line 12-19. This is the first mention of what the primary outcome is. This should be clear

throughout the manuscript. If MVPA change is the primary outcome, then all other measures

become secondary outcomes.

AUTHORS' RESPONSE:

MANY THANKS FOR THE HELPFUL FEEDBACK. WE HAVE AMENDED THROUGHOUT THE MANUSCRIPT TO ENSURE CLARITY THAT CHANGE IN MVPA IS THE PRIMARY OUTCOME AND ALL OTHER MEASURES ARE SECONDARY OUTCOMES.

The power calculation appears to be based on a t-test of change values; however, the proposed analysis is linear mixed model analysis. This means the trial will not be powered for the proposed statistical analysis. Therefore, you must power the trial specifically to the proposed analysis.

AUTHORS' RESPONSE:

WE THANK THE REVIEWER FOR POINTING THIS OUT. AS WE INTEND TO USE THE INTERACTION TERM FROM THE LINEAR MIXED MODEL TO TEST OUR PRIMARY AIM, WE HAVE NOW CALCULATED THE REQUIRED SAMPLE SIZE BASED ON THE COVARIANCE MATRIX FOR MVPA FROM THE WEARABLE ACTIVITY TECHNOLOGY AND ACTION-PLANNING TRIAL (WATAAP; MANUSCRIPT UNDER REVISIONS) AND AN ASSUMED CHANGE OF 70 MINUTES IN THE INTERVENTION GROUP AND 0 MINUTES IN THE CONTROL GROUP. WE WILL REQUIRE 86 PARTICIPANTS TO DETECT THIS EFFECT WITH 80% POWER AND ALPHA 0.05. WE HAVE CHANGED THE TEXT ON POWER CALCULATIONS IN THE REVISION AS FOLLOWS:

"The primary outcome is change in MVPA at T2. A sample size of 86 participants (43 in each arm) is required in order to achieve 80% power to detect a group (control v intervention) by time (T1 v T2) interaction at 0.05 level. Our calculations are based on the covariance matrix from a previous wearable-technology trial in survivors using accelerometers to assess MVPA [49] assuming a 70-minute increase in MVPA at T2 in the intervention group, but no change in the control arm." (PAGE 14, LINE 22 onwards).

Pg 16 line 15-17. The use of so many covariates will inflate the sample size needed (see above).

AUTHORS' RESPONSE:

WE THANK THE REVIEWER FOR BRINGING THIS TO OUR ATTENTION. THE SENTENCE WAS AMBIGUOUSLY WORDED. THE ADDITION OF COVARIATES TO THE MODEL IS NOT PLANNED AS PART OF THE PRIMARY ANALYSIS. WE INTEND TO CONSIDER ANY IMPACT COVARIATES MAY HAVE ON THE OBSERVED GROUP BY TIME INTERACTION, IN ORDER TO INFORM OUR

INTERPRETATION OF RESULTS. WE HAVE ATTEMPTED TO CLARIFY THIS IN THE TEXT AS FOLLOWS:

“Secondary adjusted models will include age, gender, baseline PA level, adjuvant therapy, cancer type, months since diagnosis, and intervention dose (number of health coaching sessions received) as covariates” (PAGE 16, LINES 20-24).

Pg 16 line 18: sedentary behaviour, psychological variables, and (I assume) the other PA variables.

AUTHORS’ RESPONSE:

BETWEEN-GROUP COMPARISONS WILL BE PERFORMED FOR ALL SECONDARY OUTCOMES INCLUDING SEDENTARY BEHAVIOUR, PSYCHOLOGICAL VARIABLES AND OTHER PA VARIABLES AND WE HAVE INCLUDED THESE IN THE REVISED MANUSCRIPT: “Between-group comparisons will be performed for all secondary outcomes (sedentary behaviour, other PA and psychological variables, quality of life) and HAPA constructs using mixed models” (PAGE 16, LINES 23-24)

Pg 17 line 3. Has the sedentary behaviour outcome been purposefully excluded from the mediation

analysis?

