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Scale-up of the Australian Fans in Training (Aussie-FIT) men's health behaviour change program: Protocol for a randomised controlled hybrid effectiveness-implementation trial.

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Abstract

Introduction

Improving physical activity and healthy eating is critical for primary and secondary prevention of cardiovascular disease (CVD). Behaviour change programs delivered in sporting clubs can engage men in health behaviour change but are rarely sustained or scaled-up post-trial. Following the success of pilot studies of the Australian Fans in Training (Aussie-FIT) program, a hybrid effectiveness-implementation trial protocol was developed. This protocol outlines methods to: i) establish if Aussie-FIT is effective at supporting men with or at risk of CVD to sustain improvements in moderate-to-vigorous physical activity (primary outcome), diet, and physical and psychological health, and ii) examine the feasibility and utility of implementation strategies to support program adoption, implementation and sustainment.

Methods and Analysis

A pragmatic multi-State/Territory hybrid type 2 effectiveness-implementation parallel group randomised controlled trial with a 6 month wait-list control arm in Australia. 320 men aged 35-75 years with or at-risk of CVD will be recruited. Aussie-FIT involves 12 weekly face-to-face sessions including coach-led interactive education workshops and physical activity delivered in Australian Football League (Western Australia, Northern Territory) and rugby (Queensland) sports club settings. Follow-up measures will be at 3- and 6-months (both groups), and at 12 months to assess maintenance (intervention group only). Implementation outcomes will be reported using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework.

Ethics and Dissemination

This multi-site study has been approved by the lead ethics committees in the lead site's jurisdiction, the South Metropolitan Health Service Human Research Ethics Committee

(Reference RGS4254) and the West Australian Aboriginal Health Ethics Committee (HREC1221). Findings will be disseminated at academic conferences, peer-reviewed journals and via presentations and reports to stakeholders, including consumers. Findings will inform a blueprint to support the sustainment and scale-up of Aussie-FIT across diverse Australian settings and populations to benefit men's health.

Strengths and Limitations

- This is the first multi-State/Territory trial of a 'fans in training' style intervention.
- Consumers and other stakeholders contributed to the development of the protocol, in particular recruitment and data collection methods.
- Using a hybrid design will facilitate the concurrent assessment of intervention effectiveness and implementation outcomes, promoting efficient implementation and long-term impact of this evidence-based program.
- Due to the nature of the intervention, participants will not be blinded to treatment allocation.

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Introduction

The cardiovascular benefits of physical activity (PA) and eating a healthy diet are well established, however, 55% of people who live in Australia do not meet PA guidelines, most eat an unhealthy diet and 67% are living with overweight or obesity (1). Among those with a cardiovascular disease (CVD) diagnosis, exercise adherence remains low. Most men with CVD fail to initiate or sustain health behaviour changes, decreasing quality of life and increasing risk of future CVD and premature death (2). For instance, only 30% of patients complete outpatient cardiac rehabilitation, and of those, less than 50% are sufficiently active 12 months after their cardiac event (2).

A patient survey showed many patients lack self-management skills and are too dependent on exercise rehabilitation staff to sustain behaviour changes upon completion of hospital-based exercise programs (3). Recent estimates suggest that increasing participation in cardiac rehabilitation in Australia from 30% to 65% would result in $36 million in healthcare savings, $58 million in social and economic benefits, and significantly reduce annual heart attack admissions (4). To reap these health and economic benefits, new strategies are required to increase PA adherence and healthy eating in people with or at-risk of CVD. Gender tailored programs are important, because men and women experience differences in CVDs risks and occurrences (5). Gender-tailored health behaviour change programs for men have been shown to be appealing and effective (6).

The internationally recognised 'Football Fans in Training' (FFIT) program, and our Australian adaptation (Aussie-FIT), are effective in engaging men to improve their health behaviours. FFIT (7) and Aussie-FIT (8) capitalise on men's interest in sport to promote weight loss via sustained improvements in diet and PA. These structured 12-week programs include 90 minutes of interactive education and group-based PA that aims to develop the skills and

confidence of participants to self-regulate and maintain behaviour change long-term. Programs are delivered to groups of men by trained coaches in professional sport facilities. The effectiveness and cost-effectiveness of FFIT was established in a Randomised Control Trial (RCT) (7). Mean between group weight lost at 12 months was 5kg, and average weight loss maintenance of 2.9kg was observed in the intervention group 3.5 years post-baseline (9) . FFIT was adapted for the European Fans in Training (EuroFIT) RCT in 5 European countries, where similar findings were revealed (10).

Kwasnicka et al (2020) demonstrated feasibility of recruitment, engagement, and retention of men living with overweight and obesity, as well as acceptability of the Aussie-FIT intervention and research procedures when delivered at top-tier Australian Football League (AFL) clubs in Western Australia (WA). Promising physical and mental health outcomes were observed (11). In a single-arm feasibility trial in Queensland (QLD), a version of Aussie-FIT adapted for rugby league (League-FIT) has engaged men living with overweight and obesity, and demonstrated promise in supporting positive physical and mental health outcomes (12). In a feasibility study of the Aussie-FIT program undertaken at second-tier AFL clubs for men with CVD, Smith et al (manuscript in preparation) demonstrated feasibility of participant engagement and retention, and acceptability of the intervention and research procedures. However, recruiting men with CVD was challenging (Smith et al., manuscript in progress). Recruitment challenges were likely due to the smaller population of men with CVD (6.5% of men in Australia) (13) compared with 75% of men with overweight and obesity in Australia (14), and the smaller fanbases of second-tier AFL clubs compared to top-tier clubs. The effectiveness of Aussie-FIT remains to be tested, as do implementation strategies designed to improve the adoption, implementation, sustainment and scale-up of the program to reach diverse populations of at-risk men. This multi-State/Territory trial aims to establish the

effectiveness of the Aussie-FIT intervention for men with or at-risk of CVD, whilst allowing for flexibility with club-size (e.g., top-tier or second-tier) across diverse Australian contexts.

A recent systematic review of five unique interventions concluded that, whilst FFIT has been successfully scaled up, not all health promotion interventions delivered through professional sport have been successfully scaled up, and thus a greater focus on the potential for scalability of these interventions is required (15). Scalability is the process of increasing the number of implementers (e.g., sports clubs) that are willing to initiate delivery of effective interventions to reach a greater proportion of the target population (16). The potential for intervention scalability is increasingly considered across the research spectrum, rather than solely positioned at the end of a linear research pipeline after effectiveness testing (17). One increasingly common approach to considering implementation and scalability earlier in the research process is the use of hybrid effectiveness-implementation study designs, which allow for the assessment of intervention effectiveness alongside implementation outcomes (18). Implementation outcomes that are important for scalability include program costs, fidelity, adaptability, delivery settings, infrastructure, workforce, reach and acceptability in diverse populations (Milat et al., 2020).

This trial adopts a hybrid effectiveness-implementation design (19) to examine the effectiveness of Aussie-FIT, and in parallel assess the feasibility and utility of implementation strategies to support program adoption, implementation, sustainment and scalability, using the RE-AIM framework. We pose two research questions to simultaneously address both the intervention and the implementation process aims (20): 1) is the Aussie-FIT program effective in increasing time spent in moderate-to-vigorous physical activity (MVPA; and improving other secondary outcomes among men with or at-risk of CVD at 6 month follow up; and 2) what are the facilitators and barriers to implementation, sustainment and scalability of the Aussie-FIT program?

Method

This protocol follows the SPIRIT reporting standards for standard protocol items (Supplementary File 1) and meets the requirements of the Standards for Reporting Implementation Studies (StaRI) (20) (Supplementary File 2).

Study design

This study is a pragmatic multi-State/Territory Hybrid Type 2 Effectiveness-Implementation parallel group RCT with a 6 months wait-list control. Follow-up measures are at 3 and 6 months (primary outcome) post-baseline for both the intervention and control groups; and at 12 months for the intervention group to assess maintenance (see Figure 1, CONSORT diagram). Observational implementation outcomes will be reported using the RE-AIM framework (21). This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12623000437662).

Context

The study is set in and around the capital cities of Darwin (Northern Territory), Perth (WA), and Brisbane (QLD). These urban centres have distinct contextual characteristics. QLD and WA make up 20% and 10% of the national population respectively and are far more populated than the Northern Territory (NT) which makes up less than 1% of the national population (22). There is significant cultural diversity across each State/Territory; for example, the proportion of males that identify as Aboriginal and/or Torres Strait Islander in the NT (26.3%) is considerably higher than in QLD (4.6%) and WA (3.3%) (23). Australian Football is the most popular sport in WA and the NT, whereas in QLD, Rugby League is most popular (24).

Consumer and Stakeholder Involvement

Consumer engagement has been central to the development of the Aussie-FIT program since its ' inception and in previous pilot studies. In preparation for this trial, community advisory groups consisting of consumers (i.e., men with or at-risk of CVD, and former Aussie-FIT participants) and stakeholders (e.g., Aussie-FIT coaches, sporting club or community representatives) have been formed in each State/Territory. These groups include representation of Aboriginal and/or Torres Strait Islander men. The first of these groups met in December 2022. Community advisory groups have helped identify potential barriers and enablers of project success and have co-designed responsive implementation strategies. These groups will continue to work in partnership with the research team throughout the lifespan of this project. This will include providing input on culturally appropriate recruitment strategies, retention strategies, involvement in dissemination planning, and if the effectiveness of the intervention is established, providing advice on the sustainment and scalability of Aussie-FIT. The outcomes of our cross-site consumer and stakeholder involvement activities during the trial set-up period, and at later stages in the trial, will be reported in future publications.

Participants

Inclusion criteria

Men aged 35-75 in WA (n=128), NT (n=96) and QLD (n=96) that self-report meeting one or more of the following criteria will be recruited:

a) CVD diagnosis more than 3 months prior to commencing the study, with no upper limit on length of time since diagnosis; OR

b) ≥10% risk of CVD, according to the online calculator created by the Australian Chronic Disease Prevention Alliance, that assesses CVD 5-year risk (www.cvdcheck.org.au/calculator); OR

c) Body mass index ≥28kg/m^2.

To determine whether they are eligible, potential participants will complete an online form, co-designed with consumers to ensure accessibility for men.

Participants from non-English speaking backgrounds will be offered interpreters if they wish to participate in the study. Men at risk of harm from PA will be excluded from vigorous PA and will instead undertake light or moderate PA as tolerated (if appropriate based on GP/cardiologist's advice). Where possible men who have not participated in previous Aussie-FIT or League-FIT programs will be prioritised.

Exclusion criteria

Exclusion criteria are: unable to comprehend information or consent documentation; unable to attend most of the weekly sessions, diagnosed with CVD less than 3 months prior to the baseline assessments date; experienced a cardiac event less than 3 months prior to the baseline assessments date; or a medical professional advises against participation (e.g., due to having a cardiac condition not suitable for an exercise trial in the community such as severe aortic stenosis or on-going angina).

Recruitment

Participants will be selected on a 'first come, first served' basis. Men with CVD will be identified from medical records at hospitals (WA only), cardiac rehabilitation programs delivered in hospitals, or in the community, and GP or other primary health care services. Men with or at-risk of CVD will be recruited from community sources including club members' newsletters, traditional/social media, match-day publicity (e.g., announcements, face-to-face recruitment), snowball sampling (25), sport publications, and local health councils. Interested individuals who see the program advertised will be directed to complete a web-based expression of interest (EOI) form. Men who prefer not to use the online EOI form will have

the opportunity to express their interest, ask questions, check their eligibility, and enrol (if eligible) by contacting the research team directly via phone or email. The online EOI form includes a series of questions to confirm eligibility.

This trial will host a nested 'study within a trial' (SWAT) (26) to examine the utility of a self-directed online enrolment in comparison to a phone call enrolment process (27). Eligible men that complete the online EOI will be randomised via the online form to either immediately book their enrolment appointment online or to receive a call from a researcher to progress their enrolment. The SWAT will evaluate the effectiveness (including cost-effectiveness) of the online approach compared to the standard phone call on enrolment rates (27).

