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Protocol for a gender-sensitised weight loss and healthy living programme for overweight and obese men delivered in Australian Football League settings (Aussie-FIT): A feasibility and pilot randomised controlled trial

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Title: Protocol for a gender-sensitised weight loss and healthy living programme for overweight and obese men delivered in Australian Football League settings (Aussie-FIT): A feasibility and pilot randomised controlled trial

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We would like to thank male AFL fans (*N*=151) for their contribution to the preliminary research that assessed the need for the Aussie-FIT study.

ABSTRACT

Introduction: Overweight and obesity are highly prevalent among Australian men. Professional sports settings can act as a powerful 'hook' to engage men in weight loss programmes; the Football Fans in Training (FFIT) programme delivered in professional UK soccer clubs was successful and cost effective in helping men lose weight. The Australian Football League (AFL) is a potentially attractive setting to engage men in a weight loss program. We aim to develop, pilot and evaluate the feasibility of a weight loss intervention for overweight/obese middle-aged men, delivered in the AFL settings, to promote weight loss and healthier lifestyles, and determine its suitability for a future randomised control trial.

Methods and Analysis: 120 overweight/obese male fans will complete baseline physical and psychological health measures and objective measures of physical activity (PA), weight, waist size, and blood pressure prior to randomisation into the intervention or waitlist comparison group. The intervention group will receive 12 weekly 90-minute workshops incorporating PA, nutrition education, behaviour change techniques and principles of effective motivation. Four community coaches will be trained to deliver Aussie-FIT at two

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AFL clubs in Western Australia. Measurements will be repeated in both groups at 3 months (post-intervention) and 6 months (follow-up). Outcomes will include programme uptake, attendance, changes in lifestyle and weight variables to inform power calculations for a future definitive trial, fidelity of programme delivery, acceptability, satisfaction with the programme, and perceptions of effectiveness. We will also determine trial feasibility and potential to gather cost effectiveness data.

Ethics and Dissemination: Ethics approval was granted by Curtin University's Human Research Ethics Committee (HREC2017-0458). Results will be disseminated via peer-reviewed publications, conference presentations, and reports. A multi-component dissemination strategy will include targeted translation and stakeholder engagement events to establish strategies for sustainability and policy change.

Registration: Australian New Zealand Clinical Trials Registry: ACTRN12617000515392.

Strengths and limitations of this study:

- This is the first study in Australia to test an intervention targeting fan health delivered in Australian Football League settings.
- The programme embeds Self-Determination Theory techniques to train the coaches to deliver the intervention using a need supportive delivery style.
- To support behaviour change maintenance, the Aussie-FIT intervention focuses on habit formation, relapse prevention, problem solving and dealing with competing goals from the onset of the intervention.
- This is a pilot study with 120 participants and is not powered to detect intervention effectiveness and a full-scale national RCT is recommended.
- The Aussie-FIT programme has great potential to impact on the programme participants as well as their family members; the impact on the close relatives should be investigated in the future studies.

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INTRODUCTION

Worldwide in 2016, more than 39% of adults aged 18 years and over (more than 1.9 billion) were overweight, and 13% were obese (over 650 million).[1] In Australia, the prevalence of overweight and obesity has steadily increased in the last 30 years, with currently about 60% of Australian adults classified as either obese or overweight, of which more than 25% are in the obese category.[2] The direct cost of obesity to the Australian economy is equivalent to 22.6% of the national health expenditure ($148.9AUD billion in 2014-15).[3] A recent Australian study estimated that the average annual health care costs for individuals classed as 'obese' (Body Mass Index, BMI $\geq$ 30kg/m) is 50% greater (i.e., 2,233AUD) than that for normal weight individuals.[4]

Approximately 70% of men in Australia are overweight/obese, compared to 56.3% of women.[5] Risks of disease and physical, psychological and sexual dysfunction are significantly increased for males whose waist circumference is 102cm or greater, and whose BMI is 30kg/m or greater.[2 6] Main drivers for weight loss are addressing the energy imbalance through increases in physical activity (PA), alongside decreases in energy intake. However, adults classed as overweight (BMI $\geq$ 25kg/m) and obese are the least likely population group to engage in PA,[7] and despite poorer health behaviours relatively few men participate in weight loss interventions, e.g., on average 27% men versus 73% women ($p<0.001$).[8]

Male participation in weight loss interventions

The specific barriers that lead to low male engagement in PA and weight loss interventions[8] are often unaddressed in attempts to promote weight loss in men.[9] Given that men are less likely to recognise the link between weight and health[10] and are also thought to be more resistant to healthy eating campaigns than women, attempts to address overweight and obesity are likely to be ineffective if they do not take account of men's underlying beliefs

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and concerns, and if they are female oriented.[11] Cultural constructions of masculinity[12] often deter men from taking appropriate action in order to improve their health (e.g., healthy eating).[11 13-15] Men are also more likely than women to aspire to large body shapes, such as those of some muscular sport celebrities.[8] Consequently, men may have a skewed perception of what is a healthy body size for men and/or perceive weight loss to be irrelevant to them. Men who aspire to lose weight face a number of cultural barriers that may limit their motivation or capacity to initiate and sustain behaviour change. For example, dieting is often viewed as a feminine activity, whereas excessive eating and drinking are often associated with a masculine identity.[16 17] Such gender stereotypes are thought to discourage men from engaging in weight loss interventions.

In a systematic review of male inclusion rates in weight loss randomised controlled trials (RCTs),[8] men typically comprised only 20% of the included samples. Interventions which were shown to be appealing and/or effective for predominantly female groups may not be similarly relevant for men. Another systematic review of obesity management interventions with follow-up data for at least one year identified only 5% of RCTs that were specifically targeted at men.[15] Of those interventions, only three men-only programmes were run in Australia; of these three programmes, only one included a PA component. This intervention was the SHED-IT trial which successfully supported reduction in BMI amongst younger men (mean age 35.9, SD 11.1 years) who were overweight and obese.[18]

Professional sport settings as an opportune setting for the promotion of weight loss

Interventions targeting males may need to capitalise on, rather than ignore, dominant cultural constructions of masculinity. Many professional sports are still typically seen as 'male' domains and therefore have recognised potential to attract men to health interventions.[19 20] As a setting in which men feel valued and comfortable, professional sport environments can act as a powerful 'hook' to engage men in health behaviour programmes.[13]

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The Football Fans in Training (FFIT) programme was designed to appeal to adult male soccer fans and was developed and delivered with support from the Scottish Professional Football League (SPFL) Trust. FFIT is delivered over 12 weeks by community coaches in the stadia of professional soccer clubs. Participants' emotional connection with soccer and/or the club is a vital aspect of the intervention.[13 14 21] This innovative approach has proved successful in attracting and retaining men aged 35-65 years, with a BMI $\geq$ 28kg/m^2 from across the socioeconomic spectrum and at high risk of ill-health. Process evaluation data, embedded within a pragmatic RCT of FFIT, showed that, within the professional soccer club setting and amongst the company of fellow fans, men felt comfortable making positive behaviour changes, such as using a pedometer to self-monitor and increase their daily PA. Participants also highly valued club community coaches' role as programme leaders.[13 21] FFIT drew on current evidence on gender and health and from PA, nutrition, male weight management, and community-based health interventions. Key behaviour change techniques (BCTs) included in the FFIT programme were self-monitoring, implementation intentions, goal setting and review, feedback on behaviour, and ongoing social support.[22]

FFIT was initially tested in a feasibility study in eleven SPFL (then Scottish Premier Football League) clubs. Following revisions based on an extensive process evaluation[23] the programme was rigorously tested in an RCT with 747 overweight and obese men from 13 SPFL soccer clubs. The trial compared men in the intervention arm with a waitlist comparison arm.[21] The adjusted mean between-arm difference in weight loss at 12 months was 4.94 kg. Economic analysis demonstrated FFIT was cost-effective, relatively inexpensive to deliver, and a good return on investment (costing approximately $285AUD per participant).[21] The programme helped male soccer fans make long-term, sustainable changes to eating, alcohol consumption and PA.[22] The participants described improved well-being and enjoyment from taking part in FFIT as part of a team and with other men like them. The

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success of the programme was further substantiated after the programme finished, as assessed in secondary outcome analyses (e.g., changes in diet and PA), in post programme focus groups[24] and follow-up measurements 3.5 years after the FFIT trial began.[25] Research has demonstrated the programme's appeal, as well as the acceptability of the club setting as a 'draw' for men to participate in a weight loss programme.

FFIT utilised soccer stadia for the delivery of the intervention, because soccer remains highly popular with men in the UK and soccer fans have a strong affiliation to their clubs; however, the PA and diet components of the programme are not soccer-specific. Hence variations of FFIT have been developed and readily delivered in other sports. FFIT has since been adapted for delivery in professional rugby club settings in England[26] and New Zealand and in junior A hockey teams in Canada;[27 28] it also formed the basis for the EuroFIT programme currently being trialled in soccer clubs in four European countries.[29 30] The Australian Football League (AFL) is the most popular spectator sport in Australia[31] with a predominantly male fan base and is potentially a viable and attractive setting through which to engage men in Australia in weight loss programmes.

The design of Aussie-FIT for Australia

It is important to develop and test an Australian version of FFIT for several reasons. There are sufficient differences in Australia (e.g., weather, sport targeted, health care provision) to warrant a pilot (and subsequently an RCT) of the program in Australia. This seems particularly important given a meta-analysis[32] showing that culturally adapted interventions for health behaviours are more likely to be effective. Contextual adaptations and testing of health behaviour change programs is also recommended by the Medical Research Council (MRC) process evaluation framework.[33] The application of motivation theory and BCTs in Aussie-FIT will also further enhance the original FFIT content, as briefly outlined below.

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In the past decade, there has been a growing recognition that to be effective, health behaviour change interventions must also be used to support individuals' capacity to self-regulate and sustain their health behaviours beyond the timeframe of the intervention delivery period. One way to achieve sustained benefits is via the inclusion of BCTs,[34] such as those motivationally relevant techniques shown to be effective in PA and eating behaviour interventions and previously utilised in FFIT[13] (e.g., self-monitoring, implementation intentions, goal setting and review, and feedback on behaviour within the intervention). A growing body of evidence suggests it is also important to consider the quality of motivation regulating the targeted behaviour change. A meta-analysis of studies based on Self-Determination Theory (SDT)[35] showed that when the reasons underlying engagement in PA and weight behaviours are of higher quality (i.e., more self-determined, because the individual wants to do so, he/she values and/or enjoys the behaviour), behavioural change is more likely to be successful and sustainable.[36]

In Aussie-FIT, the communication style of the coach delivering the program will be a specific focus of our coach training package. In addition, the Aussie-FIT programme content will include activities designed to reveal and emphasise opportunities to experience autonomy, competence and relatedness (i.e., three basic psychological needs considered in SDT as essential for optimal functioning) during and after the 12-week programme. Satisfaction of the basic psychological needs is considered critical for sustained, self-determined motivation, and successful behaviour change.[35] Therefore, the Aussie-FIT intervention will be designed to directly (i.e., through engagement in need-promoting activities) and indirectly (i.e., via training of coaches who will deliver the programme in how to use a need supportive communication style) promote greater need fulfilment and in turn more autonomous motives to engage in PA and healthy eating practices.

