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

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SCHOLARONE™
Manuscripts

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3 **1 Scale-up of the Australian Fans in Training (Aussie-FIT) men's health behaviour**
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5 **2 change program: Protocol for a randomised controlled hybrid effectiveness-**
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7 **3 implementation trial.**
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1
2
3 **26 Abstract**
4

5 **27 Introduction**
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7
8 28 Improving physical activity and healthy eating is critical for primary and secondary
9
10 29 prevention of cardiovascular disease (CVD). Behaviour change programs delivered in
11
12 30 sporting clubs can engage men in health behaviour change but are rarely sustained or scaled-
13
14 31 up post-trial. Following the success of pilot studies of the Australian Fans in Training
15
16 32 (Aussie-FIT) program, a hybrid effectiveness-implementation trial protocol was developed.
17
18 33 This protocol outlines methods to: i) establish if Aussie-FIT is effective at supporting men
19
20 34 with or at risk of CVD to sustain improvements in moderate-to-vigorous physical activity
21
22 35 (primary outcome), diet, and physical and psychological health, and ii) examine the
23
24 36 feasibility and utility of implementation strategies to support program adoption,
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26 37 implementation and sustainment.
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31 **38 Methods and Analysis**
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33 39 A pragmatic multi-State/Territory hybrid type 2 effectiveness-implementation parallel group
34
35 40 randomised controlled trial with a 6 month wait-list control arm in Australia. 320 men aged
36
37 41 35-75 years with or at-risk of CVD will be recruited. Aussie-FIT involves 12 weekly face-to-
38
39 42 face sessions including coach-led interactive education workshops and physical activity
40
41 43 delivered in Australian Football League (Western Australia, Northern Territory) and rugby
42
43 44 (Queensland) sports club settings. Follow-up measures will be at 3- and 6-months (both
44
45 45 groups), and at 12 months to assess maintenance (intervention group only). Implementation
46
47 46 outcomes will be reported using the RE-AIM (Reach, Effectiveness, Adoption,
48
49 47 Implementation, Maintenance) framework.
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53 **48 Ethics and Dissemination**
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55
56 49 This multi-site study has been approved by the lead ethics committees in the lead site's
57
58 50 jurisdiction, the South Metropolitan Health Service Human Research Ethics Committee
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3 51 (Reference RGS4254) and the West Australian Aboriginal Health Ethics Committee
4
5 52 (HREC1221). Findings will be disseminated at academic conferences, peer-reviewed journals
6
7
8 53 and via presentations and reports to stakeholders, including consumers. Findings will inform
9
10 54 a blueprint to support the sustainment and scale-up of Aussie-FIT across diverse Australian
11
12 55 settings and populations to benefit men's health.
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15 56

17 57 **Strengths and Limitations**

- 19 58 • This is the first multi-State/Territory trial of a 'fans in training' style intervention.
- 21 59 • Consumers and other stakeholders contributed to the development of the protocol, in
22 60 particular recruitment and data collection methods.
- 24 61 • Using a hybrid design will facilitate the concurrent assessment of intervention
25 62 effectiveness and implementation outcomes, promoting efficient implementation and
26 63 long-term impact of this evidence-based program.
- 28 64 • Due to the nature of the intervention, participants will not be blinded to treatment
29 65 allocation.
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40 67 **Word count:** 4550
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68 **Introduction**

69 The cardiovascular benefits of physical activity (PA) and eating a healthy diet are well
70 established, however, 55% of people who live in Australia do not meet PA guidelines, most
71 eat an unhealthy diet and 67% are living with overweight or obesity (1). Among those with a
72 cardiovascular disease (CVD) diagnosis, exercise adherence remains low. Most men with
73 CVD fail to initiate or sustain health behaviour changes, decreasing quality of life and
74 increasing risk of future CVD and premature death (2). For instance, only 30% of patients
75 complete outpatient cardiac rehabilitation, and of those, less than 50% are sufficiently active
76 12 months after their cardiac event (2).

77 A patient survey showed many patients lack self-management skills and are too dependent on
78 exercise rehabilitation staff to sustain behaviour changes upon completion of hospital-based
79 exercise programs (3). Recent estimates suggest that increasing participation in cardiac
80 rehabilitation in Australia from 30% to 65% would result in \$36 million in healthcare savings,
81 \$58 million in social and economic benefits, and significantly reduce annual heart attack
82 admissions (4). To reap these health and economic benefits, new strategies are required to
83 increase PA adherence and healthy eating in people with or at-risk of CVD. Gender tailored
84 programs are important, because men and women experience differences in CVDs risks and
85 occurrences (5). Gender-tailored health behaviour change programs for men have been shown
86 to be appealing and effective (6).

