Promoting Physical Activity in Regional and Remote Cancer Survivors (PPARCS) using Wearables and health-coaching: Randomised Controlled Trial protocol

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Promoting Physical Activity in Regional and Remote Cancer Survivors (PPARCS) using Wearables and health-coaching: Randomised Controlled Trial protocol

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ABSTRACT

Introduction: Physically active cancer survivors have significantly less cancer recurrence and improved survival compared to those who are inactive. However, the majority of survivors are insufficiently active. There are also significant geographic inequalities in cancer survival with poorer survival rates for the third of Australians who live in non-metropolitan areas compared to those living in major cities. The objective of the trial is to increase physical activity (PA), improve quality of life and reduce sedentary behaviour among cancer survivors living in regional and remote WA.

Methods and analysis: Ninety-four cancer survivors will be randomized intervention and control groups. Intervention group participants will receive: a Fitbit and up to six telephone health coaching sessions. PA, waist-circumference, quality of life and psychological variables will be assessed at baseline, 12-weeks and 24-weeks. A General Linear Mixed Model will be used to assess the effectiveness of the intervention. **Ethics and dissemination:** Ethics approval has been obtained from St John of God Hospital Subiaco (HREC/#1201). We plan to submit a manuscript of the results to a peer-reviewed journal. Results will be presented at conferences, community and consumer forums and hospital research conferences. Trial registration number: ACTRN12618001743257, prospectively registered. Universal Trial Number: U1111-1222-5698. Protocol version: 1.0.

Keywords: oncology; wearable technology; physical activity; health coaching; intervention.

Strengths and limitations of this study

- The intervention has the potential to be a low-cost and scalable and hence, integrated into existing health-care pathways.
- An objective measure of PA is used to provide accurate assessment of PA.
- Due to the postal nature of recruitment, the responders may not be a representative sample of regional and remote cancer survivors.
- The relatively short follow-up period limits our assessment of the extended acceptance of wearable technology in this population.

INTRODUCTION

Compared to the general population, cancer survivors are at an increased risk of the development of secondary cancers, cardiovascular disease (CVD) and functional decline[1, 2]. There are several possible explanations for the increased risk, one of which is shared lifestyle risk factors[3]. Insufficient PA, low fruit and vegetable intake, smoking and alcohol consumption make individuals susceptible to both cancer, CVD and other chronic diseases[3].

The American Cancer Society PA guidelines for survivors are to participate in 150-minutes of moderate-intensity PA per week[4]. However, the majority of Australian cancer survivors (~70-90%) do not meet the PA recommendations[5].

PA is associated with lower CVD-related comorbidity in survivors[2]. Physically active survivors have significantly less cancer recurrence and improved survival compared to those who are inactive, and these findings have been found across multiple cancer types[6, 7]. Many survivors suffer additional comorbidities that put them at risk of developing CVD[8]. As a result, insufficiently active survivors who fail to make

healthy lifestyle changes post-treatment are likely to have substantially higher risk of developing CVD.

Together, colorectal, breast, prostate and uterine cancer account for 41% of all cancer incidence in Western Australia (WA)[9]. Our rationale for targeting survivors of these cancers is based on established risk or comorbid cardio-metabolic disease, and a high prevalence of physical inactivity[10].

There are also significant geographic inequalities in cancer survival[8, 11]. Survival rates for Australians who live in non-metropolitan areas are poorer than for those living in major cities[12]. Those living in remote areas of Australia are often disadvantaged in relation to access to services, education, employment and income. Mortality rates for all cancers combined are 1.4 times higher in remote areas compared to major cities[12].

Existing PA programs for cancer survivors tend to be based in major cities but rarely operate beyond the inner regional areas. Further, facility-based programs that are offered for free initially, eventually incur a cost that may present a barrier to long-term exercise adherence. Previous work with survivors has identified cost, and availability of and access to exercise programs to be significant barriers to participation[13-15]. Survivors have also expressed a preference for home-based PA[13, 15, 16].

Home-based interventions are advantageous because they mitigate access and transport issues, and are less expensive than supervised, facility-based programs that require participants to attend classes or maintain a health club membership[17]. There is a current gap in the literature on less intensive home-based interventions that employ resource deployment according to patient need, and could more easily translate into practice.

Furthermore, interventions that meet support needs and offer opportunities for self-monitoring have been found to be effective in improving PA in survivors[18-20]. Wearable technology holds great potential as a low-cost self-monitoring tool to increase PA in cancer survivors. Lyons et al.[21] recently reviewed 13 different wearables and their associated mobile apps, and concluded that they use many of the same techniques employed in typical PA behaviour change interventions (i.e. self-monitoring, feedback, goal-setting, social support). Wearables are perceived as useful and acceptable to individuals with chronic conditions[22]. Wearable activity trackers are acceptable to older cancer survivors in metropolitan areas[23] and those living in regional and remote areas of WA (Under revisions). Thus, wearables may represent a relatively low-cost, feasible and scalable approach for widespread PA promotion.

The overriding aim of the study is to increase PA in adult cancer survivors residing in regional and remote areas in Australia. Our primary objective is to investigate the effectiveness of the intervention to increase PA, improve quality of life and reduce sedentary behaviour among cancer survivors living in regional and remote WA.

METHODS AND ANALYSIS

Study design

A randomised controlled parallel group design will be employed. Participants will be randomised into one of 2 arms: control vs. intervention, and assessments will be made at baseline (T1), end of intervention (12-weeks) (T2) and at 24-weeks (T3). The outcome (dependent) measures will include an objective measure of PA, Quality of life (QoL), waist circumference, plus measures that indicate constructs from the Health Action Process Approach Model (HAPA)[24] such as attitudes, action self-efficacy, outcome expectancies, action planning, intentions and maintenance self-efficacy upon

which the intervention is designed. We will also measure a number of covariates that may influence effects of the intervention including: age, gender, socio-economic status, cancer type, months since diagnosis, disease stage, adjuvant treatment, and CVD risk factors. Ethics approval was obtained from the St. John of God Hospital Human Research Ethics Committee (#1201), and reciprocal approval will be approved from other participating hospitals and sites. The trial will comply with CONsolidated Standards of Reporting Trials (CONSORT) and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)[25, 26]. A completed SPIRIT checklist for the trial can be found in Supporting Information.

Patient and public involvement

We have published several papers[13-16] from qualitative work with consumers. Such consumer engagement and feedback has informed the content and type of intervention that will be tested. For example, this work has identified motivation including 'poor self-discipline' and 'not the sporty type' as the main PA barriers. Some participants held the perception that they were already 'doing sufficient PA'. Participants also referred to the need for monitoring, support and accountability to help them in their behaviour change efforts. These findings have fed into the design of the intervention in the following ways: the promotion of lifestyle-related exercise such as walking takes away the 'sporty type' barrier; the use of activity trackers to provide objective feedback on PA can be helpful for those who erroneously think they are undertaking sufficient PA; and the use of activity trackers and health-coaching provides the self-monitoring, goal setting and support that consumers have identified as important. Consumers that have trialled the wearable trackers have reported the intervention to be acceptable and not burdensome (under

revisions). Study participants will be asked whether they wish to receive a report of the results, and asked to provide an email address for dissemination of study results.