Intervention (Aussie-FIT Program)

The intervention is described following the Template for Intervention Description and Replication (TIDieR) guidance (28), see Table 1. In brief, the 12, weekly, 90-minute sessions will be delivered to groups of 16 men. One coach and one Accredited Exercise Physiologist (AEP) or equivalent suitable health professional facilitate each group. Coaches and AEPs will be trained by the research team in the core content (PA and diet education), safe exercise for men with or at-risk of CVD, and in the use of principles of motivation and behaviour change. Coaches will lead on the program content delivery and AEPs will be primarily responsible for exercise safety. Practical activities and discussions are designed to help men understand why and how to improve PA (e.g., understanding exercise intensities, safe strength training, decreasing sedentary time) and dietary behaviours (e.g., interpreting food labels, portion sizes, meal planning, eating out), and incorporate behaviour change techniques to support participants to adopt positive health behaviours in their daily lives. A range of PA intensities are promoted, and ball skills and circuit training like those undertaken by professional players but modified to be safe for each man's limitations (e.g., ball skill drills restricted to walking) undertaken.

Men are encouraged to self-monitor walking, gradually increasing steps/day throughout the 12-weeks. The AEP will co-deliver the sessions and support the coach by monitoring participants (e.g., blood pressure checks), providing advice on safe exercise and providing first aid, if required. The waitlist control group (another 16 men from each club) will receive the program 6 months later.

Description of the implementation strategy

Our consumer advisory groups have supported the development of our implementation strategies in the study set-up phase of this project, full details of which will be reported elsewhere. The implementation study is structured by the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance) (12).

Reach: Program recruitment strategies have been co-designed with men with or at risk of cardiovascular disease (CVD). These strategies will be tailored for each State/Territory in consultation with community advisory groups.

Effectiveness: Individual effectiveness outcomes will be tested via the RCT. Negative or unintended consequences will also be documented.

Adoption: Clubs will be invited to offer formal commitments to continue deliveries pending further funding opportunities in each State/Territory. An infrastructure and costing model will be developed to support clubs in sustaining the program, and preferences for models of sustained program deliveries will be co-designed with stakeholders.

Implementation: A comprehensive coach delivery package will support fidelity of program delivery. This package includes 15 hours of training for the coaches, detailed program delivery speaking notes, a timing guide, and rationales. Reusable teaching resources will also be

provided to support high-quality delivery. Implementation costs, such as coaches' time for delivering and preparing for sessions, have been included in the program costing model.

Maintenance: Our nested SWAT will evaluate an automated enrolment strategy, designed to improve program sustainability when fewer resources are available compared to the trial phase. Resource sharing agreements will be developed, if required, to ensure the intervention materials can continue to be used post-trial. Sustainability action plans will be developed with stakeholders, including identifying suitable charities as delivery partners for ongoing program deliveries. Indications of individual participant-level behaviour change maintenance will be assessed at 12-months follow-up in the intervention group.

Throughout the implementation process, barriers and facilitators to implementation will be identified (by stakeholders, including consumers and researchers) and targeted in future modifications to the program. Interviews with stakeholders will be conducted to identify these barriers and facilitators. Contextual adaptations required for the different States and Territories will be documented and evaluated. These adaptations will be co-designed with our consumer advisory groups to ensure contextual fit while preserving fidelity.

Blinding and Randomisation

It is not possible to blind participants to condition due to the nature of the intervention. Data collectors will be blinded as far as possible. Questionnaire data will be completed online, PA data will be device measured, and participants will be asked not to reveal whether they are in the intervention or waitlist control arm, when objective measures of weight and blood pressure are taken.

Aligned with the EuroFIT trial, we propose an individual randomisation for each club, given the FFIT study confirmed that the minimal between-group contamination effects did not

warrant higher sample size and costs of a cluster trial. (10) Participants from each club (10 clubs, 32 participants per club) will be individually randomised (1:1 randomisation, in blocks of 8 to reduce prediction of group allocation). A statistician generated the randomisation list using the RANDOMBETWEEN (1,2) function using Excel. The statistician, who is not involved in data collection, will not be told if group 1 or group 2 is the intervention arm to assure blindness during the analyses. Following completion of baseline measures, trained research assistants will use opaque, sealed envelopes to assign participants to intervention or control arms.

Primary outcome: Physical Activity

Participants will also be asked to wear an Actigraph GTX9 (ActiGraph LLC, Pensacola, FL) monitor continuously for 7-days on their non-dominant wrist at each data collection time-point to provide a valid and reliable assessment of MVPA (29). The GT9X is a small (3.5 × 3.5 × 1 cm), lightweight (14 g), and waterproof tri-axial accelerometer. The monitors will be initalised to collect data at a 30hz sampling rate. Men will be provided with written instructions for wearing the Actigraph.

Secondary Outcomes

Secondary outcomes include dietary intake, weight, blood pressure, cholesterol, self-esteem, affective states, quality of life, motivation for physical activity, and use of behaviour change strategies targeted in the program. A full list of variables assessed and measurement tools is included in Table 2.

Implementation Outcomes

Implementation outcomes will be reported using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework (21). Reach: we will report on the

number of participants interested and recruited; descriptive statistics of their representativeness, using demographics (e.g., comorbidities, weight, socioeconomic status, ethnicity) of those recruited in each locality; Effectiveness: as per description of intervention outcomes and for effectiveness of implementation outcomes, with qualitative interview findings; Adoption: records of adaptation to the intervention and implementation strategies (between clubs, locations etc); Implementation: fidelity to key content (e.g., educational messages) and functions (e.g., appropriate use of behaviour change techniques) via coding of a subsample of deliveries; adaptations to delivery in each location, ascertained from coach/participant interviews; barriers and facilitators to program implementation from perspectives of coaches, administrators, and participants via interviews; Maintenance: intentions to continue delivering the program (for clubs in this trial) and intentions to initiate program delivery when further funding secured (new clubs),

Procedure

Participants will book an appointment to attend baseline measures (detailed in Table 2) at the football or rugby club. Measurement sessions will be led by a team of trained research assistants. Participants will be asked to complete a survey, which will be presented to them on an iPad using Qualtrics software. The self-administered survey will ask men demographic questions including their age, ethnicity, education, marital status, current employment status, income, and housing status. Weight, height and waist measurements will be taken by a trained researcher. Cholesterol will be check using a finger-prick test that measures non-fasting cholesterol immediately. Participants will undertake a 24-hour dietary recall using the Intake24, an open-source self-completed computerised dietary recall system based on multiple-pass 24-hour recall. A trained interviewer will assist participants to complete the recall. The self-administered survey will also include items assessing alcohol content, and participants will also be asked to respond to questions assessing their emotions (i.e., positive and negative

affect), quality of life, self-esteem, motivation to for PA and use of behaviour change strategies taught in Aussie-FIT (automaticity, goal conflict, goal facilitation, coping planning, action planning). Participants are asked to respond on Likert scales of 1-5 or 1-7. Participants can skip questions if they prefer not to answer them. All questions have established psychometric properties and have been used by the research team in studies with similar populations. The questionnaire pack should take less than 30 minutes to complete. A trained research assistant will be available to explain to participants how to complete the survey and to answer any questions they may have during completion of the questionnaire.

The full assessment process will usually take about an hour. Following randomisation, participants will be informed as to whether they will receive the 12-week intervention immediately (i.e., the intervention arm) or ~6 months later (i.e., the waitlist control group). Once the intervention arm participants have completed the program, the assessment package will be repeated for both the control and intervention groups (3 months post baseline) and then at 6 months post baseline. After the 6 months measures, the waitlist control arm will complete the 12-week program. Finally, the intervention arm will be asked to attend one final assessment, 12 months post baseline.

Where applicable, information regarding the participants' CVD diagnosis will be self-reported or obtained from medical records. Participant attendance at the program will also be recorded. At baseline, participants will be asked to tick yes or no to the question "in the future we may wish to contact you to join a group or individual interview to talk about your experiences in the program. Do you consent for us to contact you? Yes/No". Approximately 20 of those who tick 'yes', will be contacted by telephone or email at 6 months and/or 12 months, and invited to take part in an interview, which will be conducted on Microsoft Teams videoconference or in person at the football/rugby club (depending on the person's preference).

Interview questions will be developed in collaboration with PhD candidates and an ethics amendment will be submitted for approval prior to undertaking any interviews. Any changes to protocol will be reported on the study Open Science Framework page (https://osf.io/ev8px/).

Treatment of Waitlist Control Arm

All men will be directed to review evidence-based resources (i.e., Heart Foundation online material) regarding PA and healthy eating after completion of the baseline assessments and men in the waitlist control arm will be invited to participate in Aussie-FIT after the 6-month post baseline assessment.

Data Analyses

Physical activity data will be downloaded via the ActiLife software (version 6.13.4), where the raw accelerometer data will be processed in R using the GGIR V1.5-21 package (cran.r-project.org/web/packages/GGIR/index.html) (30,31). Physical activity will be estimated from 5-second epochs, with the average daily activity calculated. To be classified as moderate to vigorous physical activity (MVPA) mean acceleration needs to be ≥100 milli-g (mg) (32). Time in activities lasting at least 1 minute, for which 80% of the activity satisfied the 100 mg threshold criteria, will be calculated. Average acceleration (calculated as the mean acceleration across the 24-hour day as a proxy for the daily volume of PA) and intensity-gradient (as a reflection of the distribution of intensity across the 24-hour day) will be calculated (33,34). We will only include in the analysis those participants with four or more valid days of accelerometry data, and at least 10 hours of wear time each day.

De-identified objective measurements, questionnaire data and calculated PA data will be exported to Stata software for analyses by an independent biostatistician blinded to the group allocation. Characteristics of the participants will be summarised in mean (and standard

deviation) or median (and interquartile range) or frequency (and percentage), by treatment groups. Program efficacy will be analysed following the intention-to-treat principle and per-protocol approaches outlined below. Changes in the post-intervention outcomes will be analysed using linear mixed effect regression models whilst controlling for the baseline measures. Sensitivity analyses will also be performed to include covariates such as age, BMI, types of comorbidities in the model to compare the beta coefficient of the models with and without the covariates. If group sizes permit, sub-group analyses will be performed to examine differences in intervention effects on primary and secondary outcomes between i) States/Territories; ii) men diagnosed with and without a CVD diagnosis, iii) men with BMI ≥25 and men with BMI <25; and iii) men who identify as Aboriginal and Torres Strait Islander and men who do not. Further details are available regarding data management and statistical analysis plans on the project page of the Open Science Framework (https://osf.io/ev8px/).

Sample Size Calculations

320 men will be recruited: in WA (n=128), NT (n=96) and QLD (n=96), 160 per arm. This estimate is based on observed changes in moderate-to-vigorous PA (MVPA) in the Aussie-FIT pilot (11) and provides 90% power to detect a mean difference of 11-minutes/day (standard deviation:27-minutes/day) of MVPA at 6-months (primary endpoint). The sample size powered on MVPA because PA reduces CVD risk independently, and mitigates other risk factors, such as high blood pressure (35). Change in MVPA of 5 minutes per day is considered the minimum clinically important difference.(36) We allow for a trial attrition rate of 20%.

Economic Evaluation

We will use an economic model of the type developed in the Aussie-FIT pilot (11). The cost-effectiveness analysis will be performed from a health system perspective. Costs will include direct costs associated with the programme (including setting up and promotion) as well as

self-reported healthcare resource use. In terms of outcome measurement, we will include short-term outcomes that will allow us to look at the cost per clinically relevant change in MVPA (5 minutes per day, (36)) and cost per quality-adjusted life years (QALYs). The QALY is the most widely used approach in economic evaluations for quantifying quality of life gains (37). The EQ-5D-5L questionnaire will be used to assess quality of life (38), which is a standardized measure of health status widely adopted in economic evaluations (39). The EQ-5D-5L responses will be converted into a utility score using the most recent preference-weights generated from an Australian general population sample (40). Self-reported data relating to the number and type of health resources used will be collected at each measurement point. Unit costs for visits to health professionals (GP, practice nurses, physiotherapists etc) will be sourced from the Medical Benefits Schedule (41). Unit costs for any inpatient stays and outpatient visits will be sourced from standard Australian public sector hospital costs (42). Unit costs for prescriptions will be sourced from Pharmaceutical Benefits Schedule (PBS) (43). Given uncertainty around parameters such as unit costs and utility values for calculating QALYs, we will undertake sensitivity analysis to check the robustness of the estimates.