87 The internationally recognised 'Football Fans in Training' (FFIT) program, and our
88 Australian adaptation (Aussie-FIT), are effective in engaging men to improve their health
89 behaviours. FFIT (7) and Aussie-FIT (8) capitalise on men's interest in sport to promote weight
90 loss via sustained improvements in diet and PA. These structured 12-week programs include
91 90 minutes of interactive education and group-based PA that aims to develop the skills and

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3 92 confidence of participants to self-regulate and maintain behaviour change long-term. Programs
4
5 93 are delivered to groups of men by trained coaches in professional sport facilities. The
6
7 94 effectiveness and cost-effectiveness of FFIT was established in a Randomised Control Trial
8
9 95 (RCT) (7). Mean between group weight lost at 12 months was 5kg, and average weight loss
10
11 96 maintenance of 2.9kg was observed in the intervention group 3.5 years post-baseline (9) . FFIT
12
13 97 was adapted for the European Fans in Training (EuroFIT) RCT in 5 European countries, where
14
15 98 similar findings were revealed (10).

19
20 99 Kwasnicka et al (2020) demonstrated feasibility of recruitment, engagement, and
21
22 100 retention of men living with overweight and obesity, as well as acceptability of the Aussie-FIT
23
24 101 intervention and research procedures when delivered at top-tier Australian Football League
25
26 102 (AFL) clubs in Western Australia (WA). Promising physical and mental health outcomes were
27
28 103 observed (11). In a single-arm feasibility trial in Queensland (QLD), a version of Aussie-FIT
29
30 104 adapted for rugby league (League-FIT) has engaged men living with overweight and obesity,
31
32 105 and demonstrated promise in supporting positive physical and mental health outcomes (12). In
33
34 106 a feasibility study of the Aussie-FIT program undertaken at second-tier AFL clubs for men
35
36 107 with CVD, Smith et al (manuscript in preparation) demonstrated feasibility of participant
37
38 108 engagement and retention, and acceptability of the intervention and research procedures.
39
40 109 However, recruiting men with CVD was challenging (Smith et al., manuscript in progress).
41
42 110 Recruitment challenges were likely due to the smaller population of men with CVD (6.5% of
43
44 111 men in Australia) (13) compared with 75% of men with overweight and obesity in Australia
45
46 112 (14), and the smaller fanbases of second-tier AFL clubs compared to top-tier clubs. The
47
48 113 effectiveness of Aussie-FIT remains to be tested, as do implementation strategies designed to
49
50 114 improve the adoption, implementation, sustainment and scale-up of the program to reach
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52 115 diverse populations of at-risk men. This multi-State/Territory trial aims to establish the
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3 116 effectiveness of the Aussie-FIT intervention for men with or at-risk of CVD, whilst allowing
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5 117 for flexibility with club-size (e.g., top-tier or second-tier) across diverse Australian contexts.
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8 118 A recent systematic review of five unique interventions concluded that, whilst FFIT
9
10 119 has been successfully scaled up, not all health promotion interventions delivered through
11
12 120 professional sport have been successfully scaled up, and thus a greater focus on the potential
13
14 121 for scalability of these interventions is required (15). Scalability is the process of increasing
15
16 122 the number of implementers (e.g., sports clubs) that are willing to initiate delivery of
17
18 123 effective interventions to reach a greater proportion of the target population (16). The
19
20 124 potential for intervention scalability is increasingly considered across the research spectrum,
21
22 125 rather than solely positioned at the end of a linear research pipeline after effectiveness testing
23
24 126 (17). One increasingly common approach to considering implementation and scalability
25
26 127 earlier in the research process is the use of hybrid effectiveness-implementation study
27
28 128 designs, which allow for the assessment of intervention effectiveness alongside
29
30 129 implementation outcomes (18). Implementation outcomes that are important for scalability
31
32 130 include program costs, fidelity, adaptability, delivery settings, infrastructure, workforce,
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34 131 reach and acceptability in diverse populations (Milat et al., 2020).
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41 132 This trial adopts a hybrid effectiveness-implementation design (19) to examine the
42
43 133 effectiveness of Aussie-FIT, and in parallel assess the feasibility and utility of
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45 134 implementation strategies to support program adoption, implementation, sustainment and
46
47 135 scalability, using the RE-AIM framework. We pose two research questions to simultaneously
48
49 136 address both the intervention and the implementation process aims (20): 1) is the Aussie-FIT
50
51 137 program effective in increasing time spent in moderate-to-vigorous physical activity (MVPA);
52
53 138 and improving other secondary outcomes among men with or at-risk of CVD at 6 month
54
55 139 follow up; and 2) what are the facilitators and barriers to implementation, sustainment and
56
57 140 scalability of the Aussie-FIT program?
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141 **Method**

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

145 **Study design**

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

153 **Context**

154 The study is set in and around the capital cities of Darwin (Northern Territory), Perth
155 (WA), and Brisbane (QLD). These urban centres have distinct contextual characteristics. QLD
156 and WA make up 20% and 10% of the national population respectively and are far more
157 populated than the Northern Territory (NT) which makes up less than 1% of the national
158 population (22). There is significant cultural diversity across each State/Territory; for example,
159 the proportion of males that identify as Aboriginal and/or Torres Strait Islander in the NT
160 (26.3%) is considerably higher than in QLD (4.6%) and WA (3.3%) (23). Australian Football
161 is the most popular sport in WA and the NT, whereas in QLD, Rugby League is most popular
162 (24).