Setting and Participants

Participants will be cancer survivors diagnosed with cancer and completed active treatment in the previous 5-years. Participants will reside in Australia and will have been treated for either breast, prostate, colorectal or uterine cancer. Participants will be recruited on the basis of (1) remoteness, and (2) low levels of PA. Remoteness will be measured according to the Accessibility/Remoteness index of Australia and the Australian Statistical Geography Standard which define five major areas: *major cities*, *inner regional*, *outer regional*, *remote* and *very remote[27]*. Participants will be recruited on the basis that they reside in either a regional or remote area. Eligible participants must also be 1) insufficiently physically active (i.e., engaging in less than 150-minutes of moderate-intensity or 75-minutes of vigorous-intensity PA per week)[4, 28]; 2) aged between 18 and 80 years; 3) proficient in English-reading and speaking; 4) have no known presence of cancer at the time of recruitment; 5) have internet access at home. Exclusion criteria include individuals who 1) are still undergoing treatment for cancer except for maintenance therapy such as tamoxifen; 2) have known cardiac abnormalities including unstable angina or recent myocardial infarction; 3) have any severe disability that may affect physical function including severe arthritis; 4) have a current diagnosis of a severe psychiatric illness (those with minor psychiatric diagnoses will be eligible if they are well enough to participate; 5) are currently enrolled in a health behaviour trial or program.

Recruitment

Participants will be recruited using purposive sampling methods, involving screening the hospital records of participating oncologists, to collate a pool of eligible survivors. The preliminary participating oncologists are based at St John of God Subiaco and Murdoch Hospitals, Hollywood Private Hospital, the Women Centre in West Leederville. Oncologists in South Australia, Victoria and New South Wales may also participate in the trial depending upon recruitment uptake. Eligible individuals will be mailed an invitation letter and information sheet from their treating oncologist.

Measures

Primary outcomes

The primary outcome will be minutes of moderate-to-vigorous PA (MVPA) and sedentary behaviour ascertained from the Actigraph GT9X (Actigraph, LLC, Pensacola, Florida, USA). Participants will wear the accelerometer on their right hip for all waking hours for one week. Wear time must exceed 10-hours per day to be considered valid for analysis. Non-wear periods will be defined as intervals of at least 60-consecutive minutes of zero counts will be excluded from analyses. Activity counts will be categorised as: sedentary (<100cpm), light-intensity (100-1951cpm), moderate-intensity (1952-5724cpm) and vigorous-intensity (>5725cpm), using data recorded in 60-s epochs, according to Freedson cut points[29]. MVPA will be examined as both weekly time accumulated (minutes/week), and time in bouts of 10-consecutive minutes (minutes/week).

Sedentary behaviour

Sedentary behaviour will be defined by accelerometer activity counts of <100cpm, for 20 consecutive minutes or more, which corresponds to clinical changes in cardio-metabolic

biomarkers[30]. The accelerometer log completed by participants will assist in differentiating sedentary time from non-wear time.

Quality of life

Quality of life will be measured using the Medical Outcomes Study Short-Form survey [31]. This instrument is considered reliable across both mental and physical components (Cronbach's alpha of 0.87 and 0.84, respectively), and valid when compared to the 36-item version[31, 32].

Physical activity attitudes

PA attitudes will be assessed using previously validated items, with Cronbach's alpha scores for the subscales below ranging from 0.73 to 0.87[33]. Some items have been amended, based on previous formative work in survivors[13, 16, 34, 35], and PA recommendations[4]. The following constructs will be assessed:

Outcome expectations. Twelve items will assess outcome expectations. Five items are derived from the validated exercise pros subscale[36] and 7-items are based on formative research with survivors[14, 34, 35]. The items measure magnitude of agreement (1=disagree very strongly to 6=agree very strongly) that regular PA will help to: reduce tension or stress; feel more confident about my own health; sleep better; have a positive outlook; control my weight; regain lost strength; prevent cancer recurrence; increase fatigue; increase joint pain; weaken my immune system; feel better about my body, and increase my longevity.

Action self-efficacy. Four items will assess action self-efficacy, based on previous research with survivors[37]. Items assess participants' confidence to complete 150-minutes of MVPA per week (on a six-point Likert scale), with the item stems: 'I believe

I have the ability to…'; 'I am confident I can do…'; 'If I wanted to I could…' and 'For me to do…'.

Maintenance self-efficacy. Thirteen items will assess maintenance self-efficacy, based on formative research using a six-point Likert scale[14, 35]. Items assess confidence to participate in regular MVPA over the next 12-weeks when, for example: I lack discipline, and I am feeling tired.

Action planning. Four items using a six-point Likert scale will assess action planning for the next 3-weeks[38]. Participants will be asked to respond about whether they have made plan concerning *what*, *when*, *where*, and *how* they will engage in regular PA.

Intention. Two items, using a six-point Likert scale, will measure intention to engage in moderate-intensity PA for at least 150-minutes per week in the next 12-weeks, based on previously established measures[39]. Items are 'I intend to participate…' and 'I will try to participate…'.

Covariates

Sociodemographic information and CVD risk factors will be self-reported via the written questionnaire posted to participants at T1. The following variables will be assessed: marital status; educational attainment; gross household income; smoking status; alcohol intake; and chronic disease comorbidities.

Procedure

Participants will be sent an invitation letter, information sheet, consent form and a reply-paid envelope from their treating surgical, medical or radiation Oncologist. Upon receipt of written consent, participants will be telephoned and an initial screening questionnaire (including the Active Australia Survey; AAS)[40] to assess PA status) administered to

determine eligibility. The AAS has demonstrated acceptable convergent validity for community-dwelling older adults[41]. Only those that report participating in less than 150-minutes of MVPA per week will be eligible to participate in the trial.

If the criteria are met, participants will be sent the study questionnaire, an Actigraph GTX9 accelerometer, written accelerometer instructions, a tape measure, graphic instructions to measure waist circumference, 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. Figure 1 represents the flow of research participants through the trial.

The statistician will generate the randomisation sequence using STATA v15 with a 1:1 allocation using random block sizes of 4 and 6 to support allocation concealment. Participant allocation will be implemented using sequentially numbered, opaque sealed envelopes, and the researchers involved in assessing and enrolling participants will not be involved in the generation of the randomisation sequence. Following consent and baseline assessment, the trial coordinator will choose the next envelope in the sequence and write the participant study number onto the envelope prior to allocating the participant to that group. Carbon paper inside the envelope will transfer the number onto the card containing the details of allocation.

The trial coordinator will post the accelerometers to participants with clear instructions on how to use them, and will contact participants after the 7-days to remind them to post them back to the researchers. Participants will also complete questionnaires that measure socio-demographic variables, QoL, and constructs from the Health Action Process Approach model[24]which informs the basis of the intervention.

Both the control and intervention group will receive a mailed booklet designed to educate and motivate improvements in PA. Materials will be based on the current guidelines for PA[28] and also evidence-based behavior change techniques such as action planning, problem solving and self-monitoring[42]. The intervention group will also receive a mailed Fitbit tracker to self-monitor physical activity. The control group will receive minimal intervention to mimic usual care so that we are able to compare the effects of the intervention to usual care. Any adverse events emanating from the trial will be reported to, and managed by the ethics committee 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.