Data Management

Locked cabinets in the participating Universities will be used to store hard copy data and no identifying information will be included. A file aligning ID codes with participants' identifying information will be stored on the University server in a password-protected computer file. Only members of the research team will be able to access the physical and electronic data files.

Adverse Events

Coaches will be instructed to report any adverse events during the program sessions to the local trial co-ordinator, using a standardised form. In this trial, serious adverse events will

be defined as a medical event believed by the investigators to be attributable to participation in the Aussie-FIT program, based on the participant's previous medical conditions and clinical presentation. Participants will also be asked to report any adverse events to the coach.

Ethics and Dissemination

This multi-site study has been approved by the lead ethics committees in the lead site's jurisdiction, the South Metropolitan Health Service Human Research Ethics Committee (Reference RGS4254) and the West Australian Aboriginal Health Ethics Committee (HREC1221). Reciprocal approvals have been sought from the relevant ethics bodies in the partner site's jurisdictions. All participants will read an electronic participant information sheet and offered a hard or electronic copy to keep. They will be asked to electronically indicate consent before the program enrolment and will be offered a digital or paper copy of their consent form. The study will be disseminated via publication in peer-review journals, presentations at conferences and reports and presentations for consumers and stakeholders. The latter will be co-designed with consumers and stakeholders.

Discussion

In 2022, CVD was the leading cause of burden of disease in Australia, and this burden is higher in males than females (44). Insufficient physical activity and poor diet are key modifiable behavioural CVD risk factors. Pilot and feasibility studies of Aussie-FIT have illustrated that the program is acceptable to men in WA, and feasible to deliver in AFL and West Australian Football League clubs and rugby league clubs in QLD. Scale up of Aussie-FIT in WA, as well as out to other States and Territories creates an opportunity to reduce primary and secondary CVD risk among men with or at risk of CVD via modification of PA and dietary behaviours. Via this hybrid implementation trial, we will determine whether the

program is effective in improving health and health behaviours in men who take part, and test strategies to sustain longer term implementation of this program.

Abbreviations

Aussie-FIT: Australian Fans in Training

FFIT: Football Fans in Training

BMI: Body mass index

CVD: Cardiovascular disease

MVPA: Moderate and vigorous physical activity

PA: Physical Activity

Trial Registration

The trial has been registered with Australian and New Zealand Clinical Trials Registry (ACTRN12623000437662), prior to recruitment of the first participant (trail registration date 28 M20-2arch 2023). Results will be written up and published and will be available in an open access journal or via the Open Science Framework.

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Author Contributions

EQ, AM, GH, JS, TP, TM, DK, DAK, JM, KH, LW and HG conceived the project and obtained the project funding. EQ, MDM, AM, KH, JCM, DK, DAK, JC, TP, LW, JS, BB, BS, SH and MM have made conceptual contributions to project design with opportunities for input from all authors. Specifically, JCM, MDM, EQ and KH designed the implementation strategies. EQ, MDM, KH, and AM designed trial recruitment strategies and screening and assessment

protocols. TP, JMcV, and EQ designed the physical activity data analysis plan. SH, MDM, EQ, DAK, and DK updated the intervention materials, with input from BB, JB, NW, TP, AM. EQ, BS, AM, and MDM prepared the main ethics submission. EQ, BB, JS, and JB prepared the trial procedures and ethics submission for involvement of men who identify as Aboriginal and/or Torres Strait Islanders. MDM, BB, JS, and JB designed the project consumer involvement strategies. JC conducted the power analysis and designed the statistical analysis plan. MM designed the economic evaluation. TP, LW, JS and BB prepared ethics submissions for reciprocal ethics from local State/Territory committees. EQ and MDM drafted the manuscript and all authors read, edited, and approved the final version of the manuscript.

Competing Interests

N/A

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Tables and Figures

Table 1 – Intervention description aligned with the Template for Intervention Description and Replication (TIDieR) guidance

Table 2 – Summary of measures used in the Aussie-FIT trial and program evaluation and time points

Table 3 – Intervention content in each of the 12 sessions

Figure 1 – Consort diagram of participant flow through the trial

Table 1. Intervention description aligned with the Template for Intervention Description and Replication (TIDieR) guidance

TIDieR Checklist Item	
Why	Undertaking sufficient physical activity and healthy eating are critical to prevent people with lived experience of or at-risk of cardiovascular disease (CVD) from experiencing future heart problems. However, most people with or at-risk of CVD fail to initiate or sustain these health behaviours long-term. This increases risks of future heart conditions and premature death. CVD is more common in men, but they are less likely than women to access interventions to help them manage their weight or improve their health behaviours.
What (materials)	Men participating will receive: a wrist worn physical activity monitor, a sports club team shirt, and a participant workbook with educational content about nutrition, physical activity, and health behaviour change (which is also covered in the face-to-face sessions). Coaches will receive a detailed intervention delivery guide and educational resources (e.g., wallet cards to assess food labels) to support delivery of the weekly sessions. Coaches will utilise sports equipment (e.g., AFL and rugby league balls) from their respective clubs. The participant workbook and coach session delivery guides have previously been used in the Aussie-FIT pilot studies. The participant workbook and coach session delivery guide were developed (and educational materials sourced), adapted from resources available from: i) Football Fans in Training program, www.ffit.org.uk; Heart Foundation Australia, www.heartfoundation.org.au; Australian Government Department of Health, National Health and Medical Research Council, www.eatforhealth.gov.au; Alcohol Think Again, www.alcoholthinkagain.com.au; and Cancer Council WA, www.cancerwa.asn.au. Minor adaptations have been made to these resources to reflect the target population (men with or at-risk of CVD) and the primary

	outcome (physical activity) in this trial, and to incorporate consumer and stakeholder feedback in WA, QLD, and the Northern Territory (NT).
What (procedures)	Participants will attend 12 group sessions at their club that incorporates physical activity, and workshop style education. The education involves practical activities and discussions to help men understand why and how to improve their diet (e.g., interpreting food labels, portion sizes, meal planning, eating out) and physical activity habits (e.g., understanding exercise intensities, safe strength training, decreasing sedentary time). Men will be encouraged to use behaviour change techniques (e.g., self-monitoring, goal setting, and problem solving) to help put the recommendations into practice. Participants take part in physical activity within the sessions that starts off slowly in the initial weeks and gradually builds up over the course of the program. Activities men participate in include ball skills and circuit training similar to that undertaken by Australian football and rugby league players but modified to be safe for each man's abilities (e.g., ball skill drills restricted to walking). Men are encouraged to self-monitor walking, gradually increasing steps/day throughout the 12-weeks.
Who provides	Coaches will be recruited from ten sports clubs in Perth, Darwin, and Brisbane. Aussie-FIT coaches will be already embedded in their respective clubs, knowledgeable about Australian Football or Rugby League, and have experience of leading physical activity or sports coaching sessions. Coaches should have good communication skills and the ability to help foster a supportive atmosphere with camaraderie between participants. Accredited Exercise Physiologists (AEPs), or other suitably qualified/accredited health professionals will act as an assistant coach and co-facilitate program delivery. They will support the coach by undertaking any required health monitoring of participants (e.g., blood pressure checks), provide advice on safe exercise and provide first aid, if

	required. Club coaches and AEPs will be trained by the research team in the core program content (physical activity, nutrition, motivation, behaviour change). The training is delivered face-to-face and comprises approximately 15 hours of interactive learning content and opportunities to practice session deliveries and receive feedback from the research team and peers.
How	The intervention will be delivered face-to-face to groups of approximately 16 men. Coaches are encouraged to utilise a communication style that supports psychological need satisfaction for autonomy, competence, and relatedness in relation to physical activity and eating behaviours.
Where	The program will be delivered in Australian Football (WA and NT) and rugby league (QLD) settings. This will include a suitable space for the educational program component (e.g., indoor clubroom) and access to the pitch/oval for physical activity. In some circumstances, outdoor spaces may be utilised to deliver the educational content and indoor spaces may be used for physical activity (e.g., if there is gym access, or in adverse weather conditions).
When and how much	Participants will attend twelve, weekly, 90-minute sessions. Aussie-FIT encourages gradual increases in moderate to vigorous physical activity levels outside of the weekly sessions in daily life.
Tailoring	The Aussie-FIT sessions and resources are informed by the best available evidence and population recommendations for age and CVD risk management (e.g., Australian guide to healthy eating, physical activity guidelines, and National Heart Foundation recommendations). The program is not prescriptive in terms of physical activity and dietary changes the men make outside of the weekly sessions. Men are supported to self-monitor their diet and physical activity behaviours, then make their own education-informed decisions on setting goals that are relevant to them. Health behaviour change goals that are self-determined are more

likely to be sustainable. Personalised feedback on goals men set is provided by coaches and peers in weekly sessions throughout the program. Targeted behaviours for goal setting include portion size control, reduction of sugary drinks and energy dense foods, reduction in alcohol consumption, gradual increases in physical activity and reduced sedentary time. Men participating in Aussie-FIT will have varying physical fitness levels and health conditions. Throughout the program AEPs and coaches will modify the physical activity within the sessions to suit men with differing physical capabilities. AEPs and coaches will be aware of pre-existing conditions and will interact with and observe participants during the program sessions, and tailor activities as required.

Table 2. *Summary of measures used in the Aussie-FIT trial and program evaluation and time points*

	Measurement instrument	Baseline	3 months	6 month*
Objective measures (collected at the measurement sessions at football clubs by members of the research team or trained research assistants)				
PA and sedentary time	Participants will also be asked to wear an Actigraph GTX9 (ActiGraph LLC, Pensacola, FL) monitor continuously for 7-days on their non-dominant wrist at each data collection time-point to provide a valid and reliable assessment of PA (30). The GT9X is a small (3.5 × 3.5 × 1 cm), lightweight (14 g), and waterproof tri-axial accelerometer. The monitors will be initalised to collect data at a 30hz sampling rate. Men will be provided with written instructions for wearing the Actigraph.	X	X	X
Weight	Weight in kilograms measured with valid and reliable body scale (e.g., Tanita); light clothing, no shoes and empty pockets; assessor blinded to condition	X	X	X
Height	Height measured in centimetres using a stadiometer (e.g., Seca); without shoes	X		
BMI	Calculated as weight in kilograms divided by the square of height in metres (kg/m^2)	X	X	X
Waist circumference	Waist circumference is measured twice using a tape measure (three times, if the first two measurements differ by 5 mm or more) and the mean of all recorded	X	X	X

	measurements calculated. The participant is asked to locate the last rib and iliac crest, and the measure is performed at the midpoint between these to locate the waist. If the man cannot locate his last rib and iliac crest the researcher can ask the man to identify where his belly button is and the measurement can occur one inch/3cm or width of two fingers above where man has indicated. If the first two measurements differ by 5 mm or more, measure third time.			
Resting systolic and diastolic blood pressure	Resting blood pressure measured with a digital blood pressure monitor (Omron HBP-1320, Milton Keynes, UK) monitor after 5 min sitting still. If measured systolic blood pressure is over 150 mmHg and/or measured diastolic blood pressure is over 95 mmHg, two further measures will be taken and recorded. If blood pressure remains high the man will be provided with a letter explaining the circumstances in which they had their blood pressure measured and recorded and they will be encouraged to consult their GP. A mean will be calculated from the second and third measures. Feet flat on the floor, arm free of clothing or wearing loose/thin clothing, cuff at the level of heart and arm resting, same arm used (non-dominant arm), no talking.	X	X	X
Cholesterol	Cholesterol will be check using handheld point of care device (Accutrend Plus) that measures cholesterol immediately.	X	X	X

Self-reported measures (completed at the measurement sessions at football clubs or online in the participant's own time, depending on preference)				
Food intake	Intake24 is an open-source self-completed computerised dietary recall system based on multiple-pass 24-hour recall. A trained interviewer will assist participants who may request assistance to complete the recall.[14, 15]	X	X	X
Positive and negative affect	The Short Form of the positive and negative affect scale (PANAS) (45)	X	X	X
Self-esteem	The Rosenberg Self-Esteem (RSE) scale (46)	X	X	X
Quality of life	The health-related quality of life measured using the EQ-5D-5 L (38)	X	X	X
Demographics	Age, ethnicity, education, marital status, current employment status, income, housing status	X		
Motivation	Motivation to be physically active (47)	X	X	X
Automaticity	The 'Self-Report Behavioural Automaticity Index' (48)	X	X	X
Goal conflict, facilitation	Goal conflict and goal facilitation scale (49)	X	X	X
Action and coping planning	Action planning and copying planning scale (50)	X	X	X
Self-reported programme evaluation measures				

Recruitment	How participants found out about the programme; programme uptake (number of people who expressed interest; number of people who fit inclusion criteria)	X		
Programme evaluation: via questionnaires and interviews	Attendance to programme sessions and to measurement sessions; fidelity of programme delivery; perceptions of effectiveness and acceptability, assessed using the program evaluation questionnaire, which is adapted from the original Aussie-FIT program. Completed at T2 for first cohort and T3 for second cohort. Interviews with participants, coaches and AEPs will also provide further data on these points.		X	X
Training evaluation: via questionnaires and interviews	Coaches will evaluate the training provided to them by completing the coach training evaluation questionnaire on completing their training. The interviews will also ask the coaches about their training.			

