

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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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 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 programme. We aim to develop, pilot and evaluate the feasibility of a weight loss intervention for overweight/obese middle-aged men, delivered in 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 min 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 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 multicomponent dissemination strategy will include targeted translation and stakeholder engagement

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 randomised controlled trial 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.

events to establish strategies for sustainability and policy change.

Trial registration number ACTRN12617000515392; Pre-results.

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 (\$148.9 billion in 2014–2015).³ A recent Australian study estimated that the average annual healthcare costs for individuals classed as 'obese' (body mass index (BMI) $>30\text{ kg/m}^2$) is 50% greater (ie, \$2233) than that for normal weight individuals.⁴

Approximately 70% of men in Australia are overweight/obese, compared with 56.3% of women.⁵ Risks of disease and physical, psychological and sexual dysfunction are significantly increased for males whose waist circumference is 102 cm or greater and whose BMI is 30 kg/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 $\geq 25\text{ kg/m}^2$) 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, for example, 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 interventions⁸ 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 health¹⁰ 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 and concerns and if they are not designed to appeal to males.¹¹ Cultural constructions of masculinity¹² often deter men from taking appropriate action in order to improve their health (eg, 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 that 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 1 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 Self-help, Exercise and Diet Using Information Technology (SHED-IT) trial, which

successfully supported reduction in BMI among 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 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 $\geq 28\text{ kg/m}^2$ 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 among 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 11 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 \$A285 per participant).²⁴ The programme helped male soccer fans make long-term, sustainable changes 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 (eg, changes in diet and PA), in postprogramme focus groups²⁷ 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 used 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 England²⁹ 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 Australia³⁴ 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 (eg, weather, sport targeted and healthcare provision) to warrant a pilot (and subsequently an RCT) of the programme in Australia. This seems particularly important given a meta-analysis³⁵ showing that culturally adapted interventions for health behaviours are more likely to be effective. Contextual adaptations and testing of health behaviour change programmes is also recommended by the Medical Research Council (MRC) process evaluation framework.³⁶ The application of motivation 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 used in FFIT¹³ (eg, 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 (ie, 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 programme 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 (ie, 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 (ie, through engagement in need-promoting activities) and indirectly (ie, 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.

Participants are much more likely to succeed in losing weight and keeping weight off if they are introduced to BCTs that support long-term maintenance of behavioural changes from the beginning of the intervention rather than part way through.⁴⁰ Compared with 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 (ie, 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 an '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 (eg, 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 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 existing literature. Several differences are embedded in the Aussie-FIT intervention that 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 programme 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 (eg, 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 to apply 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.
- ▶ 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 SD 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,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-month 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 and Template for Intervention Description and Replication.^{46 47} The completed checklists are available as online supplementary files 1 and 2.

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 (eg, emails to members), and social media. 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 ≥ 28 kg/m²) from the fan base of the Fremantle Dockers and West Coast Eagles professional AFL clubs in Perth, Western Australia (60 men from each club). Our inclusion criteria (matching those used in FFIT) are: men, aged 35–65 years, objectively measured BMI ≥ 28 kg/m² 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

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 on 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 2500 kJ 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 (eg, triggers of unhealthy eating); (B) assisting them to set effective goals; (C) teaching them strategies to avoid engaging in compensatory behaviours (eg, being more sedentary or eating more following PA); and (D) educating them in how to prevent relapse (ie, returning to pre-intervention behaviours that 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 min 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 programme 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 (eg, sandbags and dumbbells) to reinforce weight loss and the fostering of peer support. Participants will receive booklets that 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 (ie, 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.

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

Week number and session title	Concepts covered	PA 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 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 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. 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.

Continued

Table 1 Continued

Week number and session title	Concepts covered	PA component
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.

AFL, Australian Football League; PA, physical activity; SMART goals, Specific, Measurable, Attainable, Relevant and Time-based goals.