Power Calculations and Sample size

The primary outcome is change in MVPA. A sample size of 94 participants (47 in each arm) is required in order to achieve 80% power to detect a difference of 70 ± 120 minutes of MVPA per week between the arms at 0.05 level. Our calculations are based on a previous wearable technology trial in survivors using Actigraphs to assess MVPA (WATAAP trial) [43] where the observed net increase was 70 ± 120 minutes of MVPA at 12-weeks. We aim to recruit 104 participants, ensuring that if 10% are lost to follow-up, the intervention will still be adequately powered at 80% to detect a meaningful change.

Intervention

The 12-week intervention includes two components: 1) a Fitbit Charge 2 activity tracker™ providing real-time monitoring and feedback on PA; 2) Up to six sessions of health coaching (4 fixed sessions) via skype/facetime/etc. or phone depending on participant preferences.

WAT tracker: Participants will be provided with a Fitbit Charge 2™ activity tracker, and encouraged to wear for the duration of the trial. This is a slim, wrist-worn device that displays steps, distance, active minutes (MVPA), heart rate and caloric expenditure. The Fitbit Charge 2™ was chosen because previous work demonstrates its usefulness and acceptance amongst cancer survivors[23] and older adults (>70)[44]. The Fitbit Charge 2™ also alerts users to sedentary behaviour and progress towards PA goals. Data from the device can be uploaded to the Fitbit™ application via Bluetooth. Participants will receive clear and simple written instructions guiding the installation of apps and device usage. Technical support will also be provided through follow-up calls to maximize uptake.

Health Coaching: The purpose of the health coaching is to motivate and support increased PA through supporting self-efficacy, action planning and problem solving, based on the principles of the HAPA. The health coaching is important to help guide action planning and problem solving since these behaviour change techniques are absent from the Apps associated with wearable devices[21]. Telephone health coaching has been successfully used in Australian and US survivors to increase PA[5, 45]. The first session (wk 1; ~ 60 minutes) will cover technical issues and the features of the Fitbit, including the importance of MVPA. It will also foster positive outcome expectancies and confidence towards PA and guide the participant to create PA action plans for the following three weeks and self-monitor their activity. The purpose of the three follow-up health coaching sessions (wk 2, 4, and 8; ~30 minutes each) will be to provide support, problem solving and help the participant to update goals and action plans as they progress. We will adopt a patient-centred and stepped-care approach by providing additional health coaching

sessions (i.e., at wk 6, and 10) to those who may need them in order to achieve meaningful sustained PA change. The weekly exercise target will be at least 180-minutes of moderate-intensity PA, based on research demonstrating better survival in patients who engaged in 3-5 hrs of moderate activity per week[7, 18]. A web-based API (Application programming interface) to collect user's activity data from the Fitbit server will be developed. Upon user consent via Fitbit authentication page, we will be able to collect participants' daily activity (step count, active minutes, duration, heart rate, stair, sleep). The health coach will review daily activity and engagement via the Fitbit app prior to each health coaching session to provide feedback, encouragement and technical support if needed. API monitoring will cease at the end of the trial (after 24-weeks) and a de-authorization email sent to participants to confirm the end of API participation.

Quality Assurance

The Health coach employed to deliver the intervention will be required to have a background in Psychology or allied health discipline (at least to degree level). The health coach will undertake training including the theoretical bases of the intervention, PA messaging, and implementation of behaviour change techniques. Training will include role-plays with supervised feedback. Health coaching consistency will be achieved by following a semi-structured script with a clear structure of questions, and behaviour change techniques to be covered in each call. Competency and quality control will be monitored by direct observation and/or audio-recordings, (with feedback to the health coach) and will continue until consistent and adequate health coaching performance is confirmed. All telephone calls to participants will be audiotaped.

After 12-weeks, participants in both groups will complete a questionnaire that measures variables from the HAPA, QoL and psycho-social variables again for a second

time and wear an accelerometer for a 7-day period. The trial coordinator will post out the accelerometers and questionnaires. Between 12-weeks and 24-weeks, participants will keep the Fitbit but there will be no further health coaching. At 24-weeks, all participants will complete the questionnaires for a third time and will receive an accelerometer to wear for a 7-day period. The health coach will work flexible hours so that they can offer early morning and/or evening calls to fit in with participants' schedules. Following trial completion (T3), participants in the control group will be offered the opportunity to trial a Fitbit ™ for 12-weeks.

Process evaluation

Acceptability and feasibility of the intervention will form the process evaluation. Feasibility of the intervention will be evaluated by comparing intervention costs (intervention equipment, staff time) with uptake rates, adherence (to wearing the wearable tracker, receipt of health coaching sessions), and completion. Acceptability and utility of the intervention, and an understanding of the active ingredients will be examined using semi-structured telephone or skype interviews.

Data Management

All personal data collected will be dealt with and stored in accordance with the Data Protection Act. All data will be stored securely to maintain confidentiality. To preserve participant anonymity, only their allocated trial number will be recorded on trial documentation or computer software except for the consent form and contact details. Documents with identifiable information will be stored separately to other study documents. Pseudonyms will be used when reporting findings from the process evaluation. The use of the data from the study will be controlled by the principal investigator. All data and documentation related to the trial will be stored in accordance

with applicable regulatory requirements and access to de-identified data will be made available on request.

Data Monitoring and Timeline

Due to the low risk nature of the intervention, we do not expect any harm or adverse events and therefore there will be no data monitoring committee or trial cessation. The trial will be overseen by the trial management team, consisting the principal investigator, co-chief investigators, the trial coordinator and health coach. Recruitment is expected to commence in January 2019 and the project completed by September 2020. The final follow-up assessment is anticipated to be completed by March 2020 with analysis and report completed by the September.

Data analysis

The effectiveness of the intervention vs. control on MVPA/week will be assessed using a linear mixed model, with group (intervention vs. control), time (T1 vs. T2 and T3) and their interaction as fixed effects, and with a random effect for participant included to account for the correlations in observations inherent in a repeated measures design. Age, gender, baseline PA level, adjuvant therapy, cancer type, months since diagnosis, and intervention dose will be considered as covariates in the model. Groups will also be compared on secondary outcomes (waist circumference, quality of life) and HAPA constructs using mixed models, including adjustment for confounding where appropriate. Missing data will be investigated for patterns in terms of observed study variables. Multiple imputation will be considered if data are arguably missing at random and less than 20% of the data are missing. We will impute 25 data sets based on all relevant observed variables, including the interaction term and outcome measure of interest for each specific analysis. Sensitivity analyses will be conducted to consider the

effect of potential missing not at random mechanisms on parameter estimates from imputed data sets. Intention-to-treat analysis will be conducted where there is participant attrition. Appropriate longitudinal mediation models will be used to investigate whether a) intervention associated changes in MVPA are mediated (at least partially) via the HAPA model and b) changes in QoL/ waist circumference are partially mediated via changes in MVPA. All data will be analysed with $p < 0.05$ considered significant.

DISCUSSION

The trial will assess the effectiveness of an intervention that combines wearable technology with behaviour change techniques (action-planning, goal-setting, and coping planning, feedback) to increase MVPA and reduce sedentary behaviour in cancer survivors living in non-metropolitan areas of Australia. This protocol describes one of the first trials using wearable technology to promote PA in regional and remote survivors, contributing to research on the effectiveness of distance-based interventions to promote PA.