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Participants are much more likely to succeed in losing weight and keeping weight off if they are introduced to BCTs which support long-term maintenance of behavioural changes from the beginning of the intervention rather than part way through.[37] Compared to the original FFIT trial, Aussie-FIT will place greater emphasis from the start of the programme on BCTs relevant for behaviour change maintenance and relapse prevention. Specifically, the Aussie-FIT intervention will be underpinned by key theoretical themes of behaviour change maintenance that will define the intervention mechanisms of action,[38 39] including maintained self-determined motivation, effective self-regulation that leads to habit development, and a supportive social and physical environment. The intervention will promote additional aspects of weight loss maintenance, including identity shift (i.e., ensuring that participants recognise the programme not as a temporary change but as a shift in their lifestyles), focusing on goal priority, and managing occasional relapses with flexibility (as opposed to 'all or nothing' approach) in order to improve long-term maintenance.

Aussie-FIT will also extend FFIT by adding greater focus on minimising the time participants spend being sedentary, in addition to forming routines to incorporate PA into their daily lives (e.g., identifying triggers that are time, person and context specific). Aussie-FIT will focus on developing healthy habits relevant to weight loss, including healthy eating, increased PA, and minimising alcohol consumption as well as how to recognise and develop strategies to cope with common behavioural barriers to weight loss such as stress, perceived lack of time, and other competing goals. The Aussie-FIT programme will emphasise action planning as well as coping planning, not only on forming Specific, Measurable, Attainable, Relevant and Time-based goals (SMART goals). From the start, relapse prevention will be a key part of the Aussie-FIT programme.

In summary, building on the FFIT programme, the new 'Aussie-FIT' intervention differs from previous weight loss interventions, adding conceptual and applied value to the

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existing literature. Several differences are embedded in the Aussie-FIT intervention which differentiates it from previous programmes that have been designed to engage sports fans in weight loss behaviours. First, Aussie-FIT capitalises on the appeal of the sport of AFL to attract overweight and obese males in Australia to take part in a weight loss and healthy lifestyle programme, and hence our new program will include content and design features to suit the context and culture of Australia. Second, the overall programme will be designed to promote self-regulated behavioural control by embedding SDT throughout the intervention via a focus on basic psychological need satisfaction within programme content (e.g., targeted activities), as well as via training the coaches to use a need supportive programme delivery style. Finally, the Aussie-FIT programme will include even greater emphasis on habit development as a means to further promote behaviour change maintenance and weight loss maintenance from the start of the programme. We will also examine the motivationally-relevant mediators and moderators of the men's health behaviour change in line with recent recommendations.[40]

Aim and study objectives

The overarching aim of the study is to determine the feasibility and potential efficacy of the 12-week Aussie-FIT intervention in the context of AFL in Australia. The specific aims are:

- To develop the resources and infrastructure required to implement Aussie-FIT;
- To assess the feasibility of training the coaches using SDT principles to deliver the intervention;
- To determine time and resources required to recruit participants, recruitment protocols, enrolment and consent procedures, inclusion/exclusion criteria, necessary length of training of coaches, and resources required to run the trial;

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- To determine the design of data collection protocols, questionnaire administration procedures, randomisation procedures, and selection of outcome measures for a future definite trial;
- To assess feasibility with regard to uptake, adherence and attrition, and programme acceptability to AFL clubs, coaches and participants in Australia;
- To examine the potential effects of the intervention on changes (and standard deviations of such changes) in: objectively measured body weight, waist circumference, time spent in moderate/vigorous PA and sedentary time, and blood pressure; self-reported diet, motivation to be physically active and to eat healthily; and indicators of psychological well-being;
- To undertake a process evaluation to identify the extent to which Aussie-FIT can be implemented as planned, and to reveal potential barriers and facilitators to implementation from the perspectives of participants, coaches and AFL club personnel;
- To examine motivation-related moderators and mediators of changes in outcome variables;
- To assess the feasibility of collecting data for an economic analysis of Aussie-FIT;

METHODS AND ANALYSIS

Study design

The project will include two key phases. First, we will develop the resources and infrastructure required to deliver Aussie-FIT. We will train four coaches (two from each club) to deliver the programme and to use motivation techniques when doing so. Second, the 12-week intervention, using waitlist control as a comparator based on FFIT, [22] will be piloted and evaluated for feasibility, effectiveness and cost and process evaluation with measures administered at baseline (week 0), and 3 and 6 months follow-ups.

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Baseline data collection will start in June 2018 with final follow-ups completed at all sites by December 2018. Hypothesis-testing is not a focus of pilot trials and therefore statistical power is irrelevant for this pilot RCT. The proposed sample size follows guidelines for appropriate sample sizes for pilot trials[41 42] and replicates the design used in piloting FFIT.[22] The study is designed to generate data to calculate the necessary power in a definitive trial. It will also enable estimation of rates for recruitment, responses to questionnaires, participant retention, effect size and variability in outcomes to inform a definitive trial.

The randomisation sequence, generated in SPSS (in block sizes of 4 and stratified by the AFL team and by BMI category), will be concealed until conditions are assigned by the blinded researcher. Participants will be allocated according to the randomisation sequence and informed about their group allocation via email/phone call. Although participants and coaches cannot possibly be blinded to the study allocation, independent researchers blinded to the study allocation will assess all study outcomes measured at 3 and 6 month follow-ups. We will record any disclosures of condition allocation and we will monitor the feasibility of our blinding procedure. The study protocol was prepared in accordance with guidelines by the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT), and Template for Intervention Description and Replication (TIDieR).[43 44] The completed checklists are available as supplementary files.

Recruitment, participants, eligibility and screening

Men will be invited to participate in the programme through a variety of methods including word of mouth, the Aussie-FIT website (www.aussiefit.org), publicity for the programme from the AFL clubs (e.g., emails to members), social media, and press releases. To express interest in the programme, potential participants will be asked to visit the programme website and to provide information about their age, weight, height, contact

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details, and their availability to attend Aussie-FIT sessions on certain days and times of the week. The men will also be asked to complete the Adult Pre-exercise Screening System (APSS) online[45] to ascertain whether they have any contraindications for participating in the PA aspect of the programme. Participants who answer 'yes' to any of the APSS questions will be recommended to consult their doctor before study participation, but it will be left to their discretion if they choose to follow the advice. They will still be invited to participate in the classroom sessions, and the PA sessions will be altered to suit their ability. All participants will be also asked to sign the disclaimer form that they are taking part in the Aussie-FIT sessions at their own discretion.

We will recruit 120 males (aged 35-65 years, BMI ≥ 28kg/m^2) from the fan base of the Fremantle Dockers and West Coast Eagles professional AFL clubs in Perth, WA (60 men from each club). Our inclusion criteria (matching those used in FFIT) are: men; aged 35 to 65 years; objectively measured BMI ≥ 28 kg/m^2 and consent for randomisation. The inclusion of this specific age group and specific BMI cut-off points have been tested and proved valuable in the FFIT programme.[21 23] Our exclusion criteria are: men who are unable to comprehend the information letter and consent documentation; and those who are already participating in a specific health promotion programme delivered at the club or elsewhere.

Intervention

Aussie-FIT will be a programme designed to promote PA, healthy eating and weight loss among overweight and physically inactive middle-aged men in Australia. Aussie-FIT will be based upon the existing, successful FFIT programme.[21 23] Aussie-FIT will also include a motivational component to the coach training and intervention resources, which was not explicitly part of FFIT. The men will be introduced to the principles of habit formation and behaviour change maintenance from the beginning of the programme. The research team will invite feedback on the prototype resources, prior to the delivery of the programme, from the

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recruited AFL coaches and from a purposive sample (N = 5) of AFL fans from the initial pool of AFL participants (interviewed during our first AFL study assessing appeal of Aussie-FIT in Australia).[46]

Aligned with the original FFIT programme, Aussie-FIT will aim to support participants to achieve a 2500kJ daily energy deficit, based on estimated weight maintenance requirements according to age, sex, and body weight. The targeted strategies will include portion control, reduction of sugary drinks and energy dense foods, reduction in alcohol consumption, and a gradual increase in moderate PA. As in FFIT, to maximise sustainability of lifestyle changes this will be integral from the outset and initiated in the club setting but with emphasis on discovering through personal experience how PA can be readily incorporated into men's daily lives. To help support the men to sustain PA changes, the programme will include self-regulation strategies, such as a) helping the men understand how to respond appropriately to certain stimuli (e.g., triggers of unhealthy eating); b) assisting them to set effective goals; c) teaching them strategies to avoid engaging in compensatory behaviours (e.g., being more sedentary or eating more following PA), and d) educating them in how to prevent relapse (i.e., returning to pre-intervention behaviours which might result in weight gain). The programme will also include activities designed to facilitate satisfaction of the psychological needs for autonomy, competence and relatedness in relation to PA and eating behaviours.

The programme will be delivered over 12 weekly, 90-minute sessions to groups of around 15 men by one coach. The sessions will include classroom-based activities and coach-led PA sessions (see Table 1 for Aussie-FIT sessions' content). Over the 12 weeks, the proportion of time dedicated to PA relative to classroom-based activities will increase to align with the men's increases in fitness. The delivery style will be informal, encouraging

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positive use of interaction for vicarious learning, and using humour to facilitate discussion of sensitive topics. Text messaging will be used to improve protocol adherence, e.g., attendance.

Gender-specific components will include emphasis on portion size and PA, discussion of the role of alcohol in weight gain, the use of physical representations to reinforce weight loss, and the fostering of peer support. Participants will receive booklets which will include information supporting key messages, and spaces for recording information to aid self-monitoring. Additional information will be available online. Throughout the 12 weeks, Aussie-FIT participants will be encouraged to think about ways they can continue to meet and exercise together after the formal sessions at the football club have finished.

Applying novel technologies. Aussie-FIT will capitalise on recent advances in technology to optimise the way in which support for behaviour change can be maintained outside of the weekly sessions, and long term. Instead of using pedometers as the main self-monitoring technology, we will provide user-friendly wrist worn activity monitors that automatically synchronise with a user based platform (i.e., a dashboard that provides continuous data that participants can monitor and access via internet enabled devices). Participants will still be encouraged to manually note down step counts in their weekly progress records; however, they will also have access to other activity indicators online should this information be of interest to them.

Earlier research suggests that many participants in FFIT may welcome more sophisticated self-monitoring technologies.[47] Wrist worn activity monitors will be handed out in week one, when participants will be fully briefed in how to wear and use the devices. Participants will be asked to wear their activity monitor throughout their waking hours and use it as a self-monitoring device (i.e., monitoring daily step count). We will also use an ActiGraph GTX-9 accelerometer as a research tool, to objectively measure participants PA at

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each time point (baseline, 3 and 6 months); FFIT programme used only self-reported measures of PA.

Aussie-FIT will also utilise a social media platform (Facebook) as an outlet for participants to share experiences, stay in touch, brainstorm ideas, and exchange suggestions, and to promote on-going basic psychological need support from others in the Aussie-FIT group. The summaries of each weekly session will be posted on Facebook, uploaded to a password protected subsection of the project website (www.aussiefit.org/resources), and/or emailed to the participants (depending on their preferences). We will test the same distribution methods for videos of PA exercises explained and shown during the sessions, and descriptions of how to perform them.

Aussie-FIT participants will receive practical tips on how to use technology to support their weight loss and maintenance, such as online applications and programmes, should they wish to do so. Participants will be provided with a list of freely available mobile phone applications that could be used to support their self-monitoring and/or goal setting (e.g., MyFitnessPal, MapMyRun) activities. Links to additional existing resources from Australian public health campaigns (e.g., 'LiveLighter' tools such as 'Healthy Meal Mixer', or 'AlcoholThinkAgain' tools such as '5 minutes drinking audit') will be embedded within the participant booklet.