163 **Consumer and Stakeholder Involvement**

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3 164 Consumer engagement has been central to the development of the Aussie-FIT program
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5 165 since its ' inception and in previous pilot studies. In preparation for this trial, community
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7 166 advisory groups consisting of consumers (i.e., men with or at-risk of CVD, and former Aussie-
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9
10 167 FIT participants) and stakeholders (e.g., Aussie-FIT coaches, sporting club or community
11
12 168 representatives) have been formed in each State/Territory. These groups include representation
13
14
15 169 of Aboriginal and/or Torres Strait Islander men. The first of these groups met in December
16
17 170 2022. Community advisory groups have helped identify potential barriers and enablers of
18
19 171 project success and have co-designed responsive implementation strategies. These groups will
20
21 172 continue to work in partnership with the research team throughout the lifespan of this project.
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23
24 173 This will include providing input on culturally appropriate recruitment strategies, retention
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26 174 strategies, involvement in dissemination planning, and if the effectiveness of the intervention
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28 175 is established, providing advice on the sustainment and scalability of Aussie-FIT. The
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30 176 outcomes of our cross-site consumer and stakeholder involvement activities during the trial
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33 177 set-up period, and at later stages in the trial, will be reported in future publications.
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36 178 **Participants**

39 179 Inclusion criteria

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43 180 Men aged 35-75 in WA (n=128), NT (n=96) and QLD (n=96) that self-report meeting
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45 181 one or more of the following criteria will be recruited:

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48 182 a) CVD diagnosis more than 3 months prior to commencing the study, with no upper
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50 183 limit on length of time since diagnosis; OR

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54 184 b) $\geq 10\%$ risk of CVD, according to the online calculator created by the Australian
55
56 185 Chronic Disease Prevention Alliance, that assesses CVD 5-year risk
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58 186 (www.cvdcheck.org.au/calculator); OR
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3 187 c) Body mass index $\geq 28\text{kg/m}^2$.
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6 188 To determine whether they are eligible, potential participants will complete an online
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9 189 form, co-designed with consumers to ensure accessibility for men.
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11 190 Participants from non-English speaking backgrounds will be offered interpreters if
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14 191 they wish to participate in the study. Men at risk of harm from PA will be excluded from
15
16 192 vigorous PA and will instead undertake light or moderate PA as tolerated (if appropriate
17
18 193 based on GP/cardiologist's advice). Where possible men who have not participated in
19
20 194 previous Aussie-FIT or League-FIT programs will be prioritised.
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23 195 *Exclusion criteria*

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26 196 Exclusion criteria are: unable to comprehend information or consent documentation;
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28 197 unable to attend most of the weekly sessions, diagnosed with CVD less than 3 months prior to
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30 198 the baseline assessments date; experienced a cardiac event less than 3 months prior to the
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32 199 baseline assessments date; or a medical professional advises against participation (e.g., due to
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34 200 having a cardiac condition not suitable for an exercise trial in the community such as severe
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36 201 aortic stenosis or on-going angina).
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40 202 **Recruitment**

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44 203 Participants will be selected on a 'first come, first served' basis. Men with CVD will be
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46 204 identified from medical records at hospitals (WA only), cardiac rehabilitation programs
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48 205 delivered in hospitals, or in the community, and GP or other primary health care services. Men
49
50 206 with or at-risk of CVD will be recruited from community sources including club members'
51
52 207 newsletters, traditional/social media, match-day publicity (e.g., announcements, face-to-face
53
54 208 recruitment), snowball sampling (25), sport publications, and local health councils. Interested
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56 209 individuals who see the program advertised will be directed to complete a web-based
57
58 210 expression of interest (EOI) form. Men who prefer not to use the online EOI form will have
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3 211 the opportunity to express their interest, ask questions, check their eligibility, and enrol (if
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5 212 eligible) by contacting the research team directly via phone or email. The online EOI form
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8 213 includes a series of questions to confirm eligibility.
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11 214 This trial will host a nested ‘study within a trial’ (SWAT) (26) to examine the utility of
12
13 215 a self-directed online enrolment in comparison to a phone call enrolment process (27). Eligible
14
15 216 men that complete the online EOI will be randomised via the online form to either immediately
16
17 217 book their enrolment appointment online or to receive a call from a researcher to progress their
18
19 218 enrolment. The SWAT will evaluate the effectiveness (including cost-effectiveness) of the
20
21 219 online approach compared to the standard phone call on enrolment rates (27).
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26 220 **Intervention (Aussie-FIT Program)**