Despite increasing evidence that PA reduces the risk of CVD and cancer recurrence[6, 46], few survivors meet the PA guidelines[4]. Furthermore, there are significant geographic inequalities in cancer survival that urgently need to be addressed, with significantly poorer survival in remote areas compared to major cities.

Existing PA programs for cancer survivors tend to be based in major cities with scarce provision outside of major cities. Limited access to exercise facilities due to access, provision or financial barriers disadvantage non-metropolitan survivors[15, 17]. Less intensive home-based interventions could be more acceptable to consumers, scalable and more cost-effective.

Conclusion

The trial is pragmatic and primarily concerned with evaluating whether a low-intensity, distance-based intervention is effective for increasing MVPA and reducing sedentary behaviour in survivors compared to usual care. If effective, the intervention, that employs resource deployment according to patient need, has the potential to be a low cost and scalable intervention that could be integrated into existing health care pathways (e.g., telehealth programs) or delivered by oncology nurses, or allied professionals.

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Figure Legends

Figure 1. Flow diagram of trial design

Acknowledgements: We thank the consumers that have kindly given their time to participate in our previous projects that have contributed to the design of the prospective intervention.

Contributors: SH led the study conceptualisation, development of intervention content and writing of the protocol. GM, PT, NB, SS, JT, GRM, ML, PC, CS and CP contributed to study conceptualisation and will recruit patients for the trial. RJ edited the protocol and will assist in the process evaluation. TB and VC contributed to physical activity measurement protocol and will be responsible for Actigraph data cleaning and analysis.

DH contributed to statistical analysis and the process for randomisation and data management and will undertake data analysis. All authors edited the manuscript.

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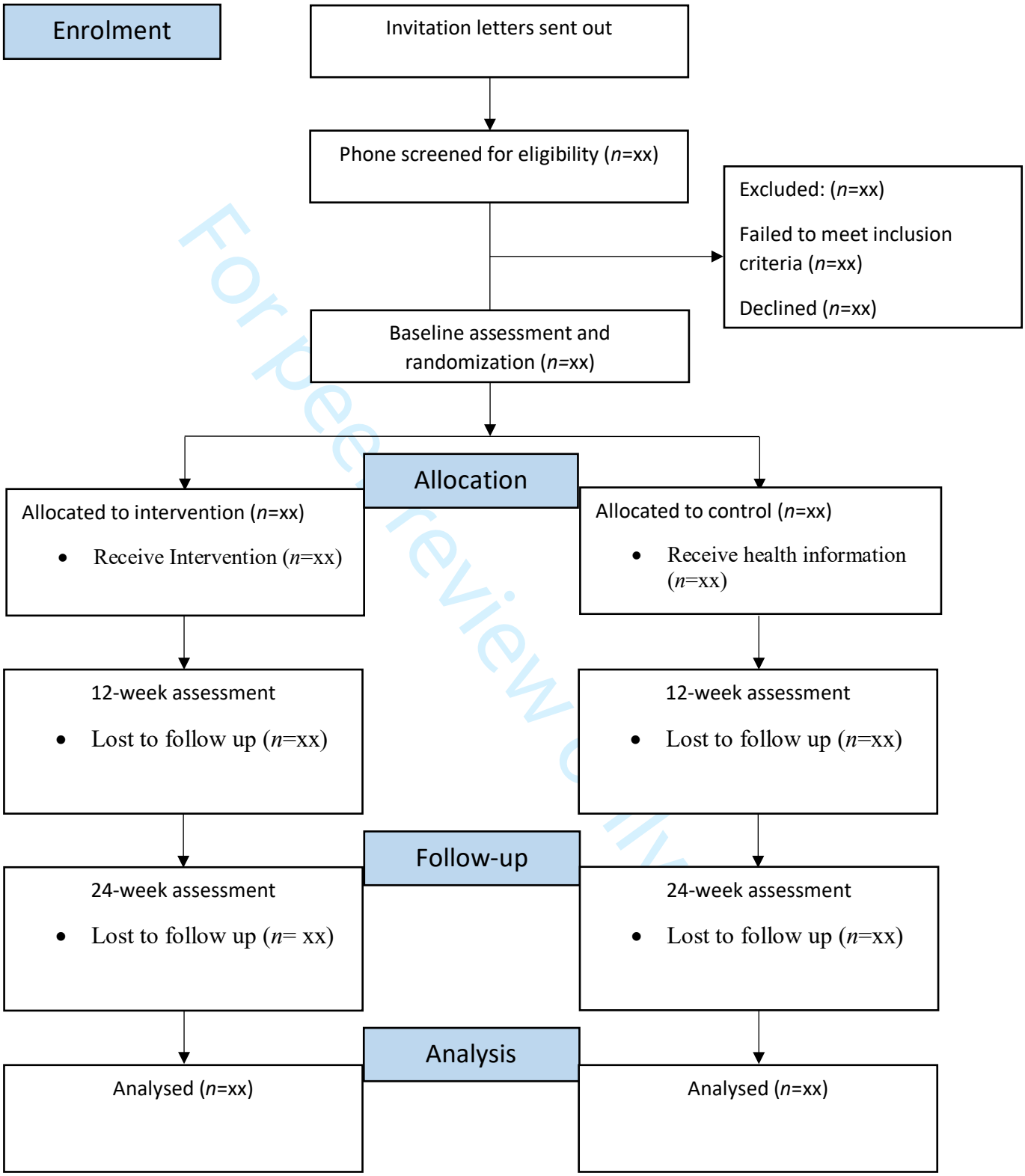
Figure 1. Flow diagram of trial design



ST JOHN OF GOD
Subiaco Hospital

Consent form

Title	**The promotion of physical activity to adult cancer survivors in regional and remote areas of Western Australia using Fitbit technology and telephone health coaching**
Principal investigator	Sarah Hardcastle

Note: All parties signing the consent section must date their own signature.

Declaration by participant

- I have read, or have had read to me, and I understand the participant information and consent form.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand the purposes, procedures and risks of the research described in this research study.
- I intend to adhere to the study requirements to the best of my ability.
- I understand that I will be given a signed copy of this document to keep.

Signature _____ Date_____

Name of participant (please print) _____

Declaration by trial doctor/senior researcher†

I have given a verbal explanation of this study, its procedures and risks and I believe that the participant has understood that explanation.