Note. * and 12 months, for intervention group only

Table 2. Intervention content

Week number and	Motivation and behaviour change	Nutrition component	Physical activity education component	Practical physical

session title				activity
Session 1. Motivation and monitoring progress	Motivation (identifying and developing higher quality motives); Monitoring progress, 'your activity' and 'your weight' progress records **Action Point:** Track daily step count and complete food diary to bring next week	Energy balance (intake vs output)	Handing out activity monitors and explaining how to use them Walking for wellbeing Exercising safely for men with Cardiovascular disease	Short tour of the oval wearing activity monitors
Session 2. Steps towards better heart health and setting goals	Food diaries compared with healthy eating recommendations and changes going forward; Changing unhealthy environmental triggers; Education on setting; SMART goals	Explanation of the Heart Foundation five key nutrition messages; Explanation of food groups and eating healthier; Balanced plate of vegetables, wholegrains and protein	PA for heart health; Baseline step counts determined; Understanding how to increase step count gradually; Setting step count goals	Walking around the oval

Session 3. Planning, food labels and physical activity recommendations	SMART goals review; Action planning and coping planning	How to read food labels	PA recommendations, benefits, types and intensities; Pros and cons of PA; Overcoming barriers to being physical inactive; Reviewing steps and thinking about alternative activities	Introduction of warming up, cooling down and aerobic exercise
Session 4. Reviewing SMART goals, healthy swaps and small changes	Reviewing goals SMART goal to reduce junk food Motivation and staying on track Importance of support from others	Junk foods impact on heart health; Allowing yourself to be flexible; Healthy snacks and heart healthy food swaps Methods to reduce junk food intake	Being active every day and sitting less	Aerobic exercise with warm up and cool down
Session 5. Reviewing plans and cutting down on booze	Reviewing goals	Pros and cons of drinking alcohol; Facts about alcohol; Alcohol standard drinks and recommendations	Reviewing steps and alternative activities	Aerobic exercise with warm up and cool down

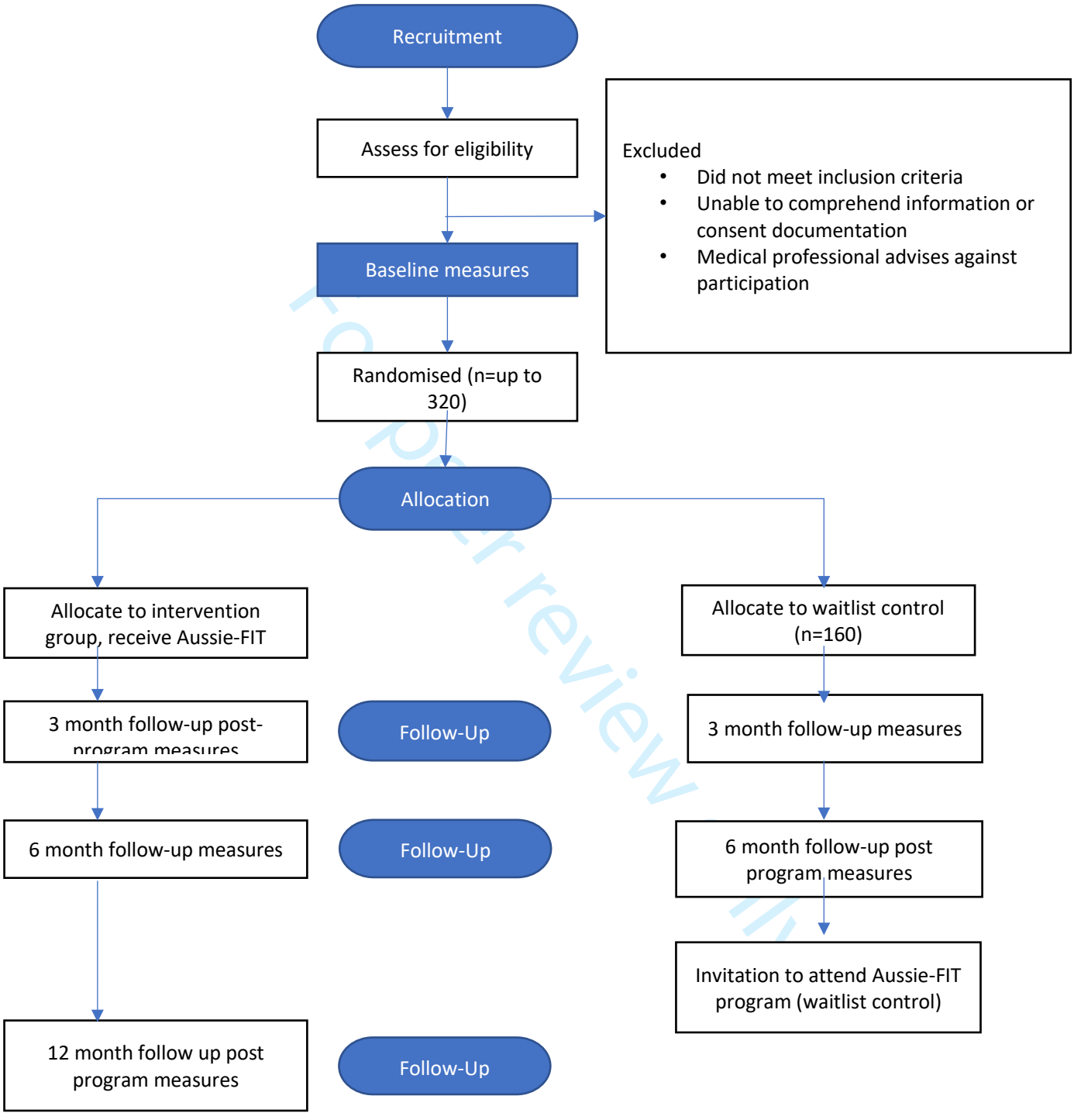
Session 6. Key factors to maintain health behaviour	Five key factors to maintain health behaviour; Sharing experiences on setbacks; Introduction to setbacks and tactics for dealing with them		Learning principles of body weight strength training; Reviewing steps and alternative activities; Introducing mobile applications for exercise	Strength exercises for major muscle groups with warm up and cool down
Session 7. Progress and staying on track	Representation of weight loss achieved and intended; Body composition in men; SMART goals and weight loss reviewed; Reviewing how things are going so far. Measurements taken to review progress and problem solving; Compensatory behaviours; Staying on track.		Reviewing steps and alternative activities Tips to increase PA, being active every day and decrease sitting time; Principles of stretching and flexibility training	Warming up and flexibility training Strength exercises for major muscle groups with warm up and cool down
Session 8. Facts about fat, salt and	Importance of developing eating routines and habits; How to	Facts about fat, salt and sugar for heart health;	Reviewing steps and alternative activities	Circuit of aerobic, strength and

sugar	choose healthier packet foods	Healthier fat alternatives; Added sugar in drinks		flexibility activities including sport drills
Session 9. Physical activity habits and healthier ways to eat out	Developing PA habits	Choosing healthier food choices when having takeaway or eating out	Reviewing steps and activity review	Circuit of aerobic, strength, flexibility activities including sport drills
Session 10. Healthy cooking at home	Reviewing goals; Triggers for setbacks and how to avoid them **Action Point:** Complete food diary to bring next week	Healthy living and busting myths; Healthy cooking and food preparation at home	Step count and activity review	Circuit of aerobic, strength, flexibility activities including sport drills

Session 11. Reviewing progress and acknowledging achievements	Revision of food diaries; Revision of eating plans; Behaviour control and staying on track; Revision of SMART goals		PA levels, types, positives and challenges Reviewing steps and alternative activities	Circuit of aerobic, strength, flexibility activities including sport drills
Session 12. Looking ahead towards maintaining a healthy lifestyle	Reviewing progress throughout the program; Celebrating achievements; Determining steps after the program	Tips to maintaining nutrition habits for heart health	Tips to maintaining PA habits	AFL or rugby game

Note. Session one also includes general introductory content including Aim and overview of the Aussie-FIT program, getting to know each other activities, creating group ground rules and Facebook group sign-ups. Rapport building activities are also incorporated into each weekly sessions

Figure 1. Consort diagram of participant flow through the trial



Note. Interviews not included in flow diagram as the interviews are not a part of the randomised control trial per se, but contribute to program evaluation.

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	Page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	7
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 20-21
	5b	Name and contact information for the trial sponsor	N/A
	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	N/A
	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)	N/A
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	4-6
	6b	Explanation for choice of comparators	16

Objectives	7	Specific objectives or hypotheses	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)	7
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	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)	8-9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-11, 31-33
	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)	14-15
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
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	13-14
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)	14-15

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	17
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9-10
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	12-13
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	13
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13-14
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	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	13-16, 35-38
	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	

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	17
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	16-17
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	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)	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	N/A
	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	18
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	18-19
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)	16

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14
	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	14-16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	21
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	18
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	19
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/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.

Supplementary File 2.

Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.	The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	2-3	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	4-5	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		

Rationale	**4**	5-6	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	5-6	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).
Aims and objectives	**5**	6	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	7	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	7	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	7-9	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	7-9	The population targeted by the intervention and any eligibility criteria.
Description	**9**	11-12	A description of the implementation strategy	10-11	A description of the intervention
Sub-groups	**10**	n/a	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	13-14	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	13-14	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	n/a	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	17-18	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	17-18	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	17	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	16-17	Methods of analysis (with reasons for that choice)		

Sub-group analyses	**16**	17	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		
Results					
Characteristics	**17**	n/a – protocol	Proportion recruited and characteristics of the recipient population for the implementation strategy	n/a – protocol	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	n/a – protocol	Primary and other outcome(s) of the implementation strategy	n/a – protocol	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	n/a – protocol	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	n/a – protocol	Resource use, costs, economic outcomes and analysis for the implementation strategy	n/a – protocol	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	n/a – protocol	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	n/a – protocol	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	n/a – protocol	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	n/a – protocol	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	n/a – protocol	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	N/A	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	n/a – protocol	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	n/a – protocol	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	20-21	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

BMJ Open

Scale-up of the Australian Fans in Training (Aussie-FIT) men's health behaviour change program: Protocol for a randomised controlled hybrid effectiveness-implementation trial.

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Scale-up of the Australian Fans in Training (Aussie-FIT) men's health behaviour change program: Protocol for a randomised controlled hybrid effectiveness-implementation trial.