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 1, 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 (ie, 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 months and 6 months); FFIT programme used only self-reported measures of PA. Aussie-FIT will also use a social media platform (Facebook) as an outlet for participants to share experiences, stay in touch, brainstorm ideas and exchange suggestions and to promote ongoing 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 (eg, MyFitnessPal and MapMyRun) activities. Links to additional existing resources from Australian public health campaigns (eg, 'LiveLighter' tools such as 'Healthy Meal Mixer' or 'AlcoholThinkAgain' tools such as '5 min 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 2 days of face-to-face training, including 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 SDT³⁸ 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 (eg, 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 (eg, 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

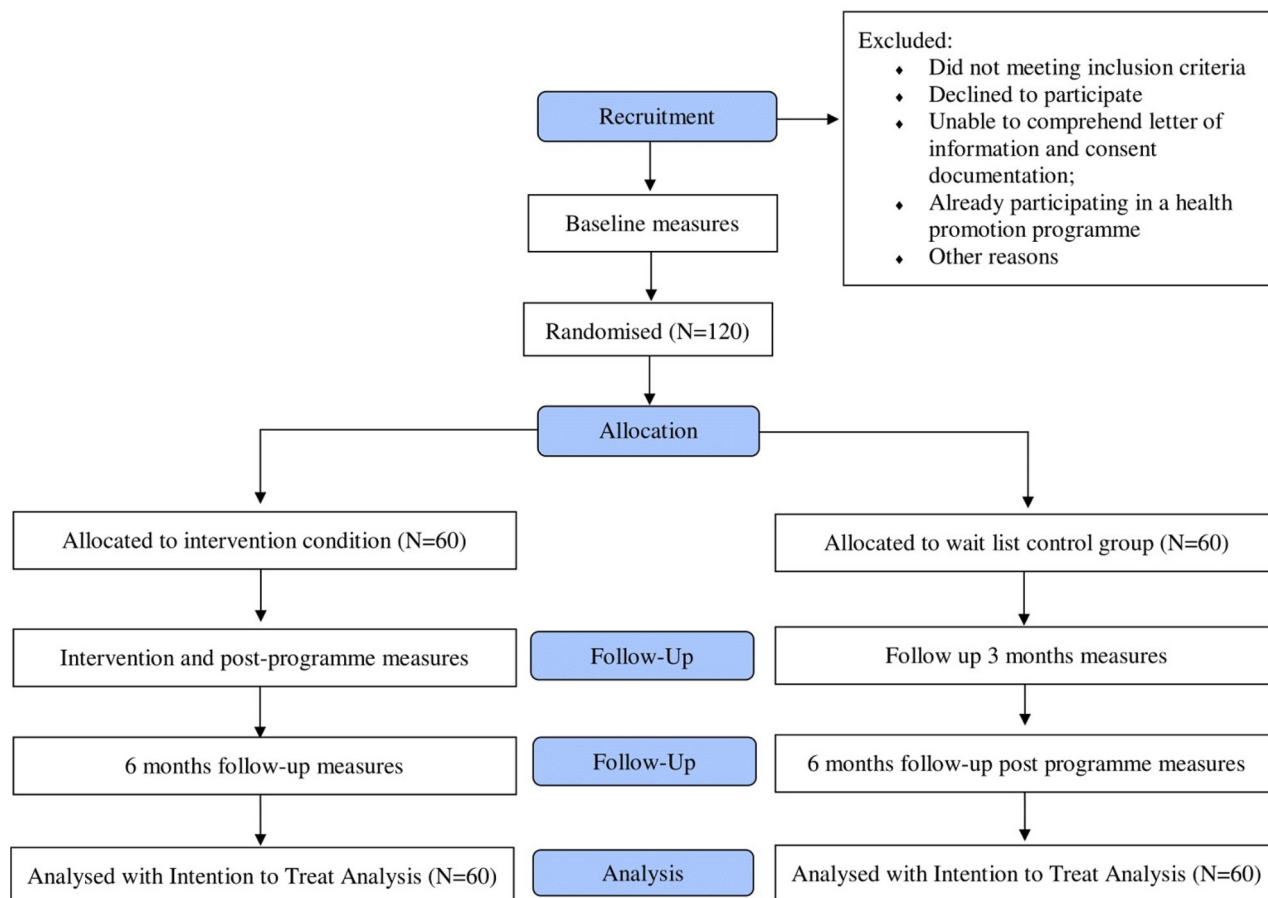


Figure 1 CONSORT flow diagram for the Aussie-FIT trial. CONSORT, Consolidated Standards of Reporting Trials.

the feedback provided during the pilot if any adjustments are required.