Signature _____ Date_____

Name of trial doctor/ researcher† (please print) _____

† A senior member of the research team must provide the explanation of, and information concerning, the research study.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym **(Page 1)**
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry **(Page 1)**
	2b	All items from the World Health Organization Trial Registration Data Set **(UTN and ACTN numbers are on Page 1)**
Protocol version	3	Date and version identifier **(Page 1)**
Funding	4	Sources and types of financial, material, and other support **(Page 20)**
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors (**Title page and Page 20)**
	5b	Name and contact information for the trial sponsor **(Page 20)**
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities **(Page 20**)
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) **(Page 20)**
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention **(Pages 2-4**)
	6b	Explanation for choice of comparators **(Page 11)**
Objectives	7	Specific objectives or hypotheses **(Page 4)**

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) **(Page 4)**
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) (and list of countries where data will be collected. Reference to where list of study sites can be obtained **(Page 7)**
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) **(Page 6 & 13)**
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered **(Page 11-13)**
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) (**N/A)**
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) **(Page 11-13)**
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial **(Page 6)**
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended **(Page 7)**
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) **(Figure 1)**
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations **(Page 11)**
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size **(Page 7)**
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. (To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions **(Page 10)**
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned **(Page 10)**
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions **(Page 10)**
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how **(Page 10)**
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial **(N/A)**
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol **(Page 7-11)**
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols **(Page 12-14)**
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol **(Page 14)**
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol **(Page 14)**
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) **(Page 14 & 15)**
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) **(Page 14)**

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed **(Page 15)**
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial **(Page 15)**
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct **(Page 11)**
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor **(Page 11)**

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval **(Page 1 & 5)**
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) **(Page 11)**
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) **(Page 9)**
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable **(N/A)**
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial **(Page 14)**
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site **(Page 20)**
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators **(Page 15)**
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation **(N/A)**

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions **(Page 1)**
	31b	Authorship eligibility guidelines and any intended use of professional writers **(Page 20)**
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code **(Page 1)**
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates **(Appendix A)**
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable **(N/A)**

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Promoting Physical Activity in Regional and Remote Cancer Survivors (PPARCS) using Wearables and health-coaching: Randomised Controlled Trial protocol

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Promoting Physical Activity in Regional and Remote Cancer Survivors (PPARCS) using Wearables and health-coaching: Randomised Controlled Trial protocol

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ABSTRACT

Introduction: Physically active cancer survivors have substantially less cancer recurrence and improved survival compared to those who are inactive. However, the majority of survivors (70-90%) are not meeting the physical activity (PA) guidelines. There are also significant geographic inequalities in cancer survival with poorer survival rates for the third of Australians who live in non-metropolitan areas compared to those living in major cities. 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. **Methods and analysis**: Eighty-six cancer survivors will be randomized into either the intervention or control group. Intervention group participants will receive: a Fitbit and up to six telephone health coaching sessions. MVPA (using Actigraphs), quality of life and psychological variables (based on the HAPA model via questionnaire) will be assessed at baseline, 12-weeks (end of intervention) and 24-weeks (end of follow-up). A General Linear Mixed Model will be used to assess the effectiveness of the intervention. **Ethics and dissemination:** Ethics approval has been obtained from St John of God Hospital Subiaco (HREC/#1201). We plan to submit a manuscript of the results to a peer-reviewed journal. Results will be presented at conferences, community and consumer forums and hospital research conferences. Trial registration number: ACTRN12618001743257, prospectively registered. Universal Trial Number: U1111-1222-5698. Protocol version: 2.0.

Keywords: oncology; wearable technology; physical activity; health coaching; intervention.

Strengths and limitations of this study

- The intervention has the potential to be a low-cost and scalable and hence, integrated into existing health-care pathways.
- An objective measure of PA is used to provide accurate assessment of PA.
- Due to the postal nature of recruitment, the responders may not be a representative sample of regional and remote cancer survivors.
- The relatively short follow-up period limits our assessment of the extended acceptance of wearable technology in this population.

INTRODUCTION

Compared to the general population, cancer survivors are at an increased risk of the development of secondary cancers, cardiovascular disease (CVD) and functional decline[1, 2]. There are several possible explanations for the increased risk, one of which is shared lifestyle risk factors[3]. Insufficient PA, low fruit and vegetable intake, smoking and alcohol consumption make individuals susceptible to cancer recurrence, CVD and other chronic diseases[3].

The American Cancer Society PA guidelines for survivors are to participate in 150-minutes of moderate-to-vigorous intensity PA per week[4]. However, the majority of Australian survivors (~70-90%) do not meet the PA recommendations[5].

PA is associated with lower CVD-related comorbidity in survivors[2]. Physically active survivors have significantly less cancer recurrence and improved survival compared to those who are inactive, and these findings have been found across multiple

cancer types[6, 7]. Many survivors suffer additional comorbidities that put them at risk of developing CVD[8]. As a result, insufficiently active survivors (i.e., those not meeting the PA guidelines) who fail to make healthy lifestyle changes post-treatment are likely to have substantially higher risk of developing CVD.

Together, colorectal, breast, prostate and uterine cancer account for 41% of all cancer incidence in Western Australia (WA)[9]. Our rationale for targeting survivors of these cancers is based on established risk or comorbid cardio-metabolic disease, and a high prevalence of physical inactivity[10].

There are also substantial geographic inequalities in cancer survival[8, 11]. Survival rates for Australians who live in non-metropolitan areas are poorer than for those living in major cities[12]. Those living in remote areas of Australia are often disadvantaged in relation to access to services, education, employment and income. Mortality rates for all cancers combined are 1.4 times higher in remote areas compared to major cities[12].

Existing PA programs for survivors tend to be based in major cities but rarely operate beyond the inner regional areas. Further, facility-based programs that are offered for free initially, eventually incur a cost that may present a barrier to long-term exercise adherence. Previous work with survivors has identified cost, and availability of and access to exercise programs to be significant barriers to participation[13-15]. Survivors have also expressed a preference for home-based PA[13, 15, 16].

Home-based interventions are advantageous because they mitigate access and transport issues, and are less expensive than facility-based programs that require participants to attend classes or maintain a health-club membership[17]. 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.

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].

Interventions that meet support needs and offer opportunities for self-monitoring have been found to be effective in improving PA in survivors[20-22]. Wearable technology holds great potential as a low-cost self-monitoring tool to increase PA in cancer survivors. Lyons et al.[23] recently reviewed 13 different wearables and their associated mobile apps, and concluded that they use many of the same techniques employed in typical PA interventions (i.e. self-monitoring, feedback, goal-setting, social support). Wearables are perceived as useful and acceptable to individuals with chronic conditions[24]. Wearables are acceptable to older cancer survivors in metropolitan areas[25] and those living in regional and remote areas[26]. Thus, wearables may represent a relatively low-cost, feasible and scalable approach for widespread PA promotion.

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.

METHODS AND ANALYSIS

Study design

A randomised controlled parallel group design will be employed. Participants will be randomised into one of 2 arms: control vs. intervention, and assessments will be made at baseline (T1), end of intervention (12-weeks) (T2) and at 24-weeks (T3). The outcome (dependent) measures will include an objective measure of PA, sedentary behaviour, Quality of life (QoL), plus measures that indicate constructs from the HAPA model[27] such as action self-efficacy, outcome expectancies, action planning, and maintenance self-efficacy upon which the intervention is designed. We will also measure a number of covariates that may influence effects of the intervention including: age, gender, socio-economic status, cancer type, months since diagnosis, disease stage, adjuvant treatment, and CVD risk factors. Ethics approval was obtained from the St. John of God Hospital Human Research Ethics Committee (#1201), and reciprocal approval will be approved from other participating hospitals and sites. The trial will comply with CONsolidated Standards of Reporting Trials (CONSORT) and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)[28, 29]. A completed SPIRIT checklist for the trial can be found in Supporting Information.