Coach Training. Four community coaches will be recruited to take the role of Aussie-FIT programme coaches. The coaches will be recommended by club personnel and are anticipated to be those individuals who usually deliver the clubs' community programmes. The coaches will be selected by the research team members and by the representatives from the participating clubs based on their interest and enthusiasm for the role, and relevant skill base and experience. They will receive two days of face-to-face training, followed by opportunities to practice session delivery and receive feedback from the research team and

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their peers. Training topics will include relevant information on the importance of and requirements for PA for health, nutrition, and behaviour change strategies.[48]

Principles from SDT[35] will be built into the communication style for programme delivery and mentoring. For example, coaches will be trained to use strategies such as providing rationales (e.g., to explain why tasks or activities are worthy of their effort, and to help the men discover the personal meaning and relevance of activities), involving the participants in the decision-making process (e.g., about what they do in PA sessions and in making their lifestyle changes), taking the perspective of and empathising with the participants, and promoting feelings of competence in behaviour change that are based on personal progression rather than comparison with others. The coaches will have access to all training and intervention materials online, and they will be free to contact the research team via email/telephone if they have any questions. The coaches' will note their reflections and feedback after each Aussie-FIT session, and these records will be passed on to the research team. The research team will have an opportunity to clarify any points and to act on the feedback provided during the pilot if any adjustments are required.

Table 1. Overview of the Aussie-FIT programme (12-week active phase)

Week number and session title	Concepts covered	Physical activity component
Session 1. Getting started and meeting your team	Aim and overview of the Aussie-FIT programme Getting to know each other and agreeing group ground rules Facebook group sign-ups Motivation (identifying and developing higher quality motives) Monitoring progress; 'your weight' and 'your activity' progress records **Action Point:** Food diary	Energy balance (intake vs output) Handing out activity monitors and explaining how to use them Short tour around the oval wearing activity monitors
Session 2. Eating better and setting SMART goals	Explanation of food groups and eating healthily Food diaries compared with healthy	Baseline step counts determined Understanding how to

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	eating recommendations Influences on choosing what to eat and staying in control The importance of portion size **Action Point:** Working on SMART goals	increase step count gradually Setting step count goal Walking around oval
Session 3. Reviewing what you eat, how active you are, and introducing small changes	Review of SMART goals Talking about junk foods Allowing yourself to be flexible Motivation and staying on track Avoiding compensatory behaviours Importance of support from others **Action Point:** Reducing junk food consumption	Tips for moving more and sitting less Health benefits associated with PA Principles of fitness: warm up; aerobic training; cool down A session of warm up exercises; aerobic training; cool down
Session 4. Planning and learning about food labels and PA recommendations	SMART goals review Action planning and coping planning Assessing food labels **Action Point:** Paying attention to food labels	PA recommendations and activity intensity Facts about PA and barriers to being physically active Reviewing steps and thinking about the alternative activities Aerobic activities, with warm up and cool down
Session 5. Reviewing goals and cutting down on booze	Reviewing goals Pros and cons of drinking alcohol Facts about alcohol Alcohol standard drinks and recommendations **Action Point**: Planning to drink less: SMART goal, action and coping plan	Reviewing steps and the alternative activities Aerobic activities, along with warm up and cool down
Session 6. Key factors to maintain health behaviour	Five key factors to maintain health behaviour Sharing experiences (personal examples of setbacks) Introduction to setbacks and tactics for dealing with them Measurements taken to review progress **Action Point:** Problem solving; come up with tactics to overcome setbacks	Reviewing steps and the alternative activities Principles of strength training using own body weight and exercises men can do at home Warm up, then strength exercises for major muscle groups and cool down
Session 7. Weight loss progress and staying on track	Representations of weight loss achieved and intended Body composition in men SMART goals and weight loss reviewed Healthy snacks and food swaps	Review of step counts Principles of stretching and flexibility training

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	Reviewing how things are going so far, and problem solving Reflecting on and identifying ways to promote autonomy, competence and relatedness satisfaction **Action point:** Food swapping	
Session 8. Facts about fat, salt and sugar and developing healthy eating habits	Facts about fat, salt and sugar The importance of developing eating routines and habits **Action Point:** Identifying prompts to eat healthily/unhealthily	Step count and activity review Circuit of aerobic, strength and flexibility activities including AFL drills
Session 9. Making right food choices when eating out and developing PA habits	Making good food choices when eating out Developing PA habits **Action Point:** Identifying prompts to be active/sedentary	Step count and activity review Circuit of aerobic, strength and flexibility activities including AFL drills
Session 10. Common ideas about healthy living and cooking healthy at home	Common ideas/ myths about healthy lifestyles Triggers for setbacks and how to avoid them Healthy cooking and food preparation Revision of SMART goals **Action point**: Food diary	Step count and activity review Circuit of aerobic, strength and flexibility activities including AFL drills
Session 11. Reviewing progress and acknowledging achievements	Revision of food diaries Revision of eating plans Staying on track **Action Point:** Considering what next after the Aussie-FIT programme (personally and as a group)	PA levels, types, positives and challenges Step count and activity review Visit to local sports facilities, if possible
Session 12. Looking ahead towards maintaining healthy lifestyles	Review progress throughout the programme and next steps Celebration of achievements **Action Point:** Keeping SMART goals going; revising them monthly Official graduation	AFL small-sided game

Intervention Procedures

An outline of the sessions is presented in Table 1 and CONSORT flow diagram in Figure 1.

Please insert Figure 1 about here

Outcome measures

At three time points (baseline, 3 months and 6 months) objective measures will be taken of body weight, height (for calculation of BMI), waist circumference, resting systolic

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and diastolic blood pressure. Self-reported measures of food intake,[49] alcohol consumption, psychological well-being (emotional states[50] and self-esteem[51]), health related quality of life,[52] and demographics will be taken.

Our choice of aforementioned measures replicates those used in the FFIT studies and will allow for cross-country comparison analysis with findings from Scotland. In addition, the men will also wear an ActiGraph GTX-9 accelerometer to objectively measure their PA and sedentary behaviour at baseline, 3 months, and 6 months. On each of these occasions, participants will be asked to wear the devices continuously on their waist (using a device-specific belt) and return them after 8 days of wearing, at each time point (baseline, 3 and 6 months) in person or by post using pre-paid and pre-addressed envelopes. The data will be downloaded and processed using a custom-built SAS program (version 9.3) that implements a series of decision rules with user-modifiable thresholds to automatically identify waking wear data for continuously worn ActiGraph data.[53] Only participants with four or more valid days of wear (including at least one weekend day) will be included in the analyses. Total daily time spent in the different PA intensities will be obtained by totalling the duration of all the bouts at each level for each day. The values will then be normalised to total wear time and averaged over the number of valid days to derive an estimate of the mean time spent within each intensity. The increase in moderate and vigorous PA minutes will be the main outcome measure from the AciGraph data.

At two measurement points (3 and 6 months), men will also complete scales assessing their experiences of autonomy, competence[54] and relatedness[55] psychological need satisfaction in relation to their weight loss behaviours. Motivation for weight loss[56] will also be assessed at baseline and at both follow ups. At 3 and 6 months participants will complete two versions of the Interpersonal Behaviours Questionnaire (IBQ),[57] one to assess their perceived need support from family and friends in relation to their weight loss behaviours and

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one to assess perceived need support from the coach and from other participants in the Aussie-FIT programme. At all measurement points we will also assess automaticity;[58] goal conflict and goal facilitation[59], coping planning and action planning[60], and quality of sleep using the Sleep Pittsburgh Sleep Questionnaire.[61] See Table 2 for the overview of the study measures.

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

	Measurement instrument	Baseline	3 months	6 months
Objective measures				
PA and sedentary time	ActiGraph GTX-9 worn for 1 week at the time, on their waist; setup to gather continuous data at 30Hz epoch; blinded assessor	X	X	X
Weight	Weight in kilograms measured with3 valid and reliable body scale (e.g., Tanita); light clothing, no shoes and empty pockets; blinded assessor	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 measured twice (three times, if the first two measurements differ by 5 mm or more) and the mean of all recorded measurements calculated	X	X	X
Resting systolic and diastolic blood pressure	Resting blood pressure measured with a digital blood pressure monitor (Omron HEM-705CP, Milton Keynes, UK) monitor after 5 min sitting still. If measured systolic blood pressure is over 139 mmHg and/or measured diastolic blood pressure is over 89 mmHg, two further measures will be taken and recorded, and in line with duty of care, men will be given a letter explaining the circumstances in which they had their blood pressure measured and recorded and they will be told 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
Self-reported measures				
Food intake	An adaptation of the Dietary Instrument for	X	X	X

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	Nutrition Education (DINE) [21] calculating a fatty food score, fruit and vegetable score, and sugary food score. High scores indicative of high consumption; items adjusted for Australian population			
Alcohol consumption	The total number of alcohol units consumed in previous week with a 7 day recall diary	X	X	X
Positive and negative affect	The Short Form of the positive and negative affect scale (PANAS)[50]	X	X	X
Self-esteem	The Rosenberg Self-Esteem (RSE) scale[51]	X	X	X
Quality of life	The health-related quality of life measured using the EQ-5D-5 L[62]	X	X	X
Basic need satisfaction in relation to weight loss behaviours	The autonomy and competence subscales from the scale by Chen and colleagues[54] and four items tapping relatedness satisfaction[55]	X	X	X
Weight loss motivation	The adapted measure from the treatment self-regulation questionnaire (TSRQ) of weight loss motivation[56]	X	X	X
Automaticity	The 'Self-Report Behavioural Automaticity Index' (SRBAI)[58]	X	X	X
Goal conflict, facilitation	Goal conflict and goal facilitation scale[59]	X	X	X
Action and coping planning	Action planning and copying planning scale[60]	X	X	X
Sleep	Pittsburgh Sleep Questionnaire[61]	X	X	X
Need support in relation to weight loss	The interpersonal behaviours questionnaire (IBQ)[57]		X	X
Demographics	Age, ethnicity, education, marital status, current employment status, income, housing status	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 (both coaches' and participants')		X	X
Training evaluation: via questionnaires and interviews	Coaches will evaluate the training provided to them; and participants will feedback on the perceptions of the trainers' style	X	X	X

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Trial feasibility	Study protocol, assessment methods/procedures, and potential to gather cost-effectiveness data.	Assessed throughout the programme

Process evaluation measures

A multicomponent process evaluation (including interviews with participants, coaches, and coded audio recordings of coaches delivery of Aussie-FIT) will be undertaken in accordance with the UK Medical Research Council guidelines.[63] The evaluation will explore issues of: (1) implementation (i.e., the process of implementing the intervention, such as when, where, and how the participants engaged in new health behaviours during and after the active 12-week intervention period), (2) mediators of outcomes (i.e., motivation to engage in PA or healthy diet), and (3) potential moderators (i.e., age, socioeconomic status, baseline PA and dietary behaviours, baseline BMI). Fidelity of the delivery of Aussie-FIT by trained club community coaches will be examined via coding the content of the audio recordings of the programme delivery sessions. We will determine whether the intervention delivery style and content were as intended by coding audio recordings for need supportive strategies.[64] We will also measure the degree to which the behaviour change techniques[34] (BCTs) have been taught appropriately by the coaches to the full group (BCTs provided in one-on-one interactions may be more difficult to capture).