Intervention procedures

An outline of the sessions is presented in [table 1](#) and the Consolidated Standards of Reporting Trials flow diagram is presented in [figure 1](#).

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 states⁵³ and self-esteem⁵⁴), health-related quality of life⁵⁵ and demographics will be taken.

Our choice of the 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 months and 6 months) in

person or by post using prepaid and preaddressed envelopes. The data will be downloaded and processed using a custom-built SAS program (V.9.3) that implements a series of decision rules with user-modifiable thresholds to automatically identify waking wear time for continuously worn ActiGraph data.⁵⁶ Only participants with four or more valid days of wear (including at least 1 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 the 3 month and 6 month measurement points, men will also complete scales assessing their feelings of autonomy, competence⁵⁷ and relatedness⁵⁸ psychological need satisfaction in relation to their weight loss behaviours. Motivation for weight loss⁵⁹ will also be assessed at baseline and at both follow-ups. At 3 months and 6 months, participants will complete two versions of the Interpersonal Behaviours Questionnaire,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 planning⁶³ and quality of sleep using the Sleep Pittsburgh Sleep Questionnaire.⁶⁴ See [table 2](#) for the overview of the study measures.

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 MRC guidelines.⁶⁵ The evaluation will explore issues of: (1) implementation (ie, 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 (ie, motivation to engage in PA or healthy diet) and (3) potential moderators (ie, age, socioeconomic status, baseline PA and dietary behaviours, and 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 sessions. We will determine whether the intervention delivery style and content were as intended by coding audio recordings for need supportive strategies.⁶⁶ 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 (eg, tone, sarcasm and so on), which are all important aspects of the motivational meaning of the communication style. We will also measure the degree to which the BCTs³⁷ 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 trained, independent coders will use transcriptions to identify and code any content related to BCTs during the programme. 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 with this. Coders will also examine the session content for evidence of BCTs (from the BCT taxonomy v1)⁶⁷ used in the sessions that were not explicitly specified for inclusion in the programme 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 (ie, 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 subsample of men from each club (n=10) will be contacted at 3 months and 6 months to participate in semistructured 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-month 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 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 nine-item scale including items such as 'I would recommend this programme to other men', which will be adapted from a previous study.⁶⁸

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 (QALYs). The QALY is the most widely used approach for estimating quality of life benefits in economic evaluations.⁶⁹ Quality of life scores will be measured using the EQ-5D-5L questionnaire,⁷⁰ which is a standardised measure of health status used in economic evaluation.⁷¹ The scores obtained from the EQ-5D-5L will be used to formulate the cost per QALY. 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 EQ-5D-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 with the data management policy at

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 three times with valid and reliable body scales (eg, Seca); light clothing, no shoes and empty pockets; blinded assessor.	X	X	X
Height	Height measured in centimetres using a stadiometer (eg, 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 mm Hg and/or measured diastolic blood pressure is over 89 mm Hg, 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 general practitioner. 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 Nutrition Education 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. ⁵³	X	X	X
Self-esteem	The Rosenberg Self-Esteem scale. ⁵⁴	X	X	X
Quality of life	The health-related quality of life measured using the EuroQol five-dimensional five level version (EQ-5D-5L). ⁷⁵	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 of weight loss motivation. ⁵⁹	X	X	X
Automaticity	The 'Self-Report Behavioural Automaticity Index'. 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. ⁶⁰		X	X
Demographics	Age, ethnicity, education, marital status, current employment status, income and housing status.	X		

Continued

Table 2 Continued

	Measurement instrument	Baseline	3months	6months
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
Trial feasibility	Study protocol, assessment methods/procedures and potential to gather cost-effectiveness data.	Assessed throughout the programme		

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 softwares.

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.^{72 73} Approaches from framework analysis⁷⁴ will also be employed to support identification of theoretically derived themes, in particular from SDT.³⁸ Steps 1 and 2 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 3–5, 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

The development of the Australian adaptation of the FFIT intervention was informed by the recently conducted

multimethod study of AFL fans in Western Australia 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 ($M=49.41\pm 8.74$). 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 programme. 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

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.

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

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