AUTHORS’ RESPONSE:

SEDENTARY BEHAVIOUR HAS BEEN PURPOSEFULLY EXCLUDED FROM THE MEDIATION ANALYSIS SINCE THE PSYCHOLOGICAL QUESTIONNAIRE ITEMS ARE ALL RELATED TO MVPA RATHER THAN, FOR EXAMPLE, TO INTENTIONS AND CONFIDENCE REGARDING ENGAGING IN LESS SEDENTARY BEHAVIOURS.

Pg 17 line 3. I have little experience of this analysis, but would using a Generalized Estimating

Equations approach be beneficial when looking at the influence of the various components of the

HAPA approach on MVPA?

AUTHORS’ RESPONSE:

THANK YOU FOR RAISING THIS POINT. THE GENERALISED LINEAR MIXED MODEL, WITH THE CORRECT DISTRIBUTION AND LINK FUNCTION, CAN ACHIEVE A SIMILAR ANALYSIS AS THE GEE, ALBEIT VIA DIFFERENT MEANS. FURTHERMORE, THE GLMM FRAMEWORK IS MORE FLEXIBLE THAN THE GEE SO WE HAVE COVERED THIS SCENARIO IN OUR PROPOSED ANALYSIS PLAN WITH RESPECT TO THE INTERVENTION EFFECT ON THE OUTCOME MEASURES (PRIMARY AND SECONDARY).

Reviewer: 2

Reviewer Name: Jessica McNeil

Institution and Country: Department of Cancer Epidemiology and Prevention Research, Alberta Health Services, Canada Please state any competing interests or state ‘None declared’: None declared

This protocol describes a randomized controlled trial aimed at comparing a physical activity intervention that combined the use of a commercially-available activity tracker (Fitbit) with behaviour change techniques in cancer survivors who live in rural areas of Australia. This is an interesting

protocol that would certainly add to current literature on the use and efficacy of activity trackers to promote physical activity behaviour change, especially in individuals living in rural areas who may not have easy access to training facilities or resources. However, some sections of the methods could be moved to facilitate the flow of this paper and understanding the procedures of this trial. For instance, the procedures and description of the intervention should be presented prior to describing the outcome measurements, and patient and public involvement. In my opinion, it is important to understand how the trial will be conducted prior to describing the tools that will be used to conduct the various measurements. Additional comments are provided for your consideration.

AUTHORS' RESPONSE:

MANY THANKS JESSICA FOR YOUR HELPFUL FEEDBACK AND POSITIVE EVALUATION OF OUR TRIAL. FOLLOWING YOUR SUGGESTION, WE HAVE MOVED SECTIONS OF THE METHODS SO THAT THE PROCEDURES AND INTERVENTION DETAIL ARE PRESENTED PRIOR TO OUTCOMES.

Abstract:

Lines 3-4: Please indicate a proportion or percentage of breast cancer survivors who are insufficiently active.

AUTHORS' RESPONSE:

WE HAVE INCLUDED AN INDICATION OF THE PROPORTION OF SURVIVORS WHO ARE INSUFFICIENTLY ACTIVE (BETWEEN 70 AND 90%). THIS IS ACROSS CANCER TYPES AND NOT LIMITED TO BREAST CANCER SINCE OUR STUDY INCLUDES OTHER CANCER TYPES.

Line 8: Please define the acronym WA.

AUTHORS' RESPONSE:

WE APOLOGISE FOR THE OMISSION. WA REFERS TO WESTERN AUSTRALIA AND WE HAVE DEFINED AS SUCH IN THE REVISION.

Line 9: Please correct this statement by stating "ninety-four cancer survivors will be randomized to the intervention and control groups".

AUTHORS' RESPONSE:

MANY THANKS FOR THE SUGGESTION. REVIEWER 1 ALSO HIGHLIGHTED THIS SENTENCE AND WE HAVE REVISED AS FOLLOWS: "Eighty-six cancer survivors will be randomized into either the intervention or control group" (PAGE 2, LINES 13-14).