Setting and Participants

Participants will be cancer survivors diagnosed with cancer and completed active treatment in the previous 5-years. Participants will reside in Australia and will have been treated for either breast, prostate, colorectal or uterine cancer. Participants will be recruited on the basis of (1) remoteness, and (2) low levels of PA. Remoteness will be measured according to the Accessibility/Remoteness index of Australia and the Australian Statistical Geography Standard which define five major areas: *major cities*, *inner regional*, *outer regional*, *remote* and *very remote*[30]. Participants will be recruited on the basis that they reside in either a regional or remote area. Eligible participants must also be 1) insufficiently physically active (i.e., engaging in less than 150-minutes of moderate-intensity or 75-minutes of vigorous-intensity PA per week)[4, 31]; 2) aged between 18 and 80 years; 3) proficient in English-reading and speaking; 4) have no known presence of cancer at the time of recruitment; 5) have internet access at home. Exclusion criteria include individuals who 1) are still undergoing treatment for cancer except for maintenance therapy such as tamoxifen; 2) have known cardiac abnormalities including unstable angina or recent myocardial infarction; 3) have any severe disability that may affect physical function including severe arthritis; 4) have a current diagnosis of a severe psychiatric illness (those with minor psychiatric diagnoses will be eligible if they are well enough to participate; 5) are currently enrolled in a health behaviour trial or program.

Recruitment

Participants will be recruited using purposive sampling methods, involving screening the hospital records of participating oncologists, to collate a pool of eligible survivors. The preliminary participating oncologists are based at St John of God Subiaco

and Murdoch Hospitals, Hollywood Private Hospital, the Women Centre in West Leederville. Oncologists in South Australia, Victoria and New South Wales may also participate in the trial depending upon recruitment uptake. Eligible individuals will be mailed an invitation letter and information sheet from their treating oncologist.

Intervention

The 12-week intervention includes two components: 1) a Fitbit Charge 2 activity tracker™ providing real-time monitoring and feedback on PA; 2) Up to six sessions of health coaching (4 fixed sessions) via skype/facetime/etc. or phone depending on participant preferences.

WAT tracker: Participants will be provided with a Fitbit Charge 2™ activity tracker. This is a slim, wrist-worn device that displays steps, distance, heart rate, active minutes (MVPA), and, provides automated prompts which nudge participants to accumulate at least 250 steps/hour. The Fitbit Charge 2™ was chosen because previous work demonstrates its usefulness and acceptance amongst survivors[25-26] and older adults (>70)[32]. Data from the device can be uploaded to the Fitbit™ application via Bluetooth. Participants will receive clear and simple written instructions guiding the installation of apps and device usage. Technical support will also be provided through follow-up calls to maximize uptake.

Health Coaching: The purpose of the health coaching is to motivate and support increased PA (i.e., deliberate bouts of MVPA) and reduced sedentary behaviour through supporting self-efficacy, action planning and problem solving, based on the principles of the HAPA. The health coaching is important to help guide action planning and problem solving since these behaviour change techniques are absent from the Apps associated with wearable

devices[23]. Telephone health coaching has been successfully used in Australian and US survivors to increase PA[5, 33]. The first session (wk 1; ~ 60 minutes) will cover technical issues and the features of the Fitbit, including the importance of MVPA. It will also foster positive outcome expectancies and confidence towards PA and guide the participant to create PA action plans for the following three weeks and self-monitor their activity. The purpose of the three follow-up health coaching sessions (wk 2, 4, and 8; ~30 minutes each) will be to provide support, problem solving and help the participant to update goals and action plans as they progress. We will adopt a patient-centred and stepped-care approach by providing additional health coaching sessions (i.e., at wk 6, and 10) to those who may need them in order to achieve meaningful sustained PA change. 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. The weekly exercise target will be at least 180-minutes of moderate-intensity PA, based on research demonstrating better survival in patients who engaged in 3-5 hrs of moderate activity per week[7, 20]. A web-based API (Application programming interface) to collect user's activity data from the Fitbit server will be developed. Upon user consent via Fitbit authentication page, we will be able to collect participants' daily activity (step count, active minutes, hourly activity, heart rate, stairs climbed). 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. API monitoring will cease at the end of

the trial (after 24-weeks) and a de-authorization email sent to participants to confirm the end of API participation.

Quality Assurance

The Health coach employed to deliver the intervention will be required to have a background in Psychology or allied health discipline (at least to degree level). The health coach will undertake training including the theoretical bases of the intervention, PA messaging, and implementation of behaviour change techniques. Training will include role-plays with supervised feedback. Health coaching consistency will be achieved by following a semi-structured script with a clear structure of questions, and behaviour change techniques to be covered in each call. Competency and quality control will be monitored by direct observation and/or audio-recordings, (with feedback to the health coach) and will continue until consistent and adequate health coaching performance is confirmed. All telephone calls to participants will be audiotaped.

Procedure

Participants will be sent an invitation letter, information sheet, consent form (Supplementary file, Appendix A) and a reply-paid envelope from their treating surgical, medical or radiation Oncologist. Upon receipt of written consent, participants will be telephoned and an initial screening questionnaire (including the Active Australia Survey; AAS)[34] to assess PA status) administered to determine eligibility. The AAS has demonstrated acceptable convergent validity for community-dwelling older adults[35]. Only those that report participating in less than 150-minutes of MVPA per week will be eligible to participate in the trial.

If the criteria are met, 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. Figure 1 represents the flow of research participants through the trial.

The statistician will generate the randomisation sequence using STATA v15 with a 1:1 allocation using random block sizes of 4 and 6 to support allocation concealment. Participant allocation will be implemented using sequentially numbered, opaque sealed envelopes, and the researchers involved in assessing and enrolling participants will not be involved in the generation of the randomisation sequence. Following consent and baseline assessment, the trial-coordinator will choose the next envelope in the sequence and write the participant study number onto the envelope prior to allocating the participant to that group. Carbon paper inside the envelope will transfer the number onto the card containing the details of allocation.

The trial-coordinator will post the accelerometers to participants with clear instructions on how to use them, and will contact participants after the 7-days to remind them to post them back to the researchers. Participants will also complete questionnaires that measure socio-demographic variables, QoL, and HAPA model constructs[27].

Both the control and intervention group will receive a mailed booklet designed to educate and motivate improvements in PA. Materials will be based on the current guidelines for PA[31] and include examples of home-based strength exercises and a guide to exercise intensity. The control group will receive minimal intervention to mimic usual care so that we are able to compare the effects of the intervention to 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.

After 12-weeks, participants in both groups will complete a questionnaire that measures variables from the HAPA, QoL and psycho-social variables again for a second time and wear an accelerometer for a 7-day period. The trial-coordinator will post out the accelerometers and questionnaires. Between 12-weeks and 24-weeks, participants will keep the Fitbit but there will be no further health coaching. At 24-weeks, all participants will complete the questionnaires for a third time and will receive an accelerometer to wear for a 7-day period. All Fitbits will be returned after the 24-week assessment alongside the accelerometer. Following trial completion (T3), participants in the control group will be offered the opportunity to trial a Fitbit ™ for 12-weeks.