A purposive sub-sample of men from each club (N = 10) will be contacted at 3 and 6 months to participate in semi-structured interviews conducted preferably face-to-face but also over the telephone if that is more convenient for the participant. The interviews will explore the men's views of various components of the programme and what they did or did not engage with (and reasons why). We will also explore cultural, personal and situational facilitators and barriers to sustained behaviour change in 3 and 6 month interviews. Men who drop out of the Aussie-FIT programme will be asked to take part in structured telephone interviews which will examine their reasons for discontinuing. Community coaches who have delivered Aussie-FIT will also be interviewed at the end of the intervention to explore their

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perceptions of the training they received, their perspectives on the feasibility of delivery, their own experiences of delivering the programme, and their perceptions of programme acceptability among the participants. Additionally, after each session they will be asked to fill in a session evaluation form to record their perceptions of what went well, as well as any challenges within the session and any suggestions for session improvements in terms of content and delivery. Attendance at Aussie-FIT sessions will be recorded via the use of a register. Attrition will be monitored by recording dropout rates, with dates and reasons for dropout also logged if possible. Acceptability of the intervention will be measured via a 9-item scale including items such as "I would recommend this programme to other men", which will be adapted from a previous study.[65]

Economic analysis

We will develop and pilot an economic model to estimate cost-effectiveness of the programme. Costs will include direct costs associated with the programme, including set up costs and cost of promotion activities. In terms of outcome measurement, we will include short-term outcomes that will enable us to look at the cost per 5% weight reduction and cost per Quality Adjusted Life Years (QALY). The QALY is the most widely used approach for estimating quality of life benefits in economic evaluations[66] Quality of Life scores will be measured using the EQ-5D- 5L questionnaire[67] which is a standardised measure of health status used in economic evaluation.[68] The scores obtained from the EQ-5D-5L will be used to formulate the cost per Quality Adjusted Life Year. Sensitivity analysis will test the robustness of the results. Including the economic component in the early pilot phase will allow us to test the sensitivity of the EQ5D-5L in detecting changes in quality of life within the study population and explore the feasibility of using this measure in the Australian context. This pilot study will report on any methodological challenges facing economic evaluations of this type and carry out any necessary modifications before a future RCT is conducted.

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Data Management

Hard copies of data will be securely stored in locked cabinets in the University and will contain ID Codes but no identifying information. A document associating ID codes with participants' identifying information will be stored in a password-protected computer file on the University's computer server. The project data will be stored securely for 25 years, in line with the data management policy at the University. Only members of the research team will be able to access the physical and electronic data files.

Analyses

Trial feasibility will be reported using descriptive statistics and percentages for each group. Mixed linear modelling will be employed to examine changes across and between groups in all measures over time, adjusting for clustering effects. Intention to treat analysis will be used to deal with missing data and we will include every participant who provided at least baseline data. We will compare the baseline characteristics of the participants who dropped out with the characteristics of the participants who completed the full study (both 3 month and 6 month measures) to check if there are any differences between the two groups. The study analysis will be predominantly performed using the SPSS and R software.

Qualitative data will be transcribed verbatim and analysed to explore acceptability, feasibility as well as implementation of the Aussie-FIT intervention. We will use a combination of inductive and deductive content analyses, following the five procedures of the thematic analysis approach.[69] Approaches from framework analysis[70] will also be employed to support identification of theoretically derived themes, in particular from SDT.[35] Two independent coders will undertake the qualitative analysis, using QSR Nvivo to facilitate the organisation, coding, and management of data. Other members of the research team will also contribute to analysis by challenging interpretations of the data.

Patient and Public Involvement

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The development of the Australian adaptation of the FFIT intervention was informed by the recently conducted a multi-method study of AFL fans in Western Australia (WA) aiming to assess the appeal of the similar programme for the target population.[46] The study has indicated the appeal for Aussie-FIT among male AFL fans (*N*=151) aged 35-65 years (*M* = 49.41±8.74). Among those surveyed, 74.2% were overweight or obese, 53.0% were insufficiently physically active, and 64.9% were seriously considering trying to lose weight in the next 6 months. After viewing an informational video about FFIT, 90.5% of those surveyed indicated that this programme would appeal to overweight AFL fans. Follow up interviews with men (*N* = 9) and coaches (N = 5) further substantiated the findings of the survey and gave insights that informed development of the program. Further research is needed to determine whether a version of FFIT, culturally sensitised for delivery to Australian middle-aged men who are overweight or obese, can be successful in increasing PA, improving diet, and reducing body weight among this population. The Aussie-FIT pilot trial will assess and explore participants experiences and preferences in quantitative and qualitative manner. Programme participants, coaches and other stakeholders are involved in programme development and will be involved in full evaluation conducted as described above (also assessing participants' burden assessment).

ETHICS AND DISSEMINATION

The study has been reviewed by the Curtin University Human Research Ethics Committee (HREC2018-0458). Participants will be asked to provide informed consent subsequent to eligibility screening. Participants will be informed that they are free to withdraw from the project at any stage and will be under no obligation to give a reason. Any substantive changes to the study protocol will be subjected to University ethical review and also documented at the Australian and New Zealand Clinical Trials Registry (ANZCTR).

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All participants in the study will be provided with a summary of the results at the end of the project. Findings will also be disseminated to stakeholders (e.g., practitioners, policy makers, academics, local community representatives) via targeted seminars and summaries of results. The findings of the study will be publicised via traditional and social media channels, including Twitter (@aussiefitorg) and the project website (www.aussiefit.org), disseminated via publications in peer reviewed journals and at relevant international conferences.

Discussion

In developed countries men are less likely than women to participate in healthy lifestyle and weight loss programmes. The design of programmes that are relevant, which align with predominant masculinity values, and use fun, positive banter and social interaction as guiding principles is essential to improve population health. Weight loss programmes that are culturally sensitive, relevant to the country where they are delivered, and which use existing interests (such as passion for AFL) as a 'hook' to encourage participation, have the potential to contribute to a decrease in the population levels of obesity if it proves possible to deliver them at scale.

Aussie-FIT is customised for delivery in Australia to reflect local PA and dietary norms and uses a gender-sensitive and motivationally embellished approach to engage men in healthy and sustainable lifestyle changes. From the outset, the programme emphasizes that the changes introduced need to be sustained long term in order to help men truly improve their lifestyles and risk of future ill-health. The programme builds upon and expands the current FFIT program. Drawing from a recent systematic reviews of literature,[38 39] Aussie-FIT incorporates specific activities that focus on creating habits that can be sustained, allowing for occasional lapses . The Aussie-FIT pilot will provide pilot data needed to scale up for a nationwide RCT. The additional components of the programme expand existing interventions delivered to sports fans. Results from the definitive RCT will have the potential

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to inform a translation strategy to support the development of Aussie-FIT programmes customised for a range of professional sports (e.g., cricket, netball, rugby) and segments of sport fans (e.g., females, children, families).

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Authors' contributions

EQ, NN, CT-N, DG, DAK, KH, SR, PJM, RN, CG and SW conceived the project and obtained the project funding. EQ, NN, CT-N, DG, DK, DAK, KH, SR, PJM, CG, SW, JMV and EM have made conceptual contributions to project design. EQ is the project lead and DK is the project manager. DK and EQ developed the intervention materials, with input from all authors. EQ and DK drafted the manuscript and all authors read, edited and approved the final version of the manuscript.

Competing interests

The authors have no competing interests to declare.

Figure 1.

CONSORT flow diagram for the Aussie-FIT trial.

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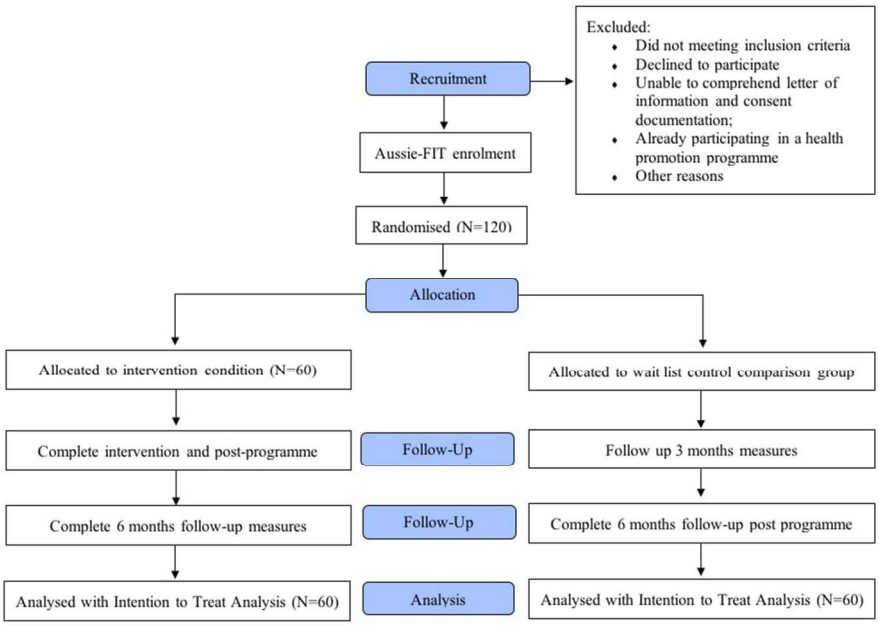

Figure 1. CONSORT flow diagram for the Aussie-FIT trial

353x231mm (72 x 72 DPI)

view only

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The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	1	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	3-9	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	13-16	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	16-18	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	15-16	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	13-14	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	12	_____

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	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	13-14	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	12-15	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	14	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist

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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, lines 1-3
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2, lines 33-34
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	26, lines 543-545
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	26, lines 536-542
	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	3-9
	6b	Explanation for choice of comparators	5, lines 113-116 7, lines 149-151

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Objectives	7	Specific objectives or hypotheses	9, lines 219-222 10, lines 223-244
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)	11, lines 249-252
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	12, lines 286-288
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)	12, lines 286-293
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	12-18
	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)	12, lines 282-285
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	14, line 326
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12, lines 292-293
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	19-24 (till line 475)
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)	Page 27 – figure 1

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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	11, lines 253-259
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12, lines 272-285
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	11, 260-267
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	11, 260-267
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11, 261-262
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11, 263-267
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11, 263-267
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	19-24 (till line 475)
	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	22, lines 442-447 23, lines 448-460

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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	24, 476-482
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	24, lines 484-492
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	24, lines 493-497 and 25, lines 498-500 (qualitative analyses)
	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)	24, lines 487-489
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	N/A
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	25, lines 502-503
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)	25, lines 505-507

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Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	25, 503-504
	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	24, 476-482
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	26, lines 546-547
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	24, lines 481-482
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	25, 508-513
	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.

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BMJ Open

Protocol for a gender-sensitised weight loss and healthy living programme for overweight and obese men delivered in Australian Football League settings (Aussie-FIT): A feasibility and pilot randomised controlled trial

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Secondary Subject Heading:	Evidence based practice
Keywords:	PUBLIC HEALTH, Protocols, physical activity, obesity, intervention, men's health

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Title: Protocol for a gender-sensitised weight loss and healthy living programme for overweight and obese men delivered in Australian Football League settings (Aussie-FIT): A feasibility and pilot randomised controlled trial.

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We would like to thank male AFL fans (*N*=151) for their contribution to the preliminary research that assessed the need for the Aussie-FIT study.