Lines 11-12: Please specify how these outcome variables will be measured.

AUTHORS' RESPONSE:

WE HAVE INCLUDED REFERENCE TO HOW THESE OUTCOME VARIABLES WILL BE ASSESSED:

"MVPA (using Actigraphs), quality of life and psychological variables (based on the HAPA model) (via questionnaire) will be assessed at baseline, 12-weeks and 24-weeks" (PAGE 2, LINES 16-18)

Line 12: What do the 12- and 24-week time points represent (e.g. end of intervention, end of follow-up?) Please specify.

AUTHORS' RESPONSE:

THE 12 AND 24 WEEK TIME POINTS REPRESENT THE END OF THE INTERVENTION AND THE END OF FOLLOW-UP AS YOU SUGGEST, AND WE HAVE INCLUDED THESE REFERENCE POINTS IN THE REVISED MANUSCIPT AS FOLLOWS: "will be assessed at baseline, 12-weeks (end of intervention) and 24-weeks (end of follow-up)" (PAGE 2, LINE 17)

Introduction:

Page 3, Line 15: If reference 3 refers to a study conducted in cancer survivors, then these individuals would be at an increased risk of developing second cancers. Please amend this statement accordingly. Also, please remove the term "both" since the authors mention more than two chronic conditions in this sentence.

AUTHORS' RESPONSE:

THANK YOU FOR THE CONSTRUCTIVE FEEDBACK. WE HAVE AMENDED THIS STATEMENT TO REFER TO CANCER RECURRENCE AND REMOVED THE WORD 'BOTH' AS FOLLOWS: "Insufficient PA, low fruit and vegetable intake, smoking and alcohol consumption make individuals susceptible to cancer recurrence, CVD and other chronic diseases[3]" (PAGE 3, LINES 17-18).

Page 4, Line 22: The design of an intervention that targets individuals living in rural areas is also a novel component in this study, especially as it relates to testing the efficacy of home-based interventions. Please mention this novel component of the study in this statement.

AUTHORS' RESPONSE:

MANY THANKS FOR THE SUGGESTION. WE HAVED AMENDED THE WORDING OF THIS PARAGRAPH TO EMPHASISE THE NOVEL COMPONENTS OF OUR STUDY; THE TARGETING OF NON-METROPOLITAN SURVIVORS; THE USE OF LESS INTENSIVE HOME-BASED INTERVENTIONS, AND THE RESOURCE DEPLOYMENT BASED ON PATIENT NEED, AS FOLLOWS:

"There is a current gap in the literature on the effectiveness of less intensive home-based interventions that could more easily translate into practice. A further novel component of the present study is the specific targeting of underserved regional and remote survivors with a home-based intervention. If effective, the intervention would be low cost and has the potential to be scalable and could be integrated into existing health care pathways." (PAGE 5, LINES 1-4)

Page 5, lines 13-15: Are these all primary study outcomes? If not, please specify which are primary and secondary study outcomes.

AUTHORS' RESPONSE:

MANY THANKS FOR THE SUGGESTION. WE HAVE CHANGED THE WORDING TO CLARIFY AND DISTINGUISH BETWEEN PRIMARY AND SECONDARY OUTCOMES, AS FOLLOWS:

"The primary aim of the study is to increase PA in adult cancer survivors residing in regional and remote areas in Australia. Secondary objectives are to reduce sedentary behavior and in conjunction with increased PA, improve quality of life in non-metropolitan survivors. Tertiary objectives are to assess the effectiveness of the Health Action Process Approach Model (HAPA) variables, upon which the intervention is based, to predict change in PA" (PAGE 6, LINES 1-6).

Methods:

Page 9, lines 1-2: Please specify whether or not participants will be asked to wear the accelerometer overnight/during sleep?