Measures

Primary outcomes

The primary outcome will be minutes of moderate-to-vigorous PA (MVPA) and sedentary behaviour ascertained from the Actigraph GT9X (Actigraph, LLC, Pensacola, Florida, USA). Participants will be mailed the accelerometer and instructed to wear on their right hip for all waking hours for one week at baseline, 12-weeks and 24-weeks. Wear time must exceed 10-hours per day to be considered valid for analysis. Non-wear periods will be defined as intervals of at least 60-consecutive minutes of zero counts will be excluded from analyses. Activity counts will be categorised as: sedentary (<100cpm), light-intensity (100-1951cpm), moderate-intensity (1952-5724cpm) and vigorous-intensity (>5725cpm), using data recorded in 60-s epochs, according to Freedson cut

points[36]. MVPA will be examined as both weekly time accumulated (minutes/week), and time in bouts of 10-consecutive minutes (minutes/week).

Sedentary behaviour

Sedentary behaviour will be defined by accelerometer activity counts of <100cpm, for 20 consecutive minutes or more, which corresponds to clinical changes in cardio-metabolic biomarkers[37]. The accelerometer log completed will assist in differentiating sedentary time from non-wear time.

Quality of life

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.

Physical activity attitudes

PA attitudes will be assessed using previously validated items, with Cronbach's alpha scores for the subscales below ranging from 0.73 to 0.87[41]. Some items have been amended, based on previous formative work in survivors[13, 16, 42, 43], and PA recommendations[4]. All items are assessed using a six-point Likert scale. The following constructs will be assessed:

Outcome expectations. Twelve-items will assess outcome expectations. Five-items are derived from the validated exercise pros subscale[44] and 7-items are based on formative research with survivors[14, 42, 43]. The items measure magnitude that regular PA will help to: reduce tension or stress; feel more confident about my own health; sleep better; have a positive outlook; control my weight; regain lost strength; prevent cancer

recurrence; increase fatigue; increase joint pain; weaken my immune system; feel better about my body, and increase my longevity.

Action self-efficacy. Four-items will assess action self-efficacy, based on previous research with survivors[45]. Items assess participants' confidence to complete 150-minutes of MVPA per week, with the item stems: 'I believe I have the ability to…'; 'I am confident I can do…'; 'If I wanted to I could…' and 'For me to do…'.

Maintenance self-efficacy. Thirteen-items will assess maintenance self-efficacy, based on formative research [14, 43]. Items assess confidence to participate in regular MVPA over the next 12-weeks when, for example: I lack discipline, and I am feeling tired.

Action planning. Four-items will assess action planning for the next 3-weeks[46]. Participants will be asked to respond about whether they have made plan concerning *what*, *when*, *where*, and *how* they will engage in regular PA.

Intention. Two-items will measure intention to engage in MVPA for at least 150-minutes per week in the next 12-weeks, based on previously established measures[47]. Items are 'I intend to participate…' and 'I will try to participate…'.

Covariates

Sociodemographic information and CVD risk factors will be self-reported. The following variables will be assessed: marital status; educational attainment; gross household income; and smoking status. Comorbidity will be assessed using the self-administered comorbidity questionnaire [48].

Power Calculations and Sample size

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. We aim to recruit 100 participants, ensuring that if 15% are lost to follow-up, the intervention will still be adequately powered at 80% to detect a meaningful change.

Patient and public involvement

We have published several papers[13-16] from qualitative work with consumers. Such consumer engagement has informed the present intervention. For example, this work has identified 'poor self-discipline' and 'not the sporty type' as the main PA barriers. Some participants held the perception that they were already 'doing sufficient PA'. Participants also referred to the need for monitoring, support and accountability to help them in their behaviour change efforts. These findings have fed into the design of the intervention in the following ways: the promotion of lifestyle-related exercise such as walking takes away the 'sporty type' barrier; the use of wearables to provide objective feedback on PA can be helpful for those who erroneously think they are undertaking sufficient PA; and the use of wearables and health-coaching provides the self-monitoring, and support that consumers have identified as important. Consumers that have trialled the wearable trackers have reported the intervention to be acceptable and not burdensome [26]. Study participants will be asked whether they wish to receive a report of the results, and asked to provide an email address for dissemination of study results.

Data Management

All personal data collected will be stored in accordance with the Data Protection Act and applicable regulatory requirements and access to de-identified data will be available on request. Data will be stored securely to maintain confidentiality. To preserve participant anonymity, only allocated trial numbers will be recorded on trial documentation or computer software except for the consent form and contact details. Documents with identifiable information will be stored separately to other study documents. Pseudonyms will be used when reporting findings from the process evaluation.

Data Monitoring and Timeline

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. Recruitment is expected to commence in Februry-2019 and the project completed by December-2020.

Data analysis

The effectiveness of the intervention vs. control on MVPA/week will be assessed using a linear mixed model, with group (intervention vs. control), time (T1 vs. T2) and their interaction as fixed effects, and with a random effect for participant included to account for the correlations in observations inherent in a repeated measures design. 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. 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, including adjustment for confounding where appropriate. Missing data will be investigated for patterns in terms of observed study variables. Multiple imputation will be considered if data are arguably missing at random and less than 20% of the data are missing. We will impute 25 data sets based on all relevant observed variables, including the interaction term and outcome measure of interest for each specific analysis. Sensitivity analyses will be conducted to consider the effect of potential missing not at random mechanisms on parameter estimates from imputed data sets. Intention-to-treat analysis will be conducted where there is participant attrition. Appropriate longitudinal mediation models will be used to investigate whether a) intervention associated changes in MVPA are mediated (at least partially) via the HAPA model and b) changes in QoL are partially mediated via changes in MVPA. All data will be analysed with $p < 0.05$ considered significant.

Process evaluation

Acceptability and feasibility of the intervention will form the process evaluation. Feasibility of the intervention will be evaluated by comparing intervention costs (intervention equipment, staff time) with uptake rates, adherence (to wearing the wearable tracker, receipt of health coaching sessions), and completion. Acceptability and utility of the intervention, and an understanding of the active ingredients will be examined using semi-structured interviews.

DISCUSSION

The trial will assess the effectiveness of an intervention that combines wearable technology with behaviour change techniques (action-planning, goal-setting, and coping planning, feedback) to increase MVPA and reduce sedentary behaviour in cancer survivors living in non-metropolitan areas of Australia. This protocol describes one of the first trials using wearable technology to promote PA in non-metropolitan survivors, contributing to research on the effectiveness of distance-based interventions to promote PA.

Despite increasing evidence that PA reduces the risk of CVD and cancer recurrence[6, 50], few survivors meet the PA guidelines[4]. Furthermore, there are significant geographic inequalities in cancer survival that urgently need to be addressed, with significantly poorer survival in rural areas compared to major-cities. Existing PA programs for survivors tend to be based in major cities with scarce provision outside of major-cities. Less intensive home-based interventions could be more acceptable to consumers, scalable and more cost-effective.

Conclusion

The trial is pragmatic and primarily concerned with evaluating whether a low-intensity, distance-based intervention is effective for increasing MVPA and reducing sedentary behaviour in survivors. If effective, the intervention, that employs resource deployment according to patient need, would be low-cost and scalable, and could be integrated into existing health care pathways.

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Figure Legends

Figure 1. Flow diagram of trial design

Acknowledgements: We thank the consumers that have kindly given their time to participate in our previous projects that have contributed to the design of the prospective intervention.