ABSTRACT

Introduction: Overweight and obesity are highly prevalent among Australian men. Professional sports settings can act as a powerful 'hook' to engage men in weight loss programmes; the Football Fans in Training (FFIT) programme delivered in professional UK soccer clubs was successful and cost effective in helping men lose weight. The Australian Football League (AFL) is a potentially attractive setting to engage men in a weight loss program. We aim to develop, pilot and evaluate the feasibility of a weight loss intervention for overweight/obese middle-aged men, delivered in the AFL settings, to promote weight loss and healthier lifestyles, and determine its suitability for a future randomised control trial.

Methods and Analysis: 120 overweight/obese male fans will complete baseline physical and psychological health measures and objective measures of physical activity (PA), weight, waist size, and blood pressure prior to randomisation into the intervention or waitlist comparison group. The intervention group will receive 12 weekly 90-minute workshops incorporating PA, nutrition education, behaviour change techniques and principles of effective motivation. Four community coaches will be trained to deliver Aussie-FIT at two

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AFL clubs in Western Australia. Measurements will be repeated in both groups at 3 months (post-intervention) and 6 months (follow-up). Outcomes will include programme uptake, attendance, changes in lifestyle and weight variables to inform power calculations for a future definitive trial, fidelity of programme delivery, acceptability, satisfaction with the programme, and perceptions of effectiveness. We will also determine trial feasibility and potential to gather cost effectiveness data.

Ethics and Dissemination: Ethics approval was granted by Curtin University's Human Research Ethics Committee (HREC2017-0458). Results will be disseminated via peer-reviewed publications, conference presentations, and reports. A multi-component dissemination strategy will include targeted translation and stakeholder engagement events to establish strategies for sustainability and policy change.

Registration: Australian New Zealand Clinical Trials Registry: ACTRN12617000515392.

Strengths and limitations of this study:

- This is the first study in Australia to test an intervention targeting fan health delivered in Australian Football League settings.
- The programme embeds Self-Determination Theory techniques to train the coaches to deliver the intervention using a need supportive delivery style.
- To support behaviour change maintenance, the Aussie-FIT intervention focuses on habit formation, relapse prevention, problem solving and dealing with competing goals from the onset of the intervention.
- This is a pilot study with 120 participants and is not powered to detect intervention effectiveness and a full-scale national RCT is recommended.
- The Aussie-FIT programme has great potential to impact on the programme participants as well as their family members; the impact on the close relatives should be investigated in the future studies.

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INTRODUCTION

Worldwide in 2016, more than 39% of adults aged 18 years and over (more than 1.9 billion) were overweight, and 13% were obese (over 650 million).[1] In Australia, the prevalence of overweight and obesity has steadily increased in the last 30 years, with currently about 60% of Australian adults classified as either obese or overweight, of which more than 25% are in the obese category.[2] The direct cost of obesity to the Australian economy is equivalent to 22.6% of the national health expenditure ($148.9AUD billion in 2014-15).[3] A recent Australian study estimated that the average annual health care costs for individuals classed as 'obese' (Body Mass Index, BMI $\geq$ 30kg/m) is 50% greater (i.e., 2,233AUD) than that for normal weight individuals.[4]

Approximately 70% of men in Australia are overweight/obese, compared to 56.3% of women.[5] Risks of disease and physical, psychological and sexual dysfunction are significantly increased for males whose waist circumference is 102cm or greater, and whose BMI is 30kg/m or greater.[2 6] Main drivers for weight loss are addressing the energy imbalance through increases in physical activity (PA), alongside decreases in energy intake. However, adults classed as overweight (BMI $\geq$ 25kg/m) and obese are the least likely population group to engage in PA,[7] and despite poorer health behaviours relatively few men participate in weight loss interventions, e.g., on average 27% men versus 73% women ($p<0.001$).[8]

Male participation in weight loss interventions

The specific barriers that lead to low male engagement in PA and weight loss interventions[8] are often unaddressed in attempts to promote weight loss in men.[9] Given that men are less likely to recognise the link between weight and health[10] and are also thought to be more resistant to healthy eating campaigns than women, attempts to address overweight and obesity are likely to be ineffective if they do not take account of men's underlying beliefs

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and concerns, and if they are female oriented.[11] Cultural constructions of masculinity[12] often deter men from taking appropriate action in order to improve their health (e.g., healthy eating).[11 13-16] Consequently, men may have a skewed perception of what is a healthy body size for men and/or perceive weight loss to be irrelevant to them and ignore health concerns to adhere to stereotypes of men being 'tough'.[17 18] Men who aspire to lose weight face a number of cultural barriers that may limit their motivation or capacity to initiate and sustain behaviour change. For example, dieting is often viewed as a feminine activity, whereas excessive eating and drinking are often associated with a masculine identity.[19 20] Such gender stereotypes are thought to discourage men from engaging in weight loss interventions.[16]

In a systematic review of male inclusion rates in weight loss randomised controlled trials (RCTs),[8] men typically comprised only 20% of the included samples. Interventions which were shown to be appealing and/or effective for predominantly female groups may not be similarly relevant for men. Another systematic review of obesity management interventions with follow-up data for at least one year identified only 5% of RCTs that were specifically targeted at men.[15] Of those interventions, only three men-only programmes were run in Australia; of these three programmes, only one included a PA component. This intervention was the SHED-IT trial which successfully supported reduction in BMI amongst younger men (mean age 35.9, SD 11.1 years) who were overweight and obese.[21]

Professional sport settings as an opportune setting for the promotion of weight loss

Interventions targeting males may need to capitalise on, rather than ignore, dominant cultural constructions of masculinity. Many professional sports are still typically seen as 'male' domains and therefore have recognised potential to attract men to health interventions.[22 23] As a setting in which many men feel valued and comfortable, professional sport environments can act as a powerful 'hook' to engage men in health behaviour programmes.[13] Those most likely to be attracted are men with a keen interest in the sport and

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who are fans of the club whose team play or train in the stadium in which the programme is being offered.

The Football Fans in Training (FFIT) programme was designed to appeal to adult male soccer fans and was developed and delivered with support from the Scottish Professional Football League (SPFL) Trust. FFIT is delivered over 12 weeks by community coaches in the stadia of professional soccer clubs. Participants' emotional connection with soccer and/or the club is a vital aspect of the intervention.[13 14 24] This innovative approach has proved successful in attracting and retaining men aged 35-65 years, with a BMI $\geq$ 28kg/m^2 from across the socioeconomic spectrum and at high risk of ill-health. Process evaluation data, embedded within a pragmatic RCT of FFIT, showed that, within the professional soccer club setting and amongst the company of fellow fans, men felt comfortable making positive behaviour changes, such as using a pedometer to self-monitor and increase their daily PA. Participants also highly valued club community coaches' role as programme leaders.[13 24] FFIT drew on current evidence on gender and health and from PA, nutrition, male weight management, and community-based health interventions. Key behaviour change techniques (BCTs) included in the FFIT programme were self-monitoring, implementation intentions, goal setting and review, feedback on behaviour, and ongoing social support.[25]

FFIT was initially tested in a feasibility study in eleven SPFL (then Scottish Premier Football League) clubs. Following revisions based on an extensive process evaluation[26] the programme was rigorously tested in an RCT with 747 overweight and obese men from 13 SPFL soccer clubs. The trial compared men in the intervention arm with a waitlist comparison arm.[24] The adjusted mean between-arm difference in weight loss at 12 months was 4.94 kg. Economic analysis demonstrated FFIT was cost-effective, relatively inexpensive to deliver, and a good return on investment (costing approximately $285AUD per participant).[24] The programme helped male soccer fans make long-term, sustainable changes

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to eating, alcohol consumption and PA.[25] The participants described improved well-being and enjoyment from taking part in FFIT as part of a team and with other men like them. The success of the programme was further substantiated after the programme finished, as assessed in secondary outcome analyses (e.g., changes in diet and PA), in post programme focus groups[27] and follow-up measurements 3.5 years after the FFIT trial began.[28] Research has demonstrated the programme's appeal, as well as the acceptability of the club setting as a 'draw' for men to participate in a weight loss programme.

FFIT utilised soccer stadia for the delivery of the intervention, because soccer remains highly popular with men in the UK and soccer fans have a strong affiliation to their clubs; however, the PA and diet components of the programme are not soccer-specific. Hence variations of FFIT have been developed and readily delivered in other sports. FFIT has since been adapted for delivery in professional rugby club settings in England[29] and New Zealand and in junior A hockey teams in Canada;[30 31] it also formed the basis for the EuroFIT programme currently being trialled in soccer clubs in four European countries.[32 33] The Australian Football League (AFL) is the most popular spectator sport in Australia[34] with a predominantly male fan base and is potentially a viable and attractive setting through which to engage men in Australia in weight loss programmes.

The design of Aussie-FIT for Australia

It is important to develop and test an Australian version of FFIT for several reasons. There are sufficient differences in Australia (e.g., weather, sport targeted, health care provision) to warrant a pilot (and subsequently an RCT) of the program in Australia. This seems particularly important given a meta-analysis[35] showing that culturally adapted interventions for health behaviours are more likely to be effective. Contextual adaptations and testing of health behaviour change programs is also recommended by the Medical Research Council (MRC) process evaluation framework.[36] The application of motivation

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theory and BCTs in Aussie-FIT will also further enhance the original FFIT content, as briefly outlined below.

In the past decade, there has been a growing recognition that to be effective, health behaviour change interventions must also be used to support individuals' capacity to self-regulate and sustain their health behaviours beyond the timeframe of the intervention delivery period. One way to achieve sustained benefits is via the inclusion of BCTs,[37] such as those motivationally relevant techniques shown to be effective in PA and eating behaviour interventions and previously utilised in FFIT[13] (e.g., self-monitoring, implementation intentions, goal setting and review, and feedback on behaviour within the intervention). A growing body of evidence suggests it is also important to consider the quality of motivation regulating the targeted behaviour change. A meta-analysis of studies based on Self-Determination Theory (SDT)[38] showed that when the reasons underlying engagement in PA and weight behaviours are of higher quality (i.e., more self-determined, because the individual wants to do so, he/she values and/or enjoys the behaviour), behavioural change is more likely to be successful and sustainable.[39]

In Aussie-FIT, the communication style of the coach delivering the program will be a specific focus of our coach training package. In addition, the Aussie-FIT programme content will include activities designed to reveal and emphasise opportunities to experience autonomy, competence and relatedness (i.e., three basic psychological needs considered in SDT as essential for optimal functioning) during and after the 12-week programme. Satisfaction of the basic psychological needs is considered critical for sustained, self-determined motivation, and successful behaviour change.[38] Therefore, the Aussie-FIT intervention will be designed to directly (i.e., through engagement in need-promoting activities) and indirectly (i.e., via training of coaches who will deliver the programme in how

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to use a need supportive communication style) promote greater need fulfilment and in turn more autonomous motives to engage in PA and healthy eating practices.

Participants are much more likely to succeed in losing weight and keeping weight off if they are introduced to BCTs which support long-term maintenance of behavioural changes from the beginning of the intervention rather than part way through.[40] Compared to the original FFIT trial, Aussie-FIT will place greater emphasis from the start of the programme on BCTs relevant for behaviour change maintenance and relapse prevention. Specifically, the Aussie-FIT intervention will be underpinned by key theoretical themes of behaviour change maintenance that will define the intervention mechanisms of action,[41 42] including maintained self-determined motivation, effective self-regulation that leads to habit development, and a supportive social and physical environment. The intervention will promote additional aspects of weight loss maintenance, including identity shift (i.e., ensuring that participants recognise the programme not as a temporary change but as a shift in their lifestyles), focusing on goal priority, and managing occasional relapses with flexibility (as opposed to 'all or nothing' approach) in order to improve long-term maintenance.