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29 221 The intervention is described following the Template for Intervention Description and
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31 222 Replication (TIDieR) guidance (28), see Table 1. In brief, the 12, weekly, 90-minute sessions
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33 223 will be delivered to groups of 16 men. One coach and one Accredited Exercise Physiologist
34
35 224 (AEP) or equivalent suitable health professional facilitate each group. Coaches and AEPs will
36
37 225 be trained by the research team in the core content (PA and diet education), safe exercise for
38
39 226 men with or at-risk of CVD, and in the use of principles of motivation and behaviour change.
40
41 227 Coaches will lead on the program content delivery and AEPs will be primarily responsible for
42
43 228 exercise safety. Practical activities and discussions are designed to help men understand why
44
45 229 and how to improve PA (e.g., understanding exercise intensities, safe strength training,
46
47 230 decreasing sedentary time) and dietary behaviours (e.g., interpreting food labels, portion sizes,
48
49 231 meal planning, eating out), and incorporate behaviour change techniques to support participants
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51 232 to adopt positive health behaviours in their daily lives. A range of PA intensities are promoted,
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53 233 and ball skills and circuit training like those undertaken by professional players but modified
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55 234 to be safe for each man’s limitations (e.g., ball skill drills restricted to walking) undertaken.
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3 235 Men are encouraged to self-monitor walking, gradually increasing steps/day throughout the 12-
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5 236 weeks. The AEP will co-deliver the sessions and support the coach by monitoring participants
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8 237 (e.g., blood pressure checks), providing advice on safe exercise and providing first aid, if
9
10 238 required. The waitlist control group (another 16 men from each club) will receive the program
11
12 239 6 months later.

15 240 **Description of the implementation strategy**

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19 241 Our consumer advisory groups have supported the development of our implementation
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21 242 strategies in the study set-up phase of this project, full details of which will be reported
22
23 243 elsewhere. The implementation study is structured by the RE-AIM framework (Reach,
24
25 244 Effectiveness, Adoption, Implementation, and Maintenance) (12).

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28
29 245 Reach: Program recruitment strategies have been co-designed with men with or at risk of
30
31 246 cardiovascular disease (CVD). These strategies will be tailored for each State/Territory in
32
33 247 consultation with community advisory groups.

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37 248 Effectiveness: Individual effectiveness outcomes will be tested via the RCT. Negative or
38
39 249 unintended consequences will also be documented.

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43 250 Adoption: Clubs will be invited to offer formal commitments to continue deliveries pending
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45 251 further funding opportunities in each State/Territory. An infrastructure and costing model will
46
47 252 be developed to support clubs in sustaining the program, and preferences for models of
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49 253 sustained program deliveries will be co-designed with stakeholders.

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53 254 Implementation: A comprehensive coach delivery package will support fidelity of program
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55 255 delivery. This package includes 15 hours of training for the coaches, detailed program delivery
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57 256 speaking notes, a timing guide, and rationales. Reusable teaching resources will also be
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257 provided to support high-quality delivery. Implementation costs, such as coaches' time for
258 delivering and preparing for sessions, have been included in the program costing model.

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

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

272 **Blinding and Randomisation**

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

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

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3 280 warrant higher sample size and costs of a cluster trial. (10) Participants from each club (10
4
5 281 clubs, 32 participants per club) will be individually randomised (1:1 randomisation, in blocks
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7 282 of 8 to reduce prediction of group allocation). A statistician generated the randomisation list
8
9 283 using the RANDBETWEEN (1,2) function using Excel. The statistician, who is not
10
11 284 involved in data collection, will not be told if group 1 or group 2 is the intervention arm to
12
13 285 assure blindness during the analyses. Following completion of baseline measures, trained
14
15 286 research assistants will use opaque, sealed envelopes to assign participants to intervention or
16
17 287 control arms.
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22 288 **Primary outcome: Physical Activity**

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25 289 Participants will also be asked to wear an Actigraph GTX9 (ActiGraph LLC, Pensacola,
26
27 290 FL) monitor continuously for 7-days on their non-dominant wrist at each data collection time-
28
29 291 point to provide a valid and reliable assessment of MVPA (29). The GT9X is a small
30
31 292 (3.5 × 3.5 × 1 cm), lightweight (14 g), and waterproof tri-axial accelerometer. The monitors
32
33 293 will be initialised to collect data at a 30hz sampling rate. Men will be provided with written
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35 294 instructions for wearing the Actigraph.
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40 295 **Secondary Outcomes**

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43 296 Secondary outcomes include dietary intake, weight, blood pressure, cholesterol, self-
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45 297 esteem, affective states, quality of life, motivation for physical activity, and use of behaviour
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47 298 change strategies targeted in the program. A full list of variables assessed and measurement
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49 299 tools is included in Table 2.
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53 300 **Implementation Outcomes**

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56 301 Implementation outcomes will be reported using the RE-AIM (Reach, Effectiveness,
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58 302 Adoption, Implementation, Maintenance) framework (21). Reach: we will report on the
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3 303 number of participants interested and recruited; descriptive statistics of their
4
5 304 representativeness, using demographics (e.g., comorbidities, weight, socioeconomic status,
6
7 305 ethnicity) of those recruited in each locality; Effectiveness: as per description of intervention
8
9 306 outcomes and for effectiveness of implementation outcomes, with qualitative interview
10
11 307 findings; Adoption: records of adaptation to the intervention and implementation strategies
12
13 308 (between clubs, locations etc); Implementation: fidelity to key content (e.g., educational
14
15 309 messages) and functions (e.g., appropriate use of behaviour change techniques) via coding of
16
17 310 a subsample of deliveries; adaptations to delivery in each location, ascertained from
18
19 311 coach/participant interviews; barriers and facilitators to program implementation from
20
21 312 perspectives of coaches, administrators, and participants via interviews; Maintenance:
22
23 313 intentions to continue delivering the program (for clubs in this trial) and intentions to initiate
24
25 314 program delivery when further funding secured (new clubs),
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30 315 **Procedure**