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Abstract

Introduction

Improving physical activity and healthy eating is critical for primary and secondary prevention of cardiovascular disease (CVD). Behaviour change programs delivered in sporting clubs can engage men in health behaviour change but are rarely sustained or scaled-up post-trial. Following the success of pilot studies of the Australian Fans in Training (Aussie-FIT) program, a hybrid effectiveness-implementation trial protocol was developed. This protocol outlines methods to: i) establish if Aussie-FIT is effective at supporting men with or at risk of CVD to sustain improvements in moderate-to-vigorous physical activity (primary outcome), diet, and physical and psychological health, and ii) examine the feasibility and utility of implementation strategies to support program adoption, implementation and sustainment.

Methods and Analysis

A pragmatic multi-State/Territory hybrid type 2 effectiveness-implementation parallel group randomised controlled trial with a 6 month wait-list control arm in Australia. 320 men aged 35-75 years with or at-risk of CVD will be recruited. Aussie-FIT involves 12 weekly face-to-face sessions including coach-led interactive education workshops and physical activity delivered in Australian Football League (Western Australia, Northern Territory) and rugby (Queensland) sports club settings. Follow-up measures will be at 3- and 6-months (both groups), and at 12 months to assess maintenance (intervention group only). Implementation outcomes will be reported using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework.

Ethics and Dissemination

This multi-site study has been approved by the lead ethics committees in the lead site's jurisdiction, the South Metropolitan Health Service Human Research Ethics Committee

(Reference RGS4254) and the West Australian Aboriginal Health Ethics Committee (HREC1221). Findings will be disseminated at academic conferences, peer-reviewed journals and via presentations and reports to stakeholders, including consumers. Findings will inform a blueprint to support the sustainment and scale-up of Aussie-FIT across diverse Australian settings and populations to benefit men's health.

Strengths and Limitations

- This is the first multi-State/Territory trial of a 'fans in training' style intervention.
- Consumers and other stakeholders contributed to the development of the protocol, in particular recruitment and data collection methods.
- Using a hybrid design will facilitate the concurrent assessment of intervention effectiveness and implementation outcomes, promoting efficient implementation and long-term impact of this evidence-based program.
- Due to the nature of the intervention, participants will not be blinded to treatment allocation.

Word count: 4550

Introduction

The cardiovascular benefits of physical activity (PA) and eating a healthy diet are well established, however, 55% of people who live in Australia do not meet PA guidelines, most eat an unhealthy diet and 67% are living with overweight or obesity (1). Among those with a cardiovascular disease (CVD) diagnosis, exercise adherence remains low. Most men with CVD fail to initiate or sustain health behaviour changes, decreasing quality of life and increasing risk of future CVD and premature death (2). For instance, only 30% of patients complete outpatient cardiac rehabilitation, and of those, less than 50% are sufficiently active 12 months after their cardiac event (2).

A patient survey showed many patients lack self-management skills and are too dependent on exercise rehabilitation staff to sustain behaviour changes upon completion of hospital-based exercise programs (3). Recent estimates suggest that increasing participation in cardiac rehabilitation in Australia from 30% to 65% would result in $36 million in healthcare savings, $58 million in social and economic benefits, and significantly reduce annual heart attack admissions (4). To reap these health and economic benefits, new strategies are required to increase PA adherence and healthy eating in people with or at-risk of CVD. Gender tailored programs are important, because men and women experience differences in CVDs risks and occurrences (5). Gender-tailored health behaviour change programs for men have been shown to be appealing and effective (6).

The internationally recognised 'Football Fans in Training' (FFIT) program, and our Australian adaptation (Aussie-FIT), are effective in engaging men to improve their health behaviours. FFIT (7) and Aussie-FIT (8) capitalise on men's interest in sport to promote weight loss via sustained improvements in diet and PA. These structured 12-week programs include 90 minutes of interactive education and group-based PA that aims to develop the skills and

confidence of participants to self-regulate and maintain behaviour change long-term. Programs are delivered to groups of men by trained coaches in professional sport facilities. The effectiveness and cost-effectiveness of FFIT was established in a Randomised Control Trial (RCT) (7). Mean between group weight lost at 12 months was 5kg, and average weight loss maintenance of 2.9kg was observed in the intervention group 3.5 years post-baseline (9) . FFIT was adapted for the European Fans in Training (EuroFIT) RCT in 5 European countries, where similar findings were revealed (10).

Kwasnicka et al (2020) demonstrated feasibility of recruitment, engagement, and retention of men living with overweight and obesity, as well as acceptability of the Aussie-FIT intervention and research procedures when delivered at top-tier Australian Football League (AFL) clubs in Western Australia (WA). Promising physical and mental health outcomes were observed (11). In a single-arm feasibility trial in Queensland (QLD), a version of Aussie-FIT adapted for rugby league (League-FIT) has engaged men living with overweight and obesity, and demonstrated promise in supporting positive physical and mental health outcomes (12). In a feasibility study of the Aussie-FIT program undertaken at second-tier AFL clubs for men with CVD, Smith et al (manuscript in preparation) demonstrated feasibility of participant engagement and retention, and acceptability of the intervention and research procedures. However, recruiting men with CVD was challenging (Smith et al., manuscript in progress). Recruitment challenges were likely due to the smaller population of men with CVD (6.5% of men in Australia) (13) compared with 75% of men with overweight and obesity in Australia (14), and the smaller fanbases of second-tier AFL clubs compared to top-tier clubs. The effectiveness of Aussie-FIT remains to be tested, as do implementation strategies designed to improve the adoption, implementation, sustainment and scale-up of the program to reach diverse populations of at-risk men. This multi-State/Territory trial aims to establish the

effectiveness of the Aussie-FIT intervention for men with or at-risk of CVD, whilst allowing for flexibility with club-size (e.g., top-tier or second-tier) across diverse Australian contexts.

A recent systematic review of five unique interventions concluded that, whilst FFIT has been successfully scaled up, not all health promotion interventions delivered through professional sport have been successfully scaled up, and thus a greater focus on the potential for scalability of these interventions is required (15). Scalability is the process of increasing the number of implementers (e.g., sports clubs) that are willing to initiate delivery of effective interventions to reach a greater proportion of the target population (16). The potential for intervention scalability is increasingly considered across the research spectrum, rather than solely positioned at the end of a linear research pipeline after effectiveness testing (17). One increasingly common approach to considering implementation and scalability earlier in the research process is the use of hybrid effectiveness-implementation study designs, which allow for the assessment of intervention effectiveness alongside implementation outcomes (18). Implementation outcomes that are important for scalability include program costs, fidelity, adaptability, delivery settings, infrastructure, workforce, reach and acceptability in diverse populations (Milat et al., 2020).

This trial adopts a hybrid effectiveness-implementation design (19) to examine the effectiveness of Aussie-FIT, and in parallel assess the feasibility and utility of implementation strategies to support program adoption, implementation, sustainment and scalability, using the RE-AIM framework. We pose two research questions to simultaneously address both the intervention and the implementation process aims (20): 1) is the Aussie-FIT program effective in increasing time spent in moderate-to-vigorous physical activity (MVPA; and improving other secondary outcomes among men with or at-risk of CVD at 6 month follow up; and 2) what are the facilitators and barriers to implementation, sustainment and scalability of the Aussie-FIT program?

Method

This protocol follows the SPIRIT approvedreporting standards for standard protocol items (Supplementary File 1) and meets the requirements of the Standards for Reporting Implementation Studies (StaRI) (20) (Supplementary File 2).

Study design

This study is a pragmatic multi-State/Territory Hybrid Type 2 Effectiveness-Implementation parallel group RCT with a 6 months wait-list control. Follow-up measures are at 3 and 6 months (primary outcome) post-baseline for both the intervention and control groups; and at 12 months for the intervention group to assess maintenance (see Figure 1, CONSORT diagram). Observational implementation outcomes will be reported using the RE-AIM framework (21). This trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12623000437662).

Context

The study is set in and around the capital cities of Darwin (Northern Territory), Perth (WA), and Brisbane (QLD). These urban centres have distinct contextual characteristics. QLD and WA make up 20% and 10% of the national population respectively and are far more populated than the Northern Territory (NT) which makes up less than 1% of the national population (22). There is significant cultural diversity across each State/Territory; for example, the proportion of males that identify as Aboriginal and/or Torres Strait Islander in the NT (26.3%) is considerably higher than in QLD (4.6%) and WA (3.3%) (23). Australian Football is the most popular sport in WA and the NT, whereas in QLD, Rugby League is most popular (24).

Patient and Public Involvement

Patient and public engagement has been central to the development of the Aussie-FIT program since its ' inception and in previous pilot studies in which the intervention was developed based on patient priorities. In preparation for and in the design of this trial, community advisory groups consisting of consumers (i.e., men with or at-risk of CVD, and former Aussie-FIT participants) and stakeholders (e.g., Aussie-FIT coaches, sporting club or community representatives) have been formed in each State/Territory. These groups include representation of Aboriginal and/or Torres Strait Islander men. The first of these groups met in December 2022. Community advisory groups have helped identify potential barriers and enablers of project success and have co-designed responsive implementation strategies. These groups will continue to work in partnership with the research team throughout the lifespan of this project. This will include providing input on culturally appropriate recruitment strategies, retention strategies, involvement in dissemination planning, and if the effectiveness of the intervention is established, providing advice on the sustainment and scalability of Aussie-FIT. The outcomes of our cross-site consumer and stakeholder involvement activities during the trial set-up period, and at later stages in the trial, will be reported in future publications. Presentations and reports for consumers and stakeholders will be co-designed with consumers and stakeholders and disseminated to participants and other consumer and community audiences.

Participants

Inclusion criteria

Men aged 35-75 in WA (n=128), NT (n=96) and QLD (n=96) that self-report meeting one or more of the following criteria will be recruited:

a) CVD diagnosis more than 3 months prior to commencing the study, with no upper limit on length of time since diagnosis; OR

b) ≥10% risk of CVD, according to the online calculator created by the Australian Chronic Disease Prevention Alliance, that assesses CVD 5-year risk (www.cvdcheck.org.au/calculator); OR

c) Body mass index ≥28kg/m^2.

To determine whether they are eligible, potential participants will complete an online form, co-designed with consumers to ensure accessibility for men.

Participants from non-English speaking backgrounds will be offered interpreters if they wish to participate in the study. Men at risk of harm from PA will be excluded from vigorous PA and will instead undertake light or moderate PA as tolerated (if appropriate based on GP/cardiologist's advice). Where possible men who have not participated in previous Aussie-FIT or League-FIT programs will be prioritised.

Exclusion criteria

Exclusion criteria are: unable to comprehend information or consent documentation; unable to attend most of the weekly sessions, diagnosed with CVD less than 3 months prior to the baseline assessments date; experienced a cardiac event less than 3 months prior to the baseline assessments date; or a medical professional advises against participation (e.g., due to having a cardiac condition not suitable for an exercise trial in the community such as severe aortic stenosis or on-going angina).

Recruitment

Participants will be selected on a 'first come, first served' basis. Men with CVD will be identified from medical records at hospitals (WA only), cardiac rehabilitation programs delivered in hospitals, or in the community, and GP or other primary health care services. Men with or at-risk of CVD will be recruited from community sources including club members'

newsletters, traditional/social media, match-day publicity (e.g., announcements, face-to-face recruitment), snowball sampling (25), sport publications, and local health councils. Interested individuals who see the program advertised will be directed to complete a web-based expression of interest (EOI) form. Men who prefer not to use the online EOI form will have the opportunity to express their interest, ask questions, check their eligibility, and enrol (if eligible) by contacting the research team directly via phone or email. The online EOI form includes a series of questions to confirm eligibility.

This trial will host a nested 'study within a trial' (SWAT) (26) to examine the utility of a self-directed online enrolment in comparison to a phone call enrolment process (27). Eligible men that complete the online EOI will be randomised via the online form to either immediately book their enrolment appointment online or to receive a call from a researcher to progress their enrolment. The SWAT will evaluate the effectiveness (including cost-effectiveness) of the online approach compared to the standard phone call on enrolment rates (27).