Aussie-FIT will also extend FFIT by adding greater focus on minimising the time participants spend being sedentary, in addition to forming routines to incorporate PA into their daily lives (e.g., identifying triggers that are time, person and context specific). Aussie-FIT will focus on developing healthy habits relevant to weight loss, including healthy eating, increased PA, and minimising alcohol consumption as well as how to recognise and develop strategies to cope with common behavioural barriers to weight loss such as stress, perceived lack of time, and other competing goals. The Aussie-FIT programme will emphasise action planning as well as coping planning, not only on forming Specific, Measurable, Attainable, Relevant and Time-based goals (SMART goals). From the start, relapse prevention will be a key part of the Aussie-FIT programme.

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In summary, building on the FFIT programme, the new 'Aussie-FIT' intervention differs from previous weight loss interventions, adding conceptual and applied value to the existing literature. Several differences are embedded in the Aussie-FIT intervention which differentiates it from previous programmes that have been designed to engage sports fans in weight loss behaviours. First, Aussie-FIT capitalises on the appeal of the sport of AFL to attract overweight and obese males in Australia to take part in a weight loss and healthy lifestyle programme, and hence our new program will include content and design features to suit the context and culture of Australia. Second, the overall programme will be designed to promote self-regulated behavioural control by embedding SDT throughout the intervention via a focus on basic psychological need satisfaction within programme content (e.g., targeted activities), as well as via training the coaches to use a need supportive programme delivery style. Finally, the Aussie-FIT programme will include even greater emphasis on habit development as a means to further promote behaviour change maintenance and weight loss maintenance from the start of the programme. We will also examine the motivationally-relevant mediators and moderators of the men's health behaviour change in line with recent recommendations.[43]

Aim and study objectives

The overarching aim of the study is to determine the feasibility and potential efficacy of the 12-week Aussie-FIT intervention in the context of AFL in Australia. The specific aims are:

- To develop the resources and infrastructure required to implement Aussie-FIT;
- To assess the feasibility of training the coaches using SDT principles to deliver the intervention;

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- To determine time and resources required to recruit participants, recruitment protocols, enrolment and consent procedures, inclusion/exclusion criteria, necessary length of training of coaches, and resources required to run the trial;
- To determine the design of data collection protocols, questionnaire administration procedures, randomisation procedures, and selection of outcome measures for a future definite trial;
- To assess feasibility with regard to uptake, adherence and attrition, and programme acceptability to AFL clubs, coaches and participants in Australia;
- To examine the potential effects of the intervention on changes (and standard deviations of such changes) in: objectively measured body weight, waist circumference, time spent in moderate/vigorous PA and sedentary time, and blood pressure; self-reported diet, motivation to be physically active and to eat healthily; and indicators of psychological well-being;
- To undertake a process evaluation to identify the extent to which Aussie-FIT can be implemented as planned, and to reveal potential barriers and facilitators to implementation from the perspectives of participants, coaches and AFL club personnel;
- To examine motivation-related moderators and mediators of changes in outcome variables;
- To assess the feasibility of collecting data for an economic analysis of Aussie-FIT;

METHODS AND ANALYSIS

Study design

The project will include two key phases. First, we will develop the resources and infrastructure required to deliver Aussie-FIT. We will train four coaches (two from each club) to deliver the programme and to use motivation techniques when doing so. Second, the 12-

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week intervention, using waitlist control as a comparator based on FFIT, [25] will be piloted and evaluated for feasibility, effectiveness and cost and process evaluation with measures administered at baseline (week 0), and 3 and 6 months follow-ups.

Baseline data collection will start in June 2018 with final follow-ups completed at all sites by December 2018. Hypothesis-testing is not a focus of pilot trials and therefore statistical power is irrelevant for this pilot RCT. The proposed sample size follows guidelines for appropriate sample sizes for pilot trials[44 45] and replicates the design used in piloting FFIT.[25] The study is designed to generate data to calculate the necessary power in a definitive trial. It will also enable estimation of rates for recruitment, responses to questionnaires, participant retention, effect size and variability in outcomes to inform a definitive trial.

The randomisation sequence, generated in SPSS (in block sizes of 4 and stratified by the AFL team and by BMI category), will be concealed until conditions are assigned by the blinded researcher. Participants will be allocated according to the randomisation sequence and informed about their group allocation via email/phone call. Although participants and coaches cannot possibly be blinded to the study allocation, independent researchers blinded to the study allocation will assess all study outcomes measured at 3 and 6 month follow-ups. We will record any disclosures of condition allocation and we will monitor the feasibility of our blinding procedure. The study protocol was prepared in accordance with guidelines by the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT), and Template for Intervention Description and Replication (TIDieR).[46 47] The completed checklists are available as supplementary files.

Recruitment, participants, eligibility and screening

Men will be invited to participate in the programme through a variety of methods including word of mouth, the Aussie-FIT website (www.aussiefit.org), publicity for the

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programme from the AFL clubs (e.g., emails to members), social media, and press releases. To express interest in the programme, potential participants will be asked to visit the programme website and to provide information about their age, weight, height, contact details, and their availability to attend Aussie-FIT sessions on certain days and times of the week. As an alternative to the online registration, the men will also be given the option to call or email the project team.

Men will be asked to complete the Adult Pre-exercise Screening System (APSS) [48] to ascertain whether they have any contraindications for participating in the PA aspect of the programme. Aligned with the recommendations of the tool, participants who answer 'yes' to any of the APSS questions will be recommended to consult an allied health professional or their doctor before study participation, but it will be left to their discretion if they choose to follow the advice. If the medical advice deems it necessary, PA sessions will be altered to suit their ability These men will still be invited to participate in the classroom sessions. All participants will be also asked to sign the disclaimer form that they are taking part in the Aussie-FIT sessions at their own discretion.

We will recruit 120 males (aged 35-65 years, BMI $\geq$ 28kg/m^2) from the fan base of the Fremantle Dockers and West Coast Eagles professional AFL clubs in Perth, WA (60 men from each club). Our inclusion criteria (matching those used in FFIT) are: men; aged 35 to 65 years; objectively measured BMI $\geq$ 28 kg/m^2 and consent for randomisation. The inclusion of this specific age group and specific BMI cut-off points have been tested and proved valuable in the FFIT programme.[24 26] Our exclusion criteria are: men who are unable to comprehend the information letter and consent documentation (despite verbal elaboration) to the extent that they are unable to provide informed consent; and those who are already participating in a specific health promotion programme delivered at the club or elsewhere.

Intervention

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Aussie-FIT will be a programme designed to promote PA, healthy eating and weight loss among overweight and physically inactive middle-aged men in Australia. Aussie-FIT will be based upon the existing, successful FFIT programme.[24 26] Aussie-FIT will also include a motivational component to the coach training and intervention resources, which was not explicitly part of FFIT. The men will be introduced to the principles of habit formation and behaviour change maintenance from the beginning of the programme. The research team will invite feedback on the prototype resources, prior to the delivery of the programme, from the recruited AFL coaches and from a purposive sample (N = 5) of AFL fans from the initial pool of AFL participants (interviewed during our first AFL study assessing appeal of Aussie-FIT in Australia).[49]

Aligned with the original FFIT programme, Aussie-FIT will aim to support participants to achieve a 2500kJ daily energy deficit, based on estimated weight maintenance requirements according to age, sex, and body weight. The targeted strategies will include portion control, reduction of sugary drinks and energy dense foods, reduction in alcohol consumption, and a gradual increase in moderate PA. As in FFIT, to maximise sustainability of lifestyle changes this will be integral from the outset and initiated in the club setting but with emphasis on discovering through personal experience how PA can be readily incorporated into men's daily lives. To help support the men to sustain PA changes, the programme will include self-regulation strategies, such as a) helping the men understand how to respond appropriately to certain stimuli (e.g., triggers of unhealthy eating); b) assisting them to set effective goals; c) teaching them strategies to avoid engaging in compensatory behaviours (e.g., being more sedentary or eating more following PA), and d) educating them in how to prevent relapse (i.e., returning to pre-intervention behaviours which might result in weight gain). The programme will also include activities designed to facilitate satisfaction of

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the psychological needs for autonomy, competence and relatedness in relation to PA and eating behaviours.

The programme will be delivered over 12 weekly, 90-minute sessions to groups of around 15 men by one coach. The sessions will include classroom-based activities and coach-led PA sessions (see Table 1 for Aussie-FIT sessions' content). Over the 12 weeks, the proportion of time dedicated to PA relative to classroom-based activities will increase to align with the men's increases in fitness. The delivery style will be informal, encouraging positive use of interaction for vicarious learning, and using humour to facilitate discussion of sensitive topics. Text messaging will be used to improve attendance, participants will receive a text message reminder the day before each session. Messages will be worded to emphasise support for men's feelings of autonomy, competence and relatedness associated with program attendance.

Gender-specific components will include emphasis on portion size and PA, discussion of the role of alcohol in weight gain, the use of physical representations (e.g., sandbags, dumbbells) to reinforce weight loss, and the fostering of peer support. Participants will receive booklets which will include information supporting key messages, and spaces for recording information to aid self-monitoring. Additional information will be available online. Throughout the 12 weeks, Aussie-FIT participants will be encouraged to think about ways they can continue to meet and exercise together after the formal sessions at the football club have finished.

Applying novel technologies. Aussie-FIT will capitalise on recent advances in technology to optimise the way in which support for behaviour change can be maintained outside of the weekly sessions, and long term. Instead of using pedometers as the main self-monitoring technology, we will provide user-friendly wrist worn activity monitors that automatically synchronise with a user based platform (i.e., a dashboard that provides continuous data that

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participants can monitor and access via internet enabled devices). Participants will still be encouraged to manually note down step counts in their weekly progress records; however, they will also have access to other activity indicators online should this information be of interest to them.

Earlier research suggests that many participants in FFIT may welcome more sophisticated self-monitoring technologies.[50] Wrist worn activity monitors will be handed out in week one, when participants will be fully briefed in how to wear and use the devices. Participants will be asked to wear their activity monitor throughout their waking hours and use it as a self-monitoring device (i.e., monitoring daily step count). We will also use an ActiGraph GTX-9 accelerometer as a research tool, to objectively measure participants PA at each time point (baseline, 3 and 6 months); FFIT programme used only self-reported measures of PA. Aussie-FIT will also utilise a social media platform (Facebook) as an outlet for participants to share experiences, stay in touch, brainstorm ideas, and exchange suggestions, and to promote on-going basic psychological need support from others in the Aussie-FIT group.

Aussie-FIT participants will receive practical tips on how to use technology to support their weight loss and maintenance, such as online applications and programmes, should they wish to do so. Participants will be provided with a list of freely available mobile phone applications that could be used to support their self-monitoring and/or goal setting (e.g., MyFitnessPal, MapMyRun) activities. Links to additional existing resources from Australian public health campaigns (e.g., 'LiveLighter' tools such as 'Healthy Meal Mixer', or 'AlcoholThinkAgain' tools such as '5 minutes drinking audit') will be embedded within the participant booklet.