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33
34 316 Participants will book an appointment to attend baseline measures (detailed in Table 2)
35
36 317 at the football or rugby club. Measurement sessions will be led by a team of trained research
37
38 318 assistants. Participants will be asked to complete a survey, which will be presented to them on
39
40 319 an iPad using Qualtrics software. The self-administered survey will ask men demographic
41
42 320 questions including their age, ethnicity, education, marital status, current employment status,
43
44 321 income, and housing status. Weight, height and waist measurements will be taken by a trained
45
46 322 researcher. Cholesterol will be checked using a finger-prick test that measures non-fasting
47
48 323 cholesterol immediately. Participants will undertake a 24-hour dietary recall using the
49
50 324 Intake24, an open-source self-completed computerised dietary recall system based on multiple-
51
52 325 pass 24-hour recall. A trained interviewer will assist participants to complete the recall. The
53
54 326 self-administered survey will also include items assessing alcohol content, and participants will
55
56 327 also be asked to respond to questions assessing their emotions (i.e., positive and negative
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3 328 affect), quality of life, self-esteem, motivation to for PA and use of behaviour change strategies
4
5 329 taught in Aussie-FIT (automaticity, goal conflict, goal facilitation, coping planning, action
6
7
8 330 planning). Participants are asked to respond on Likert scales of 1-5 or 1-7. Participants can skip
9
10 331 questions if they prefer not to answer them. All questions have established psychometric
11
12 332 properties and have been used by the research team in studies with similar populations. The
13
14 333 questionnaire pack should take less than 30 minutes to complete. A trained research assistant
15
16 334 will be available to explain to participants how to complete the survey and to answer any
17
18
19 335 questions they may have during completion of the questionnaire.
20
21

22 336 The full assessment process will usually take about an hour. Following randomisation,
23
24 337 participants will be informed as to whether they will receive the 12-week intervention
25
26 338 immediately (i.e., the intervention arm) or ~6 months later (i.e., the waitlist control group).
27
28 339 Once the intervention arm participants have completed the program, the assessment package
29
30 340 will be repeated for both the control and intervention groups (3 months post baseline) and then
31
32 341 at 6 months post baseline. After the 6 months measures, the waitlist control arm will complete
33
34 342 the 12-week program. Finally, the intervention arm will be asked to attend one final assessment,
35
36 343 12 months post baseline.
37
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42 344 Where applicable, information regarding the participants' CVD diagnosis will be self-
43
44 345 reported or obtained from medical records. Participant attendance at the program will also be
45
46 346 recorded. At baseline, participants will be asked to tick yes or no to the question "in the future
47
48 347 we may wish to contact you to join a group or individual interview to talk about your
49
50 348 experiences in the program. Do you consent for us to contact you? Yes/No". Approximately
51
52 349 20 of those who tick 'yes', will be contacted by telephone or email at 6 months and/or 12
53
54 350 months, and invited to take part in an interview, which will be conducted on Microsoft Teams
55
56 351 videoconference or in person at the football/rugby club (depending on the person's preference).
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3 352 Interview questions will be developed in collaboration with PhD candidates and an ethics
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5 353 amendment will be submitted for approval prior to undertaking any interviews. Any changes
6
7
8 354 to protocol will be reported on the study Open Science Framework page (<https://osf.io/ev8px/>).
9

10 11 355 **Treatment of Waitlist Control Arm** 12

13
14 356 All men will be directed to review evidence-based resources (i.e., Heart Foundation
15
16 357 online material) regarding PA and healthy eating after completion of the baseline assessments
17
18 358 and men in the waitlist control arm will be invited to participate in Aussie-FIT after the 6-
19
20
21 359 month post baseline assessment.
22

23 24 360 **Data Analyses** 25

26
27
28 361 Physical activity data will be downloaded via the ActiLife software (version 6.13.4),
29
30 362 where the raw accelerometer data will be processed in R using the GGIR V1.5-21 package
31
32 363 (cran.r-project.org/web/packages/GGIR/index.html) (30,31). Physical activity will be
33
34 364 estimated from 5-second epochs, with the average daily activity calculated. To be classified as
35
36 365 moderate to vigorous physical activity (MVPA) mean acceleration needs to be ≥ 100 milli-g
37
38 366 (mg) (32). Time in activities lasting at least 1 minute, for which 80% of the activity satisfied
39
40 367 the 100 mg threshold criteria, will be calculated. Average acceleration (calculated as the mean
41
42 368 acceleration across the 24-hour day as a proxy for the daily volume of PA) and intensity-
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44 369 gradient (as a reflection of the distribution of intensity across the 24-hour day) will be
45
46 370 calculated (33,34). We will only include in the analysis those participants with four or more
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49 371 valid days of accelerometry data, and at least 10 hours of wear time each day.
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54 372 De-identified objective measurements, questionnaire data and calculated PA data will
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56 373 be exported to Stata software for analyses by an independent biostatistician blinded to the group
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58 374 allocation. Characteristics of the participants will be summarised in mean (and standard
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3 375 deviation) or median (and interquartile range) or frequency (and percentage), by treatment
4
5 376 groups. Program efficacy will be analysed following the intention-to-treat principle and per-
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7
8 377 protocol approaches outlined below. Changes in the post-intervention outcomes will be
9
10 378 analysed using linear mixed effect regression models whilst controlling for the baseline
11
12 379 measures. Sensitivity analyses will also be performed to include covariates such as age, BMI,
13
14 380 types of comorbidities in the model to compare the beta coefficient of the models with and
15
16 381 without the covariates. If group sizes permit, sub-group analyses will be performed to examine
17
18 382 differences in intervention effects on primary and secondary outcomes between i)
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20 383 States/Territories; ii) men diagnosed with and without a CVD diagnosis, iii) men with BMI
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22 384 ≥ 25 and men with BMI < 25 ; and iii) men who identify as Aboriginal and Torres Strait Islander
23
24 385 and men who do not. Further details are available regarding data management and statistical
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26 386 analysis plans on the project page of the Open Science Framework (<https://osf.io/ev8px/>).
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31 387 **Sample Size Calculations**