AUTHORS' RESPONSE:

PARTICIPANTS WIL ONLY WEAR THE ACCELEROMETER DURING WAKING HOURS AND WE HAVE REFERRED TO THIS ON PAGE 11: "Participants will wear the accelerometer on their right hip for all waking hours for one week" (PAGE 11, LINES 2-3)

Page 8 (primary outcomes): Will the accelerometer be mailed to the participants for data collection? If not, will they have to come to the testing facilities to obtain the accelerometer and return it)? If they have to go into the testing facilities, please specify how often and for what length of time, as this may impact the recruitment and time commitment of participants to this study, especially since it targets cancer survivors living in rural areas.

AUTHORS' RESPONSE:

THE ACCELEROMETER WILL BE MAILED TO PARTICIPANTS FOR DATA COLLECTION. WE HAVE CLARIFIED THIS WITHIN THE PRIMARY OUTCOMES SECTION: "Participants will be mailed the accelerometer and instructed to wear…" (PAGE 12, LINES 16-17).

PARTICIPANTS WILL RETURN THE ACCELEROMETERS IN A REPLY-PAID ENVELOPE: "participants will be mailed the study questionnaire, an Actigraph GTX9 accelerometer, written accelerometer instructions, and a reply-paid envelope. Participants will be asked to complete the questionnaire and wear the accelerometer on their right hip for 7-days during waking hours, and then return the questionnaire and accelerometer in the reply-paid envelope" (PAGE 11, LINES 1-3)

The Procedure section should be placed prior to the description of study outcomes/after the section on recruitment.

AUTHORS' RESPONSE:

MANY THANKS FOR THE SUGGESTION. WE AGREE AND HAVE MOVED THE PROCEDURE SECTION TO THE SECTION FOLLOWING RECRUITMENT.

There is no mention of waist circumference measurements under the description of study outcomes (only in the Procedures section). Please amend.

AUTHORS' RESPONSE:

WE HAVE REMOVED WAIST CIRCUMFERENCE FROM THE PAPER. ITS INCLUSION WAS A MISTAKE. OUR SINCERE APOLOGIES FOR THIS ERROR.

Page 12, line 6: please describe what is meant by "receive minimal intervention to mimic usual care".

AUTHORS' RESPONSE:

BY USUAL CARE, WE MEAN MINIMAL INTERVENTION AND SIMILAR TO WHAT MAY BE PROVIDED AT BEST AT OUTPATIENT APPOINTMENTS. ALL PARTICIPANTS WILL BE GIVEN A BOOKLET DESIGNED BY CANCER COUNCIL AUSTRALIA ENTITLED: "EXERCISE FOR PEOPLE LIVING WITH CANCER" THAT INCLUDES THE PA RECOMMENDATIONS, EXAMPLES OF HOME-BASED STRENGTH EXERCISES AND A GUIDE TO EXERCISE INTENSITY. THESE BOOKELTS ARE FREELY AVAILABLE AND MAY BE FOUND IN ONCOLOGY RECEPTION AREAS. THEREFORE, WE CONSIDER THE PROVISION OF SUCH AKIN TO USUAL CARE. WE HAVE

INCLUDED THE FOLLOWING TO FURTHER EXPLAIN WHY THE PROVISION OF THESE WRITTEN MATERIALS IS DEEMED TO REPRESENT USUAL CARE:

“The booklet provided: ‘Exercise for people living with cancer’ is freely available from Cancer Council Australia and may be found in oncology reception areas, and as such, may be considered to represent usual care” (PAGE 11, LINES 22 onwards)

The intervention section should be moved prior to the Procedures section/after the description of study participants and recruitment strategies.

AUTHORS’ RESPONSE:

MANY THANKS FOR THE SUGGESTION. WE AGREE AND HAVE MOVED THE INTERVENTION SECTION TO PRIOR TO THE PROCEDURES SECTION AND FOLLOWING THE RECRUITMENT SECTION.

Will components of the intervention (either through the use of the Fitbit or behaviour change techniques) put emphasis on reducing sedentary behaviour?