Intervention (Aussie-FIT Program)

The intervention is described following the Template for Intervention Description and Replication (TIDieR) guidance (28), see Table 1. In brief, the 12, weekly, 90-minute sessions will be delivered to groups of 16 men. One coach and one Accredited Exercise Physiologist (AEP) or equivalent suitable health professional facilitate each group. Coaches and AEPs will be trained by the research team in the core content (PA and diet education), safe exercise for men with or at-risk of CVD, and in the use of principles of motivation and behaviour change. Coaches will lead on the program content delivery and AEPs will be primarily responsible for exercise safety. Practical activities and discussions are designed to help men understand why and how to improve PA (e.g., understanding exercise intensities, safe strength training, decreasing sedentary time) and dietary behaviours (e.g., interpreting food labels, portion sizes,

meal planning, eating out), and incorporate behaviour change techniques to support participants to adopt positive health behaviours in their daily lives. A range of PA intensities are promoted, and ball skills and circuit training like those undertaken by professional players but modified to be safe for each man's limitations (e.g., ball skill drills restricted to walking) undertaken. Men are encouraged to self-monitor walking, gradually increasing steps/day throughout the 12-weeks. The AEP will co-deliver the sessions and support the coach by monitoring participants (e.g., blood pressure checks), providing advice on safe exercise and providing first aid, if required. The waitlist control group (another 16 men from each club) will receive the program 6 months later.

Description of the implementation strategy

Our consumer advisory groups have supported the development of our implementation strategies in the study set-up phase of this project, full details of which will be reported elsewhere. The implementation study is structured by the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance) (12).

Reach: Program recruitment strategies have been co-designed with men with or at risk of cardiovascular disease (CVD). These strategies will be tailored for each State/Territory in consultation with community advisory groups.

Effectiveness: Individual effectiveness outcomes will be tested via the RCT. Negative or unintended consequences will also be documented.

Adoption: Clubs will be invited to offer formal commitments to continue deliveries pending further funding opportunities in each State/Territory. An infrastructure and costing model will be developed to support clubs in sustaining the program, and preferences for models of sustained program deliveries will be co-designed with stakeholders.

Implementation: A comprehensive coach delivery package will support fidelity of program delivery. This package includes 15 hours of training for the coaches, detailed program delivery speaking notes, a timing guide, and rationales. Reusable teaching resources will also be provided to support high-quality delivery. Implementation costs, such as coaches' time for delivering and preparing for sessions, have been included in the program costing model.

Maintenance: Our nested SWAT will evaluate an automated enrolment strategy, designed to improve program sustainability when fewer resources are available compared to the trial phase. Resource sharing agreements will be developed, if required, to ensure the intervention materials can continue to be used post-trial. Sustainability action plans will be developed with stakeholders, including identifying suitable charities as delivery partners for ongoing program deliveries. Indications of individual participant-level behaviour change maintenance will be assessed at 12-months follow-up in the intervention group.

Throughout the implementation process, barriers and facilitators to implementation will be identified (by stakeholders, including consumers and researchers) and targeted in future modifications to the program. Interviews with stakeholders will be conducted to identify these barriers and facilitators. Contextual adaptations required for the different States and Territories will be documented and evaluated. These adaptations will be co-designed with our consumer advisory groups to ensure contextual fit while preserving fidelity.

Blinding and Randomisation

It is not possible to blind participants to condition due to the nature of the intervention. Data collectors will be blinded as far as possible. Questionnaire data will be completed online, PA data will be device measured, and participants will be asked not to reveal whether they are in the intervention or waitlist control arm, when objective measures of weight and blood pressure are taken.

Aligned with the EuroFIT trial, we propose an individual randomisation for each club, given the FFIT study confirmed that the minimal between-group contamination effects did not warrant higher sample size and costs of a cluster trial. (10) Participants from each club (10 clubs, 32 participants per club) will be individually randomised (1:1 randomisation, in blocks of 8 to reduce prediction of group allocation). A statistician generated the randomisation list using the RANDOMBETWEEN (1,2) function using Excel. The statistician, who is not involved in data collection, will not be told if group 1 or group 2 is the intervention arm to assure blindness during the analyses. Following completion of baseline measures, trained research assistants will use opaque, sealed envelopes to assign participants to intervention or control arms.

Primary outcome: Physical Activity

Participants will also be asked to wear an Actigraph GTX9 (ActiGraph LLC, Pensacola, FL) monitor continuously for 7-days on their non-dominant wrist at each data collection time-point to provide a valid and reliable assessment of MVPA (29). The GT9X is a small (3.5 × 3.5 × 1 cm), lightweight (14 g), and waterproof tri-axial accelerometer. The monitors will be initalised to collect data at a 30hz sampling rate. Men will be provided with written instructions for wearing the Actigraph.

Secondary Outcomes

Secondary outcomes include dietary intake, weight, blood pressure, cholesterol, self-esteem, affective states, quality of life, motivation for physical activity, and use of behaviour change strategies targeted in the program. A full list of variables assessed and measurement tools is included in Table 2.

Implementation Outcomes

Implementation outcomes will be reported using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework (21). Reach: we will report on the number of participants interested and recruited; descriptive statistics of their representativeness, using demographics (e.g., comorbidities, weight, socioeconomic status, ethnicity) of those recruited in each locality; Effectiveness: as per description of intervention outcomes and for effectiveness of implementation outcomes, with qualitative interview findings; Adoption: records of adaptation to the intervention and implementation strategies (between clubs, locations etc); Implementation: fidelity to key content (e.g., educational messages) and functions (e.g., appropriate use of behaviour change techniques) via coding of a subsample of deliveries; adaptations to delivery in each location, ascertained from coach/participant interviews; barriers and facilitators to program implementation from perspectives of coaches, administrators, and participants via interviews; Maintenance: intentions to continue delivering the program (for clubs in this trial) and intentions to initiate program delivery when further funding secured (new clubs),

Procedure

Participants will book an appointment to attend baseline measures (detailed in Table 2) at the football or rugby club. Measurement sessions will be led by a team of trained research assistants. Participants will be asked to complete a survey, which will be presented to them on an iPad using Qualtrics software. The self-administered survey will ask men demographic questions including their age, ethnicity, education, marital status, current employment status, income, and housing status. Weight, height and waist measurements will be taken by a trained researcher. Cholesterol will be check using a finger-prick test that measures non-fasting cholesterol immediately. Participants will undertake a 24-hour dietary recall using the Intake24, an open-source self-completed computerised dietary recall system based on multiple-pass 24-hour recall. A trained interviewer will assist participants to complete the recall. The

self-administered survey will also include items assessing alcohol content, and participants will also be asked to respond to questions assessing their emotions (i.e., positive and negative affect), quality of life, self-esteem, motivation to for PA and use of behaviour change strategies taught in Aussie-FIT (automaticity, goal conflict, goal facilitation, coping planning, action planning). Participants are asked to respond on Likert scales of 1-5 or 1-7. Participants can skip questions if they prefer not to answer them. All questions have established psychometric properties and have been used by the research team in studies with similar populations. The questionnaire pack should take less than 30 minutes to complete. A trained research assistant will be available to explain to participants how to complete the survey and to answer any questions they may have during completion of the questionnaire. All participants will be required to complete the Exercise and Sport Science Australia (ESSA): Adult Pre-Exercise Screening System (APSS) (30) at the baseline measures session. ESSA stipulates that all participants who answer 'yes' to a screening question should see an Allied Health Professional or their general practitioner (GP). To reduce burden on participants of the need to attend a GP appointment, an Accredited Exercise Physiologist (AEP) (or other equivalent allied health professional) will review every participant's APSS form and discuss medical history with every participant, to determine whether they are at risk from physical activity. Waitlist control group participants will be re-screened at the assessment they attend prior to starting the program in case of any change in health status from baseline.

The full assessment process will usually take about 90 minutes. Following randomisation, participants will be informed as to whether they will receive the 12-week intervention immediately (i.e., the intervention arm) or ~6 months later (i.e., the waitlist control group). Once the intervention arm participants have completed the program, the assessment package will be repeated for both the control and intervention groups (3 months post baseline) and then at 6 months post baseline. After the 6 months measures, the waitlist control arm will

complete the 12-week program. Finally, the intervention arm will be asked to attend one final assessment, 12 months post baseline.

Where applicable, information regarding the participants' CVD diagnosis will be self-reported or obtained from medical records. Participant attendance at the program will also be recorded. At baseline, participants will be asked to tick yes or no to the question "in the future we may wish to contact you to join a group or individual interview to talk about your experiences in the program. Do you consent for us to contact you? Yes/No". Approximately 20 of those who tick 'yes', will be contacted by telephone or email at 6 months and/or 12 months, and invited to take part in an interview, which will be conducted on Microsoft Teams videoconference or in person at the football/rugby club (depending on the person's preference). Interview questions will be developed in collaboration with PhD candidates and an ethics amendment will be submitted for approval prior to undertaking any interviews. Any changes to protocol will be reported on the study Open Science Framework page (https://osf.io/ev8px/).

Treatment of Waitlist Control Arm

All men will be directed to review evidence-based resources (i.e., Heart Foundation online material) regarding PA and healthy eating after completion of the baseline assessments and men in the waitlist control arm will be invited to participate in Aussie-FIT after the 6-month post baseline assessment.

Data Analyses

Physical activity data will be downloaded via the ActiLife software (version 6.13.4), where the raw accelerometer data will be processed in R using the GGIR V1.5-21 package (cran.r-project.org/web/packages/GGIR/index.html) (31,32). Physical activity will be estimated from 5-second epochs, with the average daily activity calculated. To be classified as

moderate to vigorous physical activity (MVPA) mean acceleration needs to be ≥100 milli-g (mg) (33). Time in activities lasting at least 1 minute, for which 80% of the activity satisfied the 100 mg threshold criteria, will be calculated. Average acceleration (calculated as the mean acceleration across the 24-hour day as a proxy for the daily volume of PA) and intensity-gradient (as a reflection of the distribution of intensity across the 24-hour day) will be calculated (34,35). We will only include in the analysis those participants with four or more valid days of accelerometry data, and at least 10 hours of wear time each day.

De-identified objective measurements, questionnaire data and calculated PA data will be exported to Stata software for analyses by an independent biostatistician blinded to the group allocation. Characteristics of the participants will be summarised in mean (and standard deviation) or median (and interquartile range) or frequency (and percentage), by treatment groups. Program efficacy will be analysed following the intention-to-treat principle and per-protocol approaches outlined below. Changes in the post-intervention outcomes will be analysed using linear mixed effect regression models whilst controlling for the baseline measures. Sensitivity analyses will also be performed to include covariates such as age, BMI, types of comorbidities in the model to compare the beta coefficient of the models with and without the covariates. If group sizes permit, sub-group analyses will be performed to examine differences in intervention effects on primary and secondary outcomes between i) States/Territories; ii) men diagnosed with and without a CVD diagnosis, iii) men with BMI ≥25 and men with BMI <25; and iii) men who identify as Aboriginal and Torres Strait Islander and men who do not. Further details are available regarding data management and statistical analysis plans on the project page of the Open Science Framework (https://osf.io/ev8px/).

Sample Size Calculations

320 men will be recruited: in WA (n=128), NT (n=96) and QLD (n=96), 160 per arm. This estimate is based on observed changes in moderate-to-vigorous PA (MVPA) in the Aussie-FIT pilot (11) and provides 90% power to detect a mean difference of 11-minutes/day (standard deviation:27-minutes/day) of MVPA at 6-months (primary endpoint). The sample size powered on MVPA because PA reduces CVD risk independently, and mitigates other risk factors, such as high blood pressure (36). Change in MVPA of 5 minutes per day is considered the minimum clinically important difference.(37) We allow for a trial attrition rate of 20%.