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35 388 320 men will be recruited: in WA (n=128), NT (n=96) and QLD (n=96), 160 per arm. This
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37 389 estimate is based on observed changes in moderate-to-vigorous PA (MVPA) in the Aussie-FIT
38
39 390 pilot (11) and provides 90% power to detect a mean difference of 11-minutes/day (standard
40
41 391 deviation:27-minutes/day) of MVPA at 6-months (primary endpoint). The sample size
42
43 392 powered on MVPA because PA reduces CVD risk independently, and mitigates other risk
44
45 393 factors, such as high blood pressure (35). Change in MVPA of 5 minutes per day is considered
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47 394 the minimum clinically important difference.(36) We allow for a trial attrition rate of 20%.
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51 395 **Economic Evaluation**

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55 396 We will use an economic model of the type developed in the Aussie-FIT pilot (11). The cost-
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57 397 effectiveness analysis will be performed from a health system perspective. Costs will include
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59 398 direct costs associated with the programme (including setting up and promotion) as well as
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3 399 self-reported healthcare resource use. In terms of outcome measurement, we will include
4
5 400 short-term outcomes that will allow us to look at the cost per clinically relevant change in
6
7 401 MVPA (5 minutes per day, (36)) and cost per quality-adjusted life years (QALYs). The
8
9 402 QALY is the most widely used approach in economic evaluations for quantifying quality of
10
11 403 life gains (37). The EQ-5D-5L questionnaire will be used to assess quality of life (38), which
12
13 404 is a standardized measure of health status widely adopted in economic evaluations (39). The
14
15 405 EQ-5D-5L responses will be converted into a utility score using the most recent preference-
16
17 406 weights generated from an Australian general population sample (40). Self-reported data
18
19 407 relating to the number and type of health resources used will be collected at each
20
21 408 measurement point. Unit costs for visits to health professionals (GP, practice nurses,
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23 409 physiotherapists etc) will be sourced from the Medical Benefits Schedule (41). Unit costs for
24
25 410 any inpatient stays and outpatient visits will be sourced from standard Australian public
26
27 411 sector hospital costs (42). Unit costs for prescriptions will be sourced from Pharmaceutical
28
29 412 Benefits Schedule (PBS) (43). Given uncertainty around parameters such as unit costs and
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31 413 utility values for calculating QALYs, we will undertake sensitivity analysis to check the
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33 414 robustness of the estimates.
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40 **Data Management**

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43 416 Locked cabinets in the participating Universities will be used to store hard copy data and no
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45 417 identifying information will be included. A file aligning ID codes with participants' identifying
46
47 418 information will be stored on the University server in a password-protected computer file. Only
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49 419 members of the research team will be able to access the physical and electronic data files.
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54 **Adverse Events**

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57 421 Coaches will be instructed to report any adverse events during the program sessions to
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59 422 the local trial co-ordinator, using a standardised form. In this trial, serious adverse events will
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3 423 be defined as a medical event believed by the investigators to be attributable to participation in
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5 424 the Aussie-FIT program, based on the participant's previous medical conditions and clinical
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8 425 presentation. Participants will also be asked to report any adverse events to the coach.
9

10 11 426 **Ethics and Dissemination**

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13
14 427 This multi-site study has been approved by the lead ethics committees in the lead site's
15
16 428 jurisdiction, the South Metropolitan Health Service Human Research Ethics Committee
17
18 429 (Reference RGS4254) and the West Australian Aboriginal Health Ethics Committee
19
20 430 (HREC1221). Reciprocal approvals have been sought from the relevant ethics bodies in the
21
22 431 partner site's jurisdictions. All participants will read an electronic participant information sheet
23
24 432 and offered a hard or electronic copy to keep. They will be asked to electronically indicate
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26 433 consent before the program enrolment and will be offered a digital or paper copy of their
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28 434 consent form. The study will be disseminated via publication in peer-review journals,
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30 435 presentations at conferences and reports and presentations for consumers and stakeholders. The
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32 436 latter will be co-designed with consumers and stakeholders.
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38 437 **Discussion**

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41 438 In 2022, CVD was the leading cause of burden of disease in Australia, and this burden
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43 439 is higher in males than females (44). Insufficient physical activity and poor diet are key
44
45 440 modifiable behavioural CVD risk factors. Pilot and feasibility studies of Aussie-FIT have
46
47 441 illustrated that the program is acceptable to men in WA, and feasible to deliver in AFL and
48
49 442 West Australian Football League clubs and rugby league clubs in QLD. Scale up of Aussie-
50
51 443 FIT in WA, as well as out to other States and Territories creates an opportunity to reduce
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53 444 primary and secondary CVD risk among men with or at risk of CVD via modification of PA
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55 445 and dietary behaviours. Via this hybrid implementation trial, we will determine whether the
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446 program is effective in improving health and health behaviours in men who take part, and test
447 strategies to sustain longer term implementation of this program.