AUTHORS’ RESPONSE:

THE INTERVENTION (BOTH VIA THE FITBIT AND THE HEALTH COACHING) WILL EMPHASIZE REDUCING SEDENTARY BEHAVIOUR ALONGSIDE INCREASING MVPA. WE HAVE INCLUDED FURTHER DETAIL IN THE MANUSCRIPT CONCERNING THE AUTOMATED FITBIT PROMPTS SENT TO USERS THROUGHOUT THE DAY TO NUDGE THEM TO COMPLETE AT LEAST 250 STEPS PER HOUR (HENCE BREAKING UP BOUTS OF SITTING). THE FOCUS OF THE INTERVENTION WILL BE TO ENCOURAGE MORE DELIBERATE BOUTS OF PHYSICAL ACTIVITY (IE, MVPA), IN ADDITION TO REDUCING SITTING TIME AND INCREASING STEP COUNT:

“and, provides automated prompts which nudge participants to accumulate at least 250 steps/hour” (page 8, lines 12-13). AND: ”The purpose of the health coaching is to motivate and support increased PA (i.e., deliberate bouts of MVPA) and reduced sedentary behaviour” (page 8, line 21).

Page 13: Will data from the Fitbit device be used to track adherence and compliance with the intervention? Will compliance be verified during the 6 follow-up calls? If so, how will this be done? Tracking the objective physical activity and sedentary time data, as well as compliance with using the activity tracker, would provide novel and valuable information on the efficacy of using these types of activity tracker to promote physical activity behaviour change.

AUTHORS’ RESPONSE:

WE WILL TRACK ADHERENCE TO THE INTERVENTION THROUGH THE FITBIT APP/DASHBOARD. THERE WILL BE WEEKLY MONITORING TRACKING THE PHYSICAL ACTIVITY AND SEDENTARY TIME DATA AND THE HEALTH COACH WILL USE SUCH MONITORING TO INFORM THE FEEDBACK PROVIDED IN THE FOLLOW-UP TELEPHONE CALLS. WE HAVE REFERRED TO THIS IN THE ORIGINAL MANUSCRIPT BUT HAVE INCLUDED FURTHER DETAIL AS FOLLOWS:

“The health coach will log hourly activity (accumulation of 250 steps per hour), step count, active minutes (MVPA bouts of at least 10-minutes) for each participant on a weekly basis. The health coach will also review weekly activity and engagement via the Fitbit app prior to each health coaching session to provide feedback, encouragement and technical support if needed”(PAGE 9, LINES 20-24).

Page 13, lines 14-16: This is true, however, some of these activity tracker applications do offer “group chats and challenges” which could be optimized in a home-based intervention. Some of these platforms offered by the applications could be utilized in this type of trial.

AUTHORS’ RESPONSE:

CHALLENGES WILL BE AUTOMATICALLY SENT TO PARTICIPANTS ACCORDING TO THEIR PROGRESS VIA FITBIT AND THROUGH THE WEEKLY REPORT THAT FITBIT SENDS ITS USERS. WE AGREE THAT GROUP CHATS COULD BE HELPFUL AND IF PARTCIPANTS WOULD LIKE TO ‘MAKE FRIENDS’ WITH OTHERS ON THE TRIAL, WE WILL CERTAINLY ENCOURAGE THAT. HOWEVER, FROM OUR EXPERIENCE WITH A PREVIOUS SIMILAR TRIAL, MANY PARTICIPANTS DID NOT WANT TO MAKE FRIENDS WITH AND ENGAGE WITH OTHERS. THEREFORE, WE DO NOT INTEND TO DIRECTLY INCORPORATE GROUP CHATS INTO OUR INTERVENTION.

Page 13, lines 23-24: How will the need for additional health coaching sessions be determined? Will this be based on compliance data from the activity tracker or the participants may simply request additional sessions during a previous follow-up call? It would be interesting to look at how many participants do request additional sessions and whether this helped improve compliance and PA measures. This could also be used to inform the number of follow-up calls or coaching sessions that may be needed for this type of home-based intervention.