Economic Evaluation

We will use an economic model of the type developed in the Aussie-FIT pilot (11). The cost-effectiveness analysis will be performed from a health system perspective. Costs will include direct costs associated with the programme (including setting up and promotion) as well as self-reported healthcare resource use. In terms of outcome measurement, we will include short-term outcomes that will allow us to look at the cost per clinically relevant change in MVPA (5 minutes per day, (37)) and cost per quality-adjusted life years (QALYs). The QALY is the most widely used approach in economic evaluations for quantifying quality of life gains (38). The EQ-5D-5L questionnaire will be used to assess quality of life (39), which is a standardized measure of health status widely adopted in economic evaluations (40). The EQ-5D-5L responses will be converted into a utility score using the most recent preference-weights generated from an Australian general population sample (41). Self-reported data relating to the number and type of health resources used will be collected at each measurement point. Unit costs for visits to health professionals (GP, practice nurses, physiotherapists etc) will be sourced from the Medical Benefits Schedule (42). Unit costs for any inpatient stays and outpatient visits will be sourced from standard Australian public sector hospital costs (43). Unit costs for prescriptions will be sourced from Pharmaceutical

Benefits Schedule (PBS) (44). Given uncertainty around parameters such as unit costs and utility values for calculating QALYs, we will undertake sensitivity analysis to check the robustness of the estimates.

Data Management

Locked cabinets in the participating Universities will be used to store hard copy data and no identifying information will be included. A file aligning ID codes with participants' identifying information will be stored on the University server in a password-protected computer file. Only members of the research team will be able to access the physical and electronic data files.

Adverse Events

Coaches will be instructed to report any adverse events during the program sessions to the local trial co-ordinator, using a standardised form. Serious adverse events will be defined as a medical event believed by the investigators to be attributable to participation in the Aussie-FIT program, based on the participant's previous medical conditions and clinical presentation. Participants will also be asked to report any adverse events to the coach.

Ethics and Dissemination

This multi-site study has been approved by the lead ethics committees in the lead site's jurisdiction, the South Metropolitan Health Service Human Research Ethics Committee (Reference RGS4254) and the West Australian Aboriginal Health Ethics Committee (HREC1221). Reciprocal approvals have been sought from the relevant ethics bodies in the partner site's jurisdictions. All participants will read an electronic participant information sheet and offered a hard or electronic copy to keep. They will be asked to electronically indicate consent before the program enrolment and will be offered a digital or paper copy of their

consent form. The study will be disseminated to the academic community, via publication in peer-review journals, presentations at conferences and reports.

Discussion

In 2022, CVD was the leading cause of burden of disease in Australia, and this burden is higher in males than females (45). Insufficient physical activity and poor diet are key modifiable behavioural CVD risk factors. Pilot and feasibility studies of Aussie-FIT have illustrated that the program is acceptable to men in WA, and feasible to deliver in AFL and West Australian Football League clubs and rugby league clubs in QLD. Scale up of Aussie-FIT in WA, and out to other States and Territories creates an opportunity to reduce primary and secondary CVD risk among men with or at risk of CVD via modification of PA and dietary behaviours. Via this hybrid effectiveness-implementation trial, we will determine whether the program is effective in improving health and health behaviours in men who take part, and test strategies to sustain longer term implementation of this program.

Abbreviations

Aussie-FIT: Australian Fans in Training

FFIT: Football Fans in Training

BMI: Body mass index

CVD: Cardiovascular disease

MVPA: Moderate and vigorous physical activity

PA: Physical Activity

Trial Registration

The trial has been registered with Australian and New Zealand Clinical Trials Registry (ACTRN12623000437662), prior to recruitment of the first participant (trail registration date 28 M20-2arch 2023). Results will be written up and published and will be available in an open access journal or via the Open Science Framework.

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Author Contributions

EQ, AM, GH, JS, TP, TM, DK, DAK, JM, KH, LW and HG conceived the project and obtained the project funding. EQ, MDM, AM, KH, JCM, DK, DAK, JC, TP, LW, JS, BB, BS, SH and MM have made conceptual contributions to project design with opportunities for input from all authors. Specifically, JCM, MDM, EQ and KH designed the implementation strategies. EQ, MDM, KH, and AM designed trial recruitment strategies and screening and assessment

protocols. TP, JMcV, and EQ designed the physical activity data analysis plan. SH, MDM, EQ, DAK, and DK updated the intervention materials, with input from BB, JB, NW, TP, AM. EQ, BS, AM, and MDM prepared the main ethics submission. EQ, BB, JS, and JB prepared the trial procedures and ethics submission for involvement of men who identify as Aboriginal and/or Torres Strait Islanders. MDM, BB, JS, and JB designed the project consumer involvement strategies. HC conducted the power analysis and designed the statistical analysis plan. MM designed the economic evaluation. TP, LW, JS and BB prepared ethics submissions for reciprocal ethics from local State/Territory committees. EQ and MDM drafted the manuscript and all authors read, edited, and approved the final version of the manuscript.

Competing Interests

N/A

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Tables and Figures

Table 1 – Intervention description aligned with the Template for Intervention Description and Replication (TIDieR) guidance

Table 2 – Summary of measures used in the Aussie-FIT trial and program evaluation and time points

Table 3 – Intervention content in each of the 12 sessions

Figure 1 – Consort diagram of participant flow through the trial

Table 1. Intervention description aligned with the Template for Intervention Description and Replication (TIDieR) guidance

TIDieR Checklist Item	
Why	Undertaking sufficient physical activity and healthy eating are critical to prevent people with lived experience of or at-risk of cardiovascular disease (CVD) from experiencing future heart problems. However, most people with or at-risk of CVD fail to initiate or sustain these health behaviours long-term. This increases risks of future heart conditions and premature death. CVD is more common in men, but they are less likely than women to access interventions to help them manage their weight or improve their health behaviours.
What (materials)	Men participating will receive: a wrist worn physical activity monitor, a sports club team shirt, and a participant workbook with educational content about nutrition, physical activity, and health behaviour change (which is also covered in the face-to-face sessions). Coaches will receive a detailed intervention delivery guide and educational resources (e.g., wallet cards to assess food labels) to support delivery of the weekly sessions. Coaches will utilise sports equipment (e.g., AFL and rugby league balls) from their respective clubs. The participant workbook and coach session delivery guides have previously been used in the Aussie-FIT pilot studies. The participant workbook and coach session delivery guide were developed (and educational materials sourced), adapted from resources available from: i) Football Fans in Training program, www.ffit.org.uk; Heart Foundation Australia, www.heartfoundation.org.au; Australian Government Department of Health, National Health and Medical Research Council, www.eatforhealth.gov.au; Alcohol Think Again, www.alcoholthinkagain.com.au; and Cancer Council WA, www.cancerwa.asn.au. Minor adaptations have been made to these resources to reflect the target population (men with or at-risk of CVD) and the primary outcome (physical activity) in this trial, and to incorporate consumer and stakeholder feedback in WA, QLD, and the Northern Territory (NT).
What (procedures)	Participants will attend 12 group sessions at their club that incorporates physical activity, and workshop style education. The education involves practical activities and discussions to help men understand why and how to improve their diet (e.g., interpreting food labels, portion sizes, meal planning, eating out) and physical activity habits (e.g., understanding exercise intensities, safe strength training, decreasing sedentary time). Men will be encouraged to use behaviour change techniques (e.g., self-monitoring, goal setting, and problem solving) to help put the recommendations into practice. Participants take part in physical activity within the sessions that starts off slowly in the initial weeks and gradually builds up over the course of the program. Activities men participate in include ball skills and circuit training similar to that undertaken by Australian football and rugby league players but modified to be safe for each man's abilities (e.g., ball skill drills restricted to walking). Men are encouraged to self-monitor walking, gradually increasing steps/day throughout the 12-weeks.
Who provides	Coaches will be recruited from ten sports clubs in Perth, Darwin, and Brisbane. Aussie-FIT coaches will be already embedded in their respective clubs, knowledgeable about Australian Football or Rugby League, and have experience of leading physical activity or sports coaching sessions. Coaches should have good communication skills and the ability to help foster a supportive atmosphere with camaraderie between participants. Accredited Exercise Physiologists (AEPs), or other suitably qualified/accredited health

	professionals will act as an assistant coach and co-facilitate program delivery. They will support the coach by undertaking any required health monitoring of participants (e.g., blood pressure checks), provide advice on safe exercise and provide first aid, if required. Club coaches and AEPs will be trained by the research team in the core program content (physical activity, nutrition, motivation, behaviour change). The training is delivered face-to-face and comprises approximately 15 hours of interactive learning content and opportunities to practice session deliveries and receive feedback from the research team and peers.
How	The intervention will be delivered face-to-face to groups of approximately 16 men. Coaches are encouraged to utilise a communication style that supports psychological need satisfaction for autonomy, competence, and relatedness in relation to physical activity and eating behaviours.
Where	The program will be delivered in Australian Football (WA and NT) and rugby league (QLD) settings. This will include a suitable space for the educational program component (e.g., indoor clubroom) and access to the pitch/oval for physical activity. In some circumstances, outdoor spaces may be utilised to deliver the educational content and indoor spaces may be used for physical activity (e.g., if there is gym access, or in adverse weather conditions).
When and how much	Participants will attend twelve, weekly, 90-minute sessions. Aussie-FIT encourages gradual increases in moderate to vigorous physical activity levels outside of the weekly sessions in daily life.
Tailoring	The Aussie-FIT sessions and resources are informed by the best available evidence and population recommendations for age and CVD risk management (e.g., Australian guide to healthy eating, physical activity guidelines, and National Heart Foundation recommendations). The program is not prescriptive in terms of physical activity and dietary changes the men make outside of the weekly sessions. Men are supported to self-monitor their diet and physical activity behaviours, then make their own education-informed decisions on setting goals that are relevant to them. Health behaviour change goals that are self-determined are more likely to be sustainable. Personalised feedback on goals men set is provided by coaches and peers in weekly sessions throughout the program. Targeted behaviours for goal setting include portion size control, reduction of sugary drinks and energy dense foods, reduction in alcohol consumption, gradual increases in physical activity and reduced sedentary time. Men participating in Aussie-FIT will have varying physical fitness levels and health conditions. Throughout the program AEPs and coaches will modify the physical activity within the sessions to suit men with differing physical capabilities. AEPs and coaches will be aware of pre-existing conditions and will interact with and observe participants during the program sessions, and tailor activities as required.

Table 2. *Summary of measures used in the Aussie-FIT trial and program evaluation and time points*

	Measurement instrument	Baseline	3 months	6 month*
Objective measures (collected at the measurement sessions at football clubs by members of the research team or trained research assistants)				
PA and sedentary time	Participants will also be asked to wear an Actigraph GTX9 (ActiGraph LLC, Pensacola, FL) monitor continuously for 7-days on their non-dominant wrist at each data collection time-point to provide a valid and reliable assessment of PA (30). The GT9X is a small (3.5 × 3.5 × 1 cm), lightweight (14 g), and waterproof tri-axial accelerometer. The monitors will be initalised to collect data at a 30hz sampling rate. Men will be provided with written instructions for wearing the Actigraph.	X	X	X
Weight	Weight in kilograms measured with valid and reliable body scale (e.g., Tanita); light clothing, no shoes and empty pockets; assessor blinded to condition	X	X	X
Height	Height measured in centimetres using a stadiometer (e.g., Seca); without shoes	X		
BMI	Calculated as weight in kilograms divided by the square of height in metres (kg/m^2)	X	X	X
Waist circumference	Waist circumference is measured twice using a tape measure (three times, if the first two measurements differ by 5 mm or more) and the mean of all recorded measurements calculated. The participant is asked to locate the last rib and iliac crest, and the measure is performed at the midpoint between these to locate the waist. If the man cannot locate his last rib and iliac crest the researcher can ask the man to identify where his belly button is and the measurement can occur one inch/3cm or width of two fingers above where man has indicated. If the first two measurements differ by 5 mm or more, measure third time.	X	X	X
Resting systolic and diastolic blood pressure	Resting blood pressure measured with a digital blood pressure monitor (Omron HBP-1320, Milton Keynes, UK) monitor after 5 min sitting still. If measured systolic blood pressure is over 150 mmHg and/or measured diastolic blood pressure is over 95 mmHg, two further measures will be taken and recorded. If blood pressure remains high the man will be provided with a letter explaining the circumstances in which they had their blood pressure measured and recorded and they will be encouraged to consult their GP. A mean will be calculated from the second and third measures. Feet flat on the floor, arm free of clothing or wearing loose/thin clothing, cuff at the level of heart and arm resting, same arm used (non-dominant arm), no talking.	X	X	X