448

For peer review only

449 **Abbreviations**

450 Aussie-FIT: Australian Fans in Training

451 FFIT: Football Fans in Training

452 BMI: Body mass index

453 CVD: Cardiovascular disease

454 MVPA: Moderate and vigorous physical activity

455 PA: Physical Activity

456 **Trial Registration**

457 The trial has been registered with Australian and New Zealand Clinical Trials Registry
458 (ACTRN12623000437662), prior to recruitment of the first participant (trial registration date
459 28 March 2023). Results will be written up and published and will be available in an open
460 access journal or via the Open Science Framework.

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

1
2
3 470 protocols. TP, JMcV, and EQ designed the physical activity data analysis plan. SH, MDM, EQ,
4
5 471 DAK, and DK updated the intervention materials, with input from BB, JB, NW, TP, AM. EQ,
6
7 472 BS, AM, and MDM prepared the main ethics submission. EQ, BB, JS, and JB prepared the
8
9 473 trial procedures and ethics submission for involvement of men who identify as Aboriginal
10
11 474 and/or Torres Strait Islanders. MDM, BB, JS, and JB designed the project consumer
12
13 475 involvement strategies. JC conducted the power analysis and designed the statistical analysis
14
15 476 plan. MM designed the economic evaluation. TP, LW, JS and BB prepared ethics submissions
16
17 477 for reciprocal ethics from local State/Territory committees. EQ and MDM drafted the
18
19 478 manuscript and all authors read, edited, and approved the final version of the manuscript.
20
21
22

23 479 **Competing Interests**

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25
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27 480 N/A
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33
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37
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39
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41
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51
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53
54 492 (SPFLT).
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3 **662 Tables and Figures**
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6 **663** Table 1 – Intervention description aligned with the Template for Intervention Description
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9 **664** and Replication (TIDieR) guidance
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12 **665** Table 2 – Summary of measures used in the Aussie-FIT trial and program evaluation and
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14 **666** time points
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18 **667** Table 3 – Intervention content in each of the 12 sessions
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21 **668** Figure 1 – Consort diagram of participant flow through the trial
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Table 1. Intervention description aligned with the Template for Intervention Description and Replication (TIDieR) guidance**TIDieR Checklist Item**

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

outcome (physical activity) in this trial, and to incorporate consumer and stakeholder feedback in WA, QLD, and the Northern Territory (NT).

What (procedures) Participants will attend 12 group sessions at their club that incorporates physical activity, and workshop style education. The education involves practical activities and discussions to help men understand why and how to improve their diet (e.g., interpreting food labels, portion sizes, meal planning, eating out) and physical activity habits (e.g., understanding exercise intensities, safe strength training, decreasing sedentary time). Men will be encouraged to use behaviour change techniques (e.g., self-monitoring, goal setting, and problem solving) to help put the recommendations into practice. Participants take part in physical activity within the sessions that starts off slowly in the initial weeks and gradually builds up over the course of the program. Activities men participate in include ball skills and circuit training similar to that undertaken by Australian football and rugby league players but modified to be safe for each man's abilities (e.g., ball skill drills restricted to walking). Men are encouraged to self-monitor walking, gradually increasing steps/day throughout the 12-weeks.

Who provides Coaches will be recruited from ten sports clubs in Perth, Darwin, and Brisbane. Aussie-FIT coaches will be already embedded in their respective clubs, knowledgeable about Australian Football or Rugby League, and have experience of leading physical activity or sports coaching sessions. Coaches should have good communication skills and the ability to help foster a supportive atmosphere with camaraderie between participants. Accredited Exercise Physiologists (AEPs), or other suitably qualified/accredited health professionals will act as an assistant coach and co-facilitate program delivery. They will support the coach by undertaking any required health monitoring of participants (e.g., blood pressure checks), provide advice on safe exercise and provide first aid, if

required. Club coaches and AEPs will be trained by the research team in the core program content (physical activity, nutrition, motivation, behaviour change). The training is delivered face-to-face and comprises approximately 15 hours of interactive learning content and opportunities to practice session deliveries and receive feedback from the research team and peers.

How The intervention will be delivered face-to-face to groups of approximately 16 men. Coaches are encouraged to utilise a communication style that supports psychological need satisfaction for autonomy, competence, and relatedness in relation to physical activity and eating behaviours.