AUTHORS’ RESPONSE:

THANKS FOR RAISING THIS POINT. THE NEED FOR ADDITIONAL HEALTH COACH SESSIONS WILL BE NEGOTIATED BETWEEN THE HEALTH COACH AND THE PARTICIPANT AND WILL BE BASED ON DATA FROM THE DASHBOARD CONCERNING PROGRESS AND PARTICIPANTS’ PERCEPTIONS CONCERNING FURTHER SUPPORT. A DISCUSSION CONCERNING ADDITIONAL SESSIONS WILL COMMENCE DURING THE PREVIOUS FOLLOW-UP CALL. THE NUMBER OF SESSIONS RECEIVED WILL BE INCLUDED AS A COVARIATE IN THE ANALYSIS (INTERVENTION DOSE) AND COULD BE USED TO INFORM THE NUMBER OF HEALTH COACHING SESSIONS NEEDED IN THIS TYPE OF HOME-BASED INTERVENTION TO DERIVE EFFECTIVE BEHAVIOUR CHANGE. WE HAVE INCLUDED FURTHER DETAIL IN THE REVISION CONCERNING HOW THE NEED FOR ADDITIONAL HEALTH COACHING SESSIONS WILL BE DETERMINED AS FOLLOWS:

“Additional health coaching sessions will be negotiated between the health coach and the participant, and will be based on both data from the Fitbit dashboard concerning progress, and, participants’ perceptions concerning support needs. Additional sessions will be negotiated during the previous follow-up call.” (page 9, lines 10-14)

Do participants have to return the Fitbit to the study team at the end of the 24-week period?

AUTHORS’ RESPONSE:

PARTICIPANTS WILL HAVE TO RETURN THE FITBIT TO THE STUDY TEAM AFTER 24-WEEKS SO THAT THOSE IN THE CONTROL GROUP WHO WISH TO TRIAL ONE MAY DO SO. WE HAVE ADDED THIS DETAIL IN THE REVISION: “All Fitbits will be returned after the 24-week assessment alongside the accelerometer.” (PAGE 12, LINES 9-11)

Page 16, line 17: Please define the covariate “intervention dose”. Is this the amount of PA that is measured by the Fitbit during the intervention?

AUTHORS' RESPONSE:

INTERVENTION DOSE REFERS TO THE NUMBER OF HEALTH COACHING SESSIONS RECEIVED. WE HAVE INCLUDED THIS DETAIL IN THE REVISED MANUSCRIPT: "(number of health coaching sessions received)" (PAGE 16, LINE 22).

Figure 1:

Could you please add the number of letters that you would expect to mail given the targeted sample size?

AUTHORS' RESPONSE:

THANKS FOR THE SUGGESTION. WE EXPECT THAT WE MAY NEED TO MAIL UP TO 800 LETTERS IN ORDER TO ATTAIN THE TARGET SAMPLE SIZE. THIS IS BASED ON A 25% RECRUITMENT RATE AND A 50% ENROLMENT RATE. A PREVIOUS STUDY, SIMILAR IN DESIGN TO THE PROPOSED STUDY (USING FITBITS WITH CANCER SURVIVORS INVITED BY THEIR ONCOLOGIST) LED BY THE FIRST AUTHOR ACHIEVED RECRUITMENT AND ENROLMENT RATES OF 27% AND 54% RESPECTIVELY. WE HAVE ADDED THE NUMBER OF LETTERS TO FIGURE 1.

VERSION 2 – REVIEW

REVIEWER	Ian Lahart University of Wolverhampton, UK
REVIEW RETURNED	04-Mar-2019

GENERAL COMMENTS	Dear authors, Many thanks for addressing each of the comments I made in detail. I hope the study goes well. Best wishes, Ian

REVIEWER	Jessica McNeil Alberta Health Services, Canada
REVIEW RETURNED	15-Feb-2019

GENERAL COMMENTS	The authors have made substantial improvements to the manuscript. I have no further recommendations.