Coach Training. Four community coaches will be recruited to take the role of Aussie-FIT programme coaches. The coaches will be recommended by club personnel and are anticipated to be those individuals who usually deliver the clubs' community programmes. The coaches

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will be selected by the research team members and by the representatives from the participating clubs based on their interest and enthusiasm for the role, and relevant skill base and experience. They will receive two days of face-to-face training, followed by opportunities to practice session delivery and receive feedback from the research team and their peers. Training topics will include relevant information on the importance of and requirements for PA for health, nutrition, and behaviour change strategies.[51]

Principles from SDT[38] will be built into the communication style for programme delivery and mentoring. For example, coaches will be trained to use strategies such as providing rationales (e.g., to explain why tasks or activities are worthy of their effort, and to help the men discover the personal meaning and relevance of activities), involving the participants in the decision-making process (e.g., about what they do in PA sessions and in making their lifestyle changes), taking the perspective of and empathising with the participants, and promoting feelings of competence in behaviour change that are based on personal progression rather than comparison with others. The coaches will have access to all training and intervention materials online, and they will be free to contact the research team via email/telephone if they have any questions. The coaches' will note their reflections and feedback after each Aussie-FIT session, and these records will be passed on to the research team. The research team will have an opportunity to clarify any points and to act on the feedback provided during the pilot if any adjustments are required.

Table 1. Overview of the Aussie-FIT programme (12-week active phase)

Week number and session title	Concepts covered	Physical activity component
Session 1. Getting started and meeting your team	Aim and overview of the Aussie-FIT programme Getting to know each other and agreeing group ground rules Facebook group sign-ups Motivation (identifying and developing	Energy balance (intake vs output) Handing out activity monitors and explaining how to use them Short tour around the oval

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	higher quality motives) Monitoring progress; 'your weight' and 'your activity' progress records **Action Point:** Food diary	wearing activity monitors
Session 2. Eating better and setting SMART goals	Explanation of food groups and eating healthily Food diaries compared with healthy eating recommendations Influences on choosing what to eat and staying in control The importance of portion size **Action Point:** Working on SMART goals	Baseline step counts determined Understanding how to increase step count gradually Setting step count goal Walking around oval
Session 3. Reviewing what you eat, how active you are, and introducing small changes	Review of SMART goals Talking about junk foods Allowing yourself to be flexible Motivation and staying on track Avoiding compensatory behaviours Importance of support from others **Action Point:** Reducing junk food consumption	Tips for moving more and sitting less Health benefits associated with PA Principles of fitness: warm up; aerobic training; cool down A session of warm up exercises; aerobic training; cool down
Session 4. Planning and learning about food labels and PA recommendations	SMART goals review Action planning and coping planning Assessing food labels **Action Point:** Paying attention to food labels	PA recommendations and activity intensity Facts about PA and barriers to being physically active Reviewing steps and thinking about the alternative activities Aerobic activities, with warm up and cool down
Session 5. Reviewing goals and cutting down on booze	Reviewing goals Pros and cons of drinking alcohol Facts about alcohol Alcohol standard drinks and recommendations **Action Point**: Planning to drink less: SMART goal, action and coping plan	Reviewing steps and the alternative activities Aerobic activities, along with warm up and cool down
Session 6. Key factors to maintain health behaviour	Five key factors to maintain health behaviour Sharing experiences (personal examples of setbacks) Introduction to setbacks and tactics for dealing with them Measurements taken to review progress **Action Point:** Problem solving; come	Reviewing steps and the alternative activities Principles of strength training using own body weight and exercises men can do at home Warm up, then strength exercises for major muscle

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	up with tactics to overcome setbacks	groups and cool down
Session 7. Weight loss progress and staying on track	Representations of weight loss achieved and intended Body composition in men SMART goals and weight loss reviewed Healthy snacks and food swaps Reviewing how things are going so far, and problem solving Reflecting on and identifying ways to promote autonomy, competence and relatedness satisfaction **Action point:** Food swapping	Review of step counts Principles of stretching and flexibility training
Session 8. Facts about fat, salt and sugar and developing healthy eating habits	Facts about fat, salt and sugar The importance of developing eating routines and habits **Action Point:** Identifying prompts to eat healthily/unhealthily	Step count and activity review Circuit of aerobic, strength and flexibility activities including AFL drills
Session 9. Making right food choices when eating out and developing PA habits	Making good food choices when eating out Developing PA habits **Action Point:** Identifying prompts to be active/sedentary	Step count and activity review Circuit of aerobic, strength and flexibility activities including AFL drills
Session 10. Common ideas about healthy living and cooking healthy at home	Common ideas/ myths about healthy lifestyles Triggers for setbacks and how to avoid them Healthy cooking and food preparation Revision of SMART goals **Action point**: Food diary	Step count and activity review Circuit of aerobic, strength and flexibility activities including AFL drills
Session 11. Reviewing progress and acknowledging achievements	Revision of food diaries Revision of eating plans Staying on track **Action Point:** Considering what next after the Aussie-FIT programme (personally and as a group)	PA levels, types, positives and challenges Step count and activity review Visit to local sports facilities, if possible
Session 12. Looking ahead towards maintaining healthy lifestyles	Review progress throughout the programme and next steps Celebration of achievements **Action Point:** Keeping SMART goals going; revising them monthly Official graduation	AFL small-sided game

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419 **Intervention Procedures**

420 An outline of the sessions is presented in Table 1 and CONSORT flow diagram in Figure 1.

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Please insert Figure 1 about here

Outcome measures

At three time points (baseline, 3 months and 6 months) objective measures will be taken of body weight, height (for calculation of BMI), waist circumference, resting systolic and diastolic blood pressure. Self-reported measures of food intake,[52] alcohol consumption, psychological well-being (emotional states[53] and self-esteem[54]), health related quality of life,[55] and demographics will be taken.

Our choice of aforementioned measures replicates those used in the FFIT studies and will allow for cross-country comparison analysis with findings from Scotland. In addition, the men will also wear an ActiGraph GTX-9 accelerometer to objectively measure their PA and sedentary behaviour at baseline, 3 months, and 6 months. On each of these occasions, participants will be asked to wear the devices continuously on their waist (using a device-specific belt) and return them after 8 days of wearing, at each time point (baseline, 3 and 6 months) in person or by post using pre-paid and pre-addressed envelopes. The data will be downloaded and processed using a custom-built SAS program (version 9.3) that implements a series of decision rules with user-modifiable thresholds to automatically identify waking wear data for continuously worn ActiGraph data.[56] Only participants with four or more valid days of wear (including at least one weekend day) will be included in the analyses. Total daily time spent in the different PA intensities will be obtained by totalling the duration of all the bouts at each level for each day. The values will then be normalised to total wear time and averaged over the number of valid days to derive an estimate of the mean time spent within each intensity. The increase in moderate and vigorous PA minutes will be the main outcome measure from the ActiGraph data.

At two measurement points (3 and 6 months), men will also complete scales assessing their experiences of autonomy, competence[57] and relatedness[58] psychological need

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satisfaction in relation to their weight loss behaviours. Motivation for weight loss[59] will also be assessed at baseline and at both follow ups. At 3 and 6 months participants will complete two versions of the Interpersonal Behaviours Questionnaire (IBQ),[60] one to assess their perceived need support from family and friends in relation to their weight loss behaviours and one to assess perceived need support from the coach and from other participants in the Aussie-FIT programme. At all measurement points we will also assess automaticity;[61] goal conflict and goal facilitation[62], coping planning and action planning[63], and quality of sleep using the Sleep Pittsburgh Sleep Questionnaire.[64] See Table 2 for the overview of the study measures.

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

	Measurement instrument	Baseline	3 months	6 months
Objective measures				
PA and sedentary time	ActiGraph GTX-9 worn for 1 week at the time, on their waist; setup to gather continuous data at 30Hz epoch; blinded assessor	X	X	X
Weight	Weight in kilograms measured with3 valid and reliable body scale (e.g., Tanita); light clothing, no shoes and empty pockets; blinded assessor	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 measured twice (three times, if the first two measurements differ by 5 mm or more) and the mean of all recorded measurements calculated	X	X	X
Resting systolic and diastolic blood pressure	Resting blood pressure measured with a digital blood pressure monitor (Omron HEM-705CP, Milton Keynes, UK) monitor after 5 min sitting still. If measured systolic blood pressure is over 139 mmHg and/or measured diastolic blood pressure is over 89 mmHg, two further measures will be taken and recorded, and in line with duty of care, men will be given a letter explaining the circumstances in which they had their blood pressure measured and recorded and they	X	X	X

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	will be told 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			
Self-reported measures				
Food intake	An adaptation of the Dietary Instrument for Nutrition Education (DINE) [24] calculating a fatty food score, fruit and vegetable score, and sugary food score. High scores indicative of high consumption; items adjusted for Australian population	X	X	X
Alcohol consumption	The total number of alcohol units consumed in previous week with a 7 day recall diary	X	X	X
Positive and negative affect	The Short Form of the positive and negative affect scale (PANAS)[53]	X	X	X
Self-esteem	The Rosenberg Self-Esteem (RSE) scale[54]	X	X	X
Quality of life	The health-related quality of life measured using the EQ-5D-5 L[65]	X	X	X
Basic need satisfaction in relation to weight loss behaviours	The autonomy and competence subscales from the scale by Chen and colleagues[57] and four items tapping relatedness satisfaction[58]	X	X	X
Weight loss motivation	The adapted measure from the treatment self-regulation questionnaire (TSRQ) of weight loss motivation[59]	X	X	X
Automaticity	The 'Self-Report Behavioural Automaticity Index' (SRBAI)[61]	X	X	X
Goal conflict, facilitation	Goal conflict and goal facilitation scale[62]	X	X	X
Action and coping planning	Action planning and copying planning scale[63]	X	X	X
Sleep	Pittsburgh Sleep Questionnaire[64]	X	X	X
Need support in relation to weight loss	The interpersonal behaviours questionnaire (IBQ)[60]		X	X
Demographics	Age, ethnicity, education, marital status, current employment status, income, housing status	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		

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Programme evaluation: via questionnaires and interviews	Attendance to programme sessions and to measurement sessions; fidelity of programme delivery; perceptions of effectiveness and acceptability (both coaches' and participants')		X	X
Training evaluation: via questionnaires and interviews	Coaches will evaluate the training provided to them; and participants will feedback on the perceptions of the trainers' style	X	X	X
Trial feasibility	Study protocol, assessment methods/procedures, and potential to gather cost-effectiveness data.	Assessed throughout the programme		

Process evaluation measures

A multicomponent process evaluation (including interviews with participants, coaches, and coded audio recordings of coaches delivery of Aussie-FIT) will be undertaken in accordance with the UK Medical Research Council guidelines.[66] The evaluation will explore issues of: (1) implementation (i.e., the process of implementing the intervention, such as when, where, and how the participants engaged in new health behaviours during and after the active 12-week intervention period), (2) mediators of outcomes (i.e., motivation to engage in PA or healthy diet), and (3) potential moderators (i.e., age, socioeconomic status, baseline PA and dietary behaviours, baseline BMI). Fidelity of the delivery of Aussie-FIT by trained club community coaches will be examined via coding the content of the audio recordings of the programme delivery sessions. We will determine whether the intervention delivery style and content were as intended by coding audio recordings for need supportive strategies.[67] Specifically, this tool is designed to code the frequency and intensity of need supportive, indifferent and thwarting communication used by the coaches during session delivery. Audio recordings are used so that the coder can get a clearer indication of the qualities of delivery (e.g., tone, sarcasm, etc.) which are all important aspects of the motivational meaning of the communication style. We will also measure the degree to which the behaviour change techniques[37] (BCTs) have been taught appropriately by the coaches to the full group (BCTs provided in one-on-one interactions may be more difficult to capture). Specifically, two

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trained, independent coders will use transcriptions to identify and code any content related to BCTs during the program. We will use the content of the coaches' session delivery guide and the recommendations from the training undertaken by the coaches to create a rubric to represent 'gold standard' use of BCTs and delivery in each session will be compared to this. Coders will also examine the session content for evidence of BCTs (from the BCT taxonomy v1)[68] used in the sessions that were not explicitly specified for inclusion in the program design. We consider this to be an important aspect of the pilot as it will enable us to determine the effectiveness of the Aussie-FIT training (i.e., whether we were successful in training the coaches to apply motivation strategies and BCTs in the sessions, in addition to educating the coaches on the 'what' and 'how' of delivery).