Cholesterol	Cholesterol will be check using handheld point of care device (Accutrend Plus) that measures cholesterol immediately.	X	X	X
Self-reported measures (completed at the measurement sessions at football clubs or online in the participant's own time, depending on preference)				
Food intake	Intake24 is an open-source self-completed computerised dietary recall system based on multiple-pass 24-hour recall. A trained interviewer will assist participants who may request assistance to complete the recall.[14, 15]	X	X	X
Positive and negative affect	The Short Form of the positive and negative affect scale (PANAS) (46)	X	X	X
Self-esteem	The Rosenberg Self-Esteem (RSE) scale (47)	X	X	X
Quality of life	The health-related quality of life measured using the EQ-5D-5 L (39)	X	X	X
Demographics	Age, ethnicity, education, marital status, current employment status, income, housing status	X		
Motivation	Motivation to be physically active (48)	X	X	X
Automaticity	The 'Self-Report Behavioural Automaticity Index' (49)	X	X	X
Goal conflict, facilitation	Goal conflict and goal facilitation scale (50)	X	X	X
Action and coping planning	Action planning and copying planning scale (51)	X	X	X
Self-reported programme evaluation measures				
Recruitment	How participants found out about the programme; programme uptake (number of people who expressed interest; number of people who fit inclusion criteria)	X		
Programme evaluation: via questionnaires and interviews	Attendance to programme sessions and to measurement sessions; fidelity of programme delivery; perceptions of effectiveness and acceptability, assessed using the program evaluation questionnaire, which is adapted from the original Aussie-FIT program. Interviews with participants, coaches and AEPs will also provide further data on these points.			
Training evaluation: via questionnaires and interviews	Coaches will evaluate the training provided to them by completing the coach training evaluation questionnaire on completing their training. The interviews will also ask the coaches about their training.			

Note. * and 12 months, for intervention group only

Table 3. Intervention content

Week number and session title	Motivation and behaviour change	Nutrition component	Physical activity education component	Practical physical activity
Session 1. Motivation and monitoring progress	Motivation (identifying and developing higher quality motives); Monitoring progress, 'your activity' and 'your weight' progress records. **Action Point:** Track daily step count and complete food diary	Energy balance (intake vs output)	Handing out activity monitors and explaining how to use them Walking for wellbeing Exercising safely for men with cardiovascular disease	Short tour of the oval wearing activity monitors
Session 2. Steps towards better heart health and setting goals	Food diaries compared with healthy eating recommendations and changes going forward; Changing unhealthy environmental triggers; Education on setting; SMART goals	Heart Foundation five key nutrition messages, food groups and eating healthier; Balanced plate (vegetables, wholegrains and protein)	PA for heart health; Baseline step counts determined; Understanding how to increase step count gradually; Setting step count goals	Walking around the oval
Session 3. Planning, food labels and physical activity recommendations	SMART goals review; Action planning and coping planning	How to read food labels	PA recommendations, benefits, types and intensities; Pros and cons of PA; Overcoming barriers to being physical inactive; Reviewing steps and thinking about alternative activities	Introduction of warming up, cooling down and aerobic exercise
Session 4. Reviewing SMART goals, healthy swaps and small changes	Reviewing goals SMART goal to reduce junk food Motivation and staying on track Importance of support from others	Junk foods impact on heart health; Allowing yourself to be flexible; Healthy snacks and heart healthy food swaps; reducing junk food intake	Being active every day and sitting less	Aerobic exercise with warm up and cool down
Session 5. Reviewing plans and cutting down on booze	Reviewing goals	Pros and cons of drinking alcohol; Facts about alcohol; Alcohol standard drinks, recommendations	Reviewing steps and alternative activities	Aerobic exercise with warm up and cool down

Session 6. Key factors to maintain health behaviour	Five key factors to maintain health behaviour; Sharing experiences on setbacks; Introduction to setbacks and tactics for dealing with them		Learning principles of body weight strength training; Reviewing steps and alternative activities; Introducing mobile applications for exercise	Strength exercises for major muscle groups with warm up and cool down
Session 7. Progress and staying on track	Representation of step increases achieved; SMART goals reviewed; Reviewing how things are going so far and problem solving; Compensatory behaviours; Staying on track.		Reviewing steps and alternative activities Tips to increase PA, being active every day and decrease sitting time; Principles of stretching and flexibility training	Warming up and flexibility training Strength exercises for major muscle groups with warm up and cool down
Session 8. Facts about fat, salt and sugar	Importance of developing eating routines and habits; How to choose healthier packet foods	Facts about fat, salt and sugar for heart health; Healthier fat alternatives; Added sugar in drinks	Reviewing steps and alternative activities	Aerobic, strength and flexibility activities inc. sport drills
Session 9. Physical activity habits and healthier ways to eat out	Developing PA habits	Choosing healthier food choices when having takeaway or eating out	Reviewing steps and activity review	Aerobic, strength and flexibility activities inc. sport drills
Session 10. Healthy cooking at home	Reviewing goals; Triggers for setbacks and how to avoid them **Action Point:** Complete food diary to bring next week	Healthy living and busting myths; Healthy cooking and food preparation at home	Step count and activity review	Aerobic, strength and flexibility activities inc. sport drills
Session 11. Reviewing progress and acknowledging achievements	Revision of food diaries; Revision of eating plans; Behaviour control and staying on track; Revision of SMART goals		PA levels, types, positives and challenges Reviewing steps and alternative activities	Aerobic, strength and flexibility activities inc. sport drills
Session 12. Looking ahead towards maintaining a healthy lifestyle	Reviewing progress throughout the program; Celebrating achievements; Determining steps after the program	Tips to maintaining nutrition habits for heart health	Tips to maintaining PA habits	AFL or rugby game

Note. Session one also includes general introductory content including Aim and overview of the Aussie-FIT program, getting to know each other activities, creating group ground rules and Facebook group sign-ups. Rapport building activities are also incorporated into each weekly session

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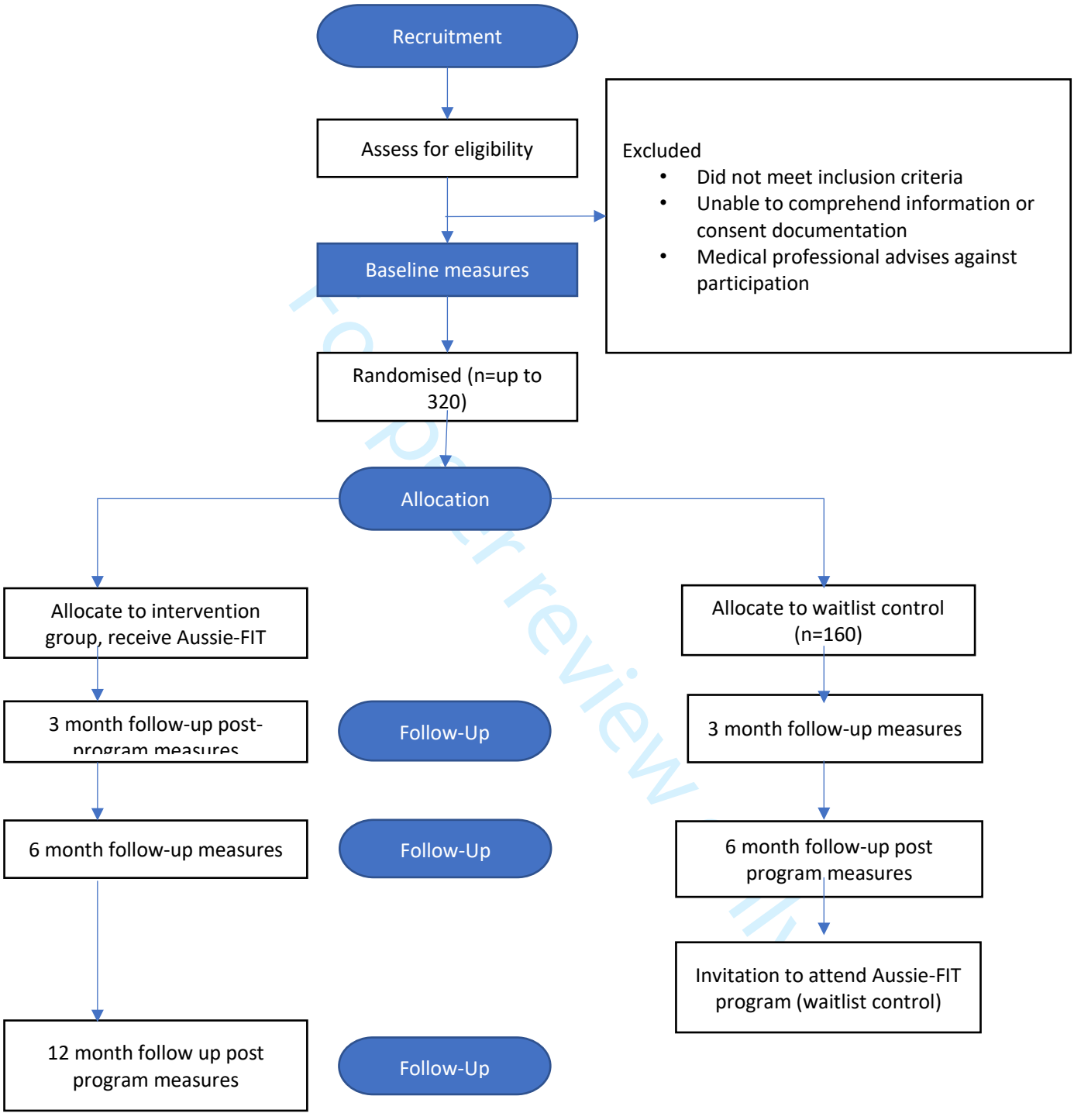
Figure 1. Consort diagram of participant flow through the trial



Note. Interviews not included in flow diagram as the interviews are not a part of the randomised control trial per se, but contribute to program evaluation.

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	Page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	7
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 20-21
	5b	Name and contact information for the trial sponsor	N/A
	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	N/A
	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)	N/A
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	4-6
	6b	Explanation for choice of comparators	16

Objectives	7	Specific objectives or hypotheses	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)	7
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	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)	8-9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10-11, 31-33
	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)	14-15
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
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	13-14
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)	14-15

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	17
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9-10
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	12-13
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	13
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13-14
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	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	13-16, 35-38
	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	

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	17
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	16-17
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	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)	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	N/A
	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	18
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	18-19
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)	16

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14
	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	14-16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	21
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	18
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	19
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/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.

Supplementary File 2.

Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.	The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	2-3	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	4-5	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		

Rationale	**4**	5-6	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	5-6	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).
Aims and objectives	**5**	6	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	7	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	7	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	7-9	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	7-9	The population targeted by the intervention and any eligibility criteria.
Description	**9**	11-12	A description of the implementation strategy	10-11	A description of the intervention
Sub-groups	**10**	n/a	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	13-14	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	13-14	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	n/a	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	17-18	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	17-18	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	17	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	16-17	Methods of analysis (with reasons for that choice)		

Sub-group analyses	**16**	17	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		
Results					
Characteristics	**17**	n/a – protocol	Proportion recruited and characteristics of the recipient population for the implementation strategy	n/a – protocol	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	n/a – protocol	Primary and other outcome(s) of the implementation strategy	n/a – protocol	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	n/a – protocol	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	n/a – protocol	Resource use, costs, economic outcomes and analysis for the implementation strategy	n/a – protocol	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	n/a – protocol	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	n/a – protocol	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	n/a – protocol	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	n/a – protocol	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	n/a – protocol	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	N/A	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	n/a – protocol	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	n/a – protocol	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	20-21	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		