Contributors: SH led the study conceptualisation, development of intervention content and writing of the protocol. GM, PT, SS, JT, GRM, ML, PC, CS and CP contributed to study conceptualisation and will recruit patients for the trial. RJ edited the protocol and will assist in the process evaluation. TB and VC contributed to physical activity measurement protocol and will be responsible for Actigraph data cleaning and analysis. DH contributed to statistical analysis and the process for randomisation and data management and will undertake data analysis. All authors edited the manuscript.

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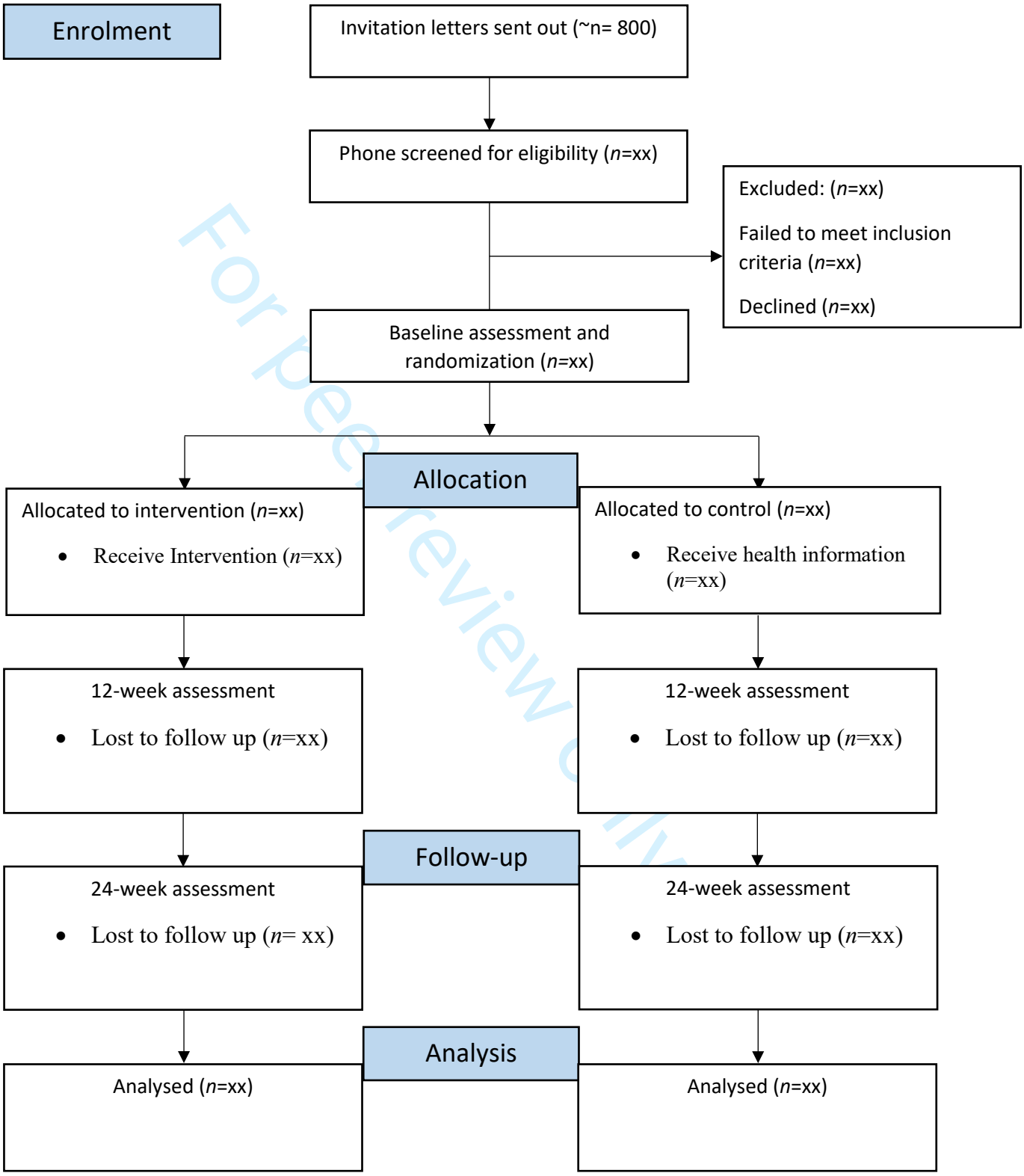
Competing interests: None declared

Figure 1. Flow diagram of trial design



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Subiaco Hospital

Supplementary File, Appendix A: Consent form

Title	**The promotion of physical activity to adult cancer survivors in regional and remote areas of Western Australia using Fitbit technology and telephone health coaching**
Principal investigator	Sarah Hardcastle

Note: All parties signing the consent section must date their own signature.

Declaration by participant

- I have read, or have had read to me, and I understand the participant information and consent form.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand the purposes, procedures and risks of the research described in this research study.
- I intend to adhere to the study requirements to the best of my ability.
- I understand that I will be given a signed copy of this document to keep.

Signature _____ Date_____

Name of participant (please print) _____

Declaration by trial doctor/senior researcher†

I have given a verbal explanation of this study, its procedures and risks and I believe that the participant has understood that explanation.

Signature _____ Date_____

Name of trial doctor/ researcher† (please print) _____

† A senior member of the research team must provide the explanation of, and information concerning, the research study.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym **(Page 1)**
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry **(Page 1)**
	2b	All items from the World Health Organization Trial Registration Data Set **(UTN and ACTN numbers are on Page 1)**
Protocol version	3	Date and version identifier **(Page 1)**
Funding	4	Sources and types of financial, material, and other support **(Page 24)**
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors (**Title page and Page 23)**
	5b	Name and contact information for the trial sponsor **(Page 24)**
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities **(Page 24**)
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) **(Page 23)**
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention **(Pages 3-6**)
	6b	Explanation for choice of comparators **(Page 11)**
Objectives	7	Specific objectives or hypotheses **(Page 6)**

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) **(Page 6)**
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) (and list of countries where data will be collected. Reference to where list of study sites can be obtained **(Page 7)**
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) **(Page 7-10)**
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered **(Page 8-10)**
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) (**N/A)**
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) **(Page 8-10)**
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial **(Page 7)**
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended **(Page 6, & Page 12-14)**
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) **(Figure 1)**
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations **(Page 14)**
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size **(Page 7)**
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. (To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions **(Page 11)**
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned **(Page 11)**
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions **(Page 11)**
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how **(Page 11)**
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial **(N/A)**
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol **(Page 7-11)**
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols **(Page 8)**
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol **(Page 15-16)**
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol **(Page 16-17)**
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) **(Page 16-17)**
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) **(Page 17)**

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed **(Page 16)**
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial **(N/A)**
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct **(Page 16)**
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor **(Page 16)**

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval **(Page 1 & 6)**
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) **(Page 16)**
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) **(Page 10)**
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable **(N/A)**
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial **(Page 15-16)**
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site **(Page 24)**
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators **(Page 24)**
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation **(N/A)**

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions **(Page 1)**
	31b	Authorship eligibility guidelines and any intended use of professional writers **(Page 23-24)**
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code **(Page 1)**
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates **(Appendix A)**
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable **(N/A)**

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.