A purposive sub-sample of men from each club (N = 10) will be contacted at 3 and 6 months to participate in semi-structured interviews conducted preferably face-to-face but also over the telephone if that is more convenient for the participant. The interviews will explore the men's views of various components of the programme and what they did or did not engage with (and reasons why). We will also explore cultural, personal and situational facilitators and barriers to sustained behaviour change in 3 and 6 month interviews. Men who drop out of the Aussie-FIT programme will be asked to take part in structured telephone interviews which will examine their reasons for discontinuing. Community coaches who have delivered Aussie-FIT will also be interviewed at the end of the intervention to explore their perceptions of the training they received, their perspectives on the feasibility of delivery, their own experiences of delivering the programme, and their perceptions of programme acceptability among the participants. Additionally, after each session they will be asked to fill in a session evaluation form to record their perceptions of what went well, as well as any challenges within the session and any suggestions for session improvements in terms of content and delivery. Attendance at Aussie-FIT sessions will be recorded via the use of a

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register. Attrition will be monitored by recording dropout rates, with dates and reasons for dropout also logged if possible. Acceptability of the intervention will be measured via a 9-item scale including items such as "I would recommend this programme to other men", which will be adapted from a previous study.[69]

Economic analysis

We will develop and pilot an economic model to estimate cost-effectiveness of the programme. Costs will include direct costs associated with the programme, including set up costs and cost of promotion activities. In terms of outcome measurement, we will include short-term outcomes that will enable us to look at the cost per 5% weight reduction and cost per Quality Adjusted Life Years (QALY). The QALY is the most widely used approach for estimating quality of life benefits in economic evaluations[70] Quality of Life scores will be measured using the EQ-5D- 5L questionnaire[71] which is a standardised measure of health status used in economic evaluation.[72] The scores obtained from the EQ-5D-5L will be used to formulate the cost per Quality Adjusted Life Year. Sensitivity analysis will test the robustness of the results. Including the economic component in the early pilot phase will allow us to test the sensitivity of the EQ5D-5L in detecting changes in quality of life within the study population and explore the feasibility of using this measure in the Australian context. This pilot study will report on any methodological challenges facing economic evaluations of this type and carry out any necessary modifications before a future RCT is conducted.

Data Management

Hard copies of data will be securely stored in locked cabinets in the University and will contain ID Codes but no identifying information. A document associating ID codes with participants' identifying information will be stored in a password-protected computer file on the University's computer server. The project data will be stored securely for 25 years, in line

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with the data management policy at the University. Only members of the research team will be able to access the physical and electronic data files.

Analyses

Trial feasibility will be reported using descriptive statistics and percentages for each group. Mixed linear modelling will be employed to examine changes across and between groups in all measures over time, adjusting for clustering effects. Intention to treat analysis will be used to deal with missing data and we will include every participant who provided at least baseline data. We will compare the baseline characteristics of the participants who dropped out with the characteristics of the participants who completed the full study (both 3 month and 6 month measures) to check if there are any differences between the two groups. The study analysis will be predominantly performed using the SPSS and R software.

Qualitative data will be transcribed verbatim and analysed to explore acceptability, feasibility as well as implementation of the Aussie-FIT intervention. We will use a combination of inductive and deductive content analyses, following the six procedures of the thematic analysis approach.[73] [74] Approaches from framework analysis[75] will also be employed to support identification of theoretically derived themes, in particular from SDT.[38] Steps one and two will focus on familiarisation with the data via analytic engagement to identify how the participants experienced and made sense of their experience, and applying representative codes. Via steps three to five, themes will be developed, refined and named, ensuring that the analysis remains a "good fit" to the data. The final phase involves writing up an analytic narrative of the results. Two independent coders will undertake the qualitative analysis, using QSR Nvivo to facilitate the organisation, coding, and management of data. Other members of the research team will also contribute to analysis by challenging interpretations of the data.

Patient and Public Involvement

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The development of the Australian adaptation of the FFIT intervention was informed by the recently conducted a multi-method study of AFL fans in Western Australia (WA) aiming to assess the appeal of the similar programme for the target population.[49] The study has indicated the appeal for Aussie-FIT among male AFL fans (*N*=151) aged 35-65 years (*M* = 49.41±8.74). Among those surveyed, 74.2% were overweight or obese, 53.0% were insufficiently physically active, and 64.9% were seriously considering trying to lose weight in the next 6 months. After viewing an informational video about FFIT, 90.5% of those surveyed indicated that this programme would appeal to overweight AFL fans. Follow up interviews with men (*N* = 9) and coaches (N = 5) further substantiated the findings of the survey and gave insights that informed development of the program. Further research is needed to determine whether a version of FFIT, culturally sensitised for delivery to Australian middle-aged men who are overweight or obese, can be successful in increasing PA, improving diet, and reducing body weight among this population. The Aussie-FIT pilot trial will assess and explore participants' experiences and preferences in quantitative and qualitative manner. Programme participants, coaches and other stakeholders are involved in programme development and will be involved in full evaluation conducted as described above (also assessing participants' burden assessment).

ETHICS AND DISSEMINATION

The study has been reviewed by the Curtin University Human Research Ethics Committee (HREC2018-0458). Participants will be asked to provide informed consent subsequent to eligibility screening. Participants will be informed that they are free to withdraw from the project at any stage and will be under no obligation to give a reason. Any substantive changes to the study protocol will be subjected to University ethical review and also documented at the Australian and New Zealand Clinical Trials Registry (ANZCTR).

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All participants in the study will be provided with a summary of the results at the end of the project. Findings will also be disseminated to stakeholders (e.g., practitioners, policy makers, academics, local community representatives) via targeted seminars and summaries of results. The findings of the study will be publicised via traditional and social media channels, including Twitter (@aussiefitorg) and the project website (www.aussiefit.org), disseminated via publications in peer reviewed journals and at relevant international conferences.

Discussion

In developed countries men are less likely than women to participate in healthy lifestyle and weight loss programmes. The design of programmes that are relevant, which align with predominant masculinity values, and use fun, positive banter and social interaction as guiding principles is essential to improve population health. Weight loss programmes that are culturally sensitive, relevant to the country where they are delivered, and which use existing interests (such as passion for AFL) as a 'hook' to encourage participation, have the potential to contribute to a decrease in the population levels of obesity if it proves possible to deliver them at scale.

Aussie-FIT is customised for delivery in Australia to reflect local PA and dietary norms and uses a gender-sensitive and motivationally embellished approach to engage men in healthy and sustainable lifestyle changes. From the outset, the programme emphasizes that the changes introduced need to be sustained long term in order to help men truly improve their lifestyles and risk of future ill-health. The programme builds upon and expands the current FFIT program. Drawing from a recent systematic reviews of literature,[41 42] Aussie-FIT incorporates specific activities that focus on creating habits that can be sustained, allowing for occasional lapses . The' Aussie-FIT pilot will provide pilot data needed to scale up for a nationwide RCT. The additional components of the programme expand existing interventions delivered to sports fans. Results from the definitive RCT will have the potential

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to inform a translation strategy to support the development of Aussie-FIT programmes customised for a range of professional sports (e.g., cricket, netball, rugby) and segments of sport fans (e.g., females, children, families). Specifically, in future endeavours we will aim to explore how to extend reach in without jeopardising the involvement of the original target group of overweight and obese, male middle-aged AFL fans.

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Authors' contributions

EQ, NN, CT-N, DG, DAK, KH, SR, PJM, RN, CG and SW conceived the project and obtained the project funding. EQ, NN, CT-N, DG, DK, DAK, KH, SR, PJM, CG, SW, JMV and EM have made conceptual contributions to project design. EQ is the project lead and DK is the project manager. DK and EQ developed the intervention materials, with input from all authors. EQ and DK drafted the manuscript and all authors read, edited and approved the final version of the manuscript.

Competing interests

The authors have no competing interests to declare.

Figure 1.

CONSORT flow diagram for the Aussie-FIT trial.

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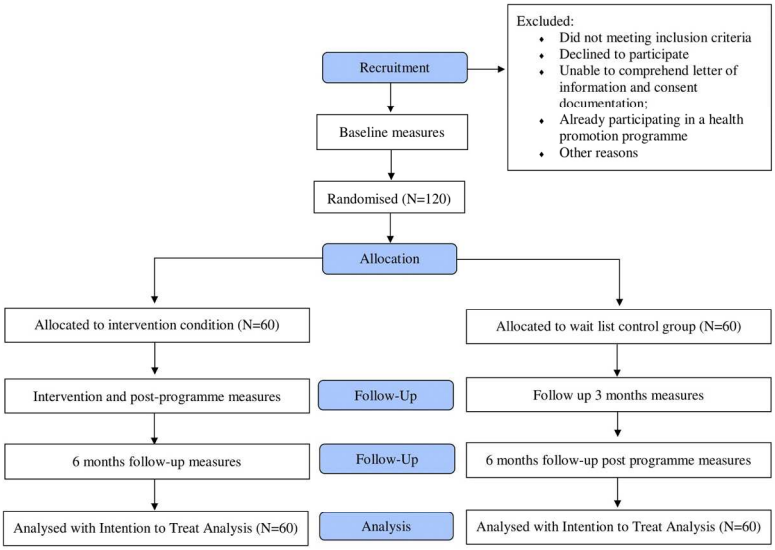

CONSORT flow diagram for the Aussie-FIT pilot

169x119mm (300 x 300 DPI)

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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, lines 1-3
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2, lines 33-34
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	26, lines 543-545
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	26, lines 536-542
	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	3-9
	6b	Explanation for choice of comparators	5, lines 113-116 7, lines 149-151

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Objectives	7	Specific objectives or hypotheses	9, lines 219-222 10, lines 223-244
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)	11, lines 249-252
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	12, lines 286-288
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)	12, lines 286-293
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	12-18
	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)	12, lines 282-285
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	14, line 326
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12, lines 292-293
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	19-24 (till line 475)
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)	Page 27 – figure 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11, lines 253-259
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12, lines 272-285
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	11, 260-267
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	11, 260-267
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11, 261-262
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11, 263-267
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11, 263-267
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	19-24 (till line 475)
	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	22, lines 442-447 23, lines 448-460

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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	24, 476-482
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	24, lines 484-492
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	24, lines 493-497 and 25, lines 498-500 (qualitative analyses)
	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)	24, lines 487-489
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	N/A
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	25, lines 502-503
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)	25, lines 505-507

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	25, 503-504
	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	24, 476-482
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	26, lines 546-547
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	24, lines 481-482
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	25, 508-513
	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.

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The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	1	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	3-9	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	13-16	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	16-18	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	15-16	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	13-14	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	12	

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	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	13-14	
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	12-15	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	14	
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

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