Where The program will be delivered in Australian Football (WA and NT) and rugby league (QLD) settings. This will include a suitable space for the educational program component (e.g., indoor clubroom) and access to the pitch/oval for physical activity. In some circumstances, outdoor spaces may be utilised to deliver the educational content and indoor spaces may be used for physical activity (e.g., if there is gym access, or in adverse weather conditions).

When and how much Participants will attend twelve, weekly, 90-minute sessions. Aussie-FIT encourages gradual increases in moderate to vigorous physical activity levels outside of the weekly sessions in daily life.

Tailoring The Aussie-FIT sessions and resources are informed by the best available evidence and population recommendations for age and CVD risk management (e.g., Australian guide to healthy eating, physical activity guidelines, and National Heart Foundation recommendations). The program is not prescriptive in terms of physical activity and dietary changes the men make outside of the weekly sessions. Men are supported to self-monitor their diet and physical activity behaviours, then make their own education-informed decisions on setting goals that are relevant to them. Health behaviour change goals that are self-determined are more

1
2 likely to be sustainable. Personalised feedback on goals men set is provided by coaches and peers in weekly sessions throughout
3
4 the program. Targeted behaviours for goal setting include portion size control, reduction of sugary drinks and energy dense foods,
5
6 reduction in alcohol consumption, gradual increases in physical activity and reduced sedentary time. Men participating in Aussie-
7
8 FIT will have varying physical fitness levels and health conditions. Throughout the program AEPs and coaches will modify the
9
10 physical activity within the sessions to suit men with differing physical capabilities. AEPs and coaches will be aware of pre-
11
12 existing conditions and will interact with and observe participants during the program sessions, and tailor activities as required.
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Table 2. Summary of measures used in the Aussie-FIT trial and program evaluation and time points

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

1				
2		measurements calculated. The participant is asked to locate the last rib and iliac crest,		
3				
4		and the measure is performed at the midpoint between these to locate the waist. If the		
5				
6		man cannot locate his last rib and iliac crest the researcher can ask the man to identify		
7				
8		where his belly button is and the measurement can occur one inch/3cm or width of		
9				
10		two fingers above where man has indicated. If the first two measurements differ by 5		
11				
12		mm or more, measure third time.		
13				
14				
15				
16	Resting systolic and	Resting blood pressure measured with a digital blood pressure monitor (Omron HBP-	X	X
17				
18	diastolic blood pressure	1320, Milton Keynes, UK) monitor after 5 min sitting still. If measured systolic blood		
19				
20		pressure is over 150 mmHg and/or measured diastolic blood pressure is over 95		
21				
22		mmHg, two further measures will be taken and recorded. If blood pressure remains		
23				
24		high the man will be provided with a letter explaining the circumstances in which		
25				
26		they had their blood pressure measured and recorded and they will be encouraged to		
27				
28		consult their GP. A mean will be calculated from the second and third measures. Feet		
29				
30		flat on the floor, arm free of clothing or wearing loose/thin clothing, cuff at the level		
31				
32		of heart and arm resting, same arm used (non-dominant arm), no talking.		
33				
34				
35				
36	Cholesterol	Cholesterol will be check using handheld point of care device (Accutrend Plus) that	X	X
37				
38		measures cholesterol immediately.		X
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Self-reported measures (completed at the measurement sessions at football clubs or online in the participant’s own time, depending on preference)

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

Self-reported programme evaluation measures

1				
2	Recruitment	How participants found out about the programme; programme uptake (number of	X	
3		people who expressed interest; number of people who fit inclusion criteria)		
4				
5				
6	Programme evaluation:	Attendance to programme sessions and to measurement sessions; fidelity of		X
7				X
8	via questionnaires and	programme delivery; perceptions of effectiveness and acceptability, assessed using		
9				
10	interviews	the program evaluation questionnaire, which is adapted from the original Aussie-FIT		
11		program. Completed at T2 for first cohort and T3 for second cohort. Interviews with		
12		participants, coaches and AEPs will also provide further data on these points.		
13				
14	Training evaluation: via	Coaches will evaluate the training provided to them by completing the coach training		
15				
16	questionnaires and	evaluation questionnaire on completing their training. The interviews will also ask the		
17				
18	interviews	coaches about their training.		
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25 *Note.* * and 12 months, for intervention group only

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38 *Table 2.* Intervention content

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

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

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

1				
2	sugar	choose healthier packet foods	Healthier fat alternatives;	flexibility
3				
4			Added sugar in drinks	activities
5				
6				including sport
7				
8				drills
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10				
11	Session 9. Physical	Developing PA habits	Choosing healthier food	Reviewing steps and activity review
12				Circuit of aerobic,
13	activity habits and		choices when having	strength,
14				
15	healthier ways to eat		takeaway or eating out	flexibility
16				
17	out			activities
18				
19				including sport
20				
21				drills
22				
23				
24				
25	Session 10. Healthy	Reviewing goals; Triggers for	Healthy living and busting	Step count and activity review
26				Circuit of aerobic,
27	cooking at home	setbacks and how to avoid them	myths; Healthy cooking	strength,
28				
29		Action Point: Complete food	and food preparation at	flexibility
30				
31		diary to bring next week	home	activities
32				
33				including sport
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35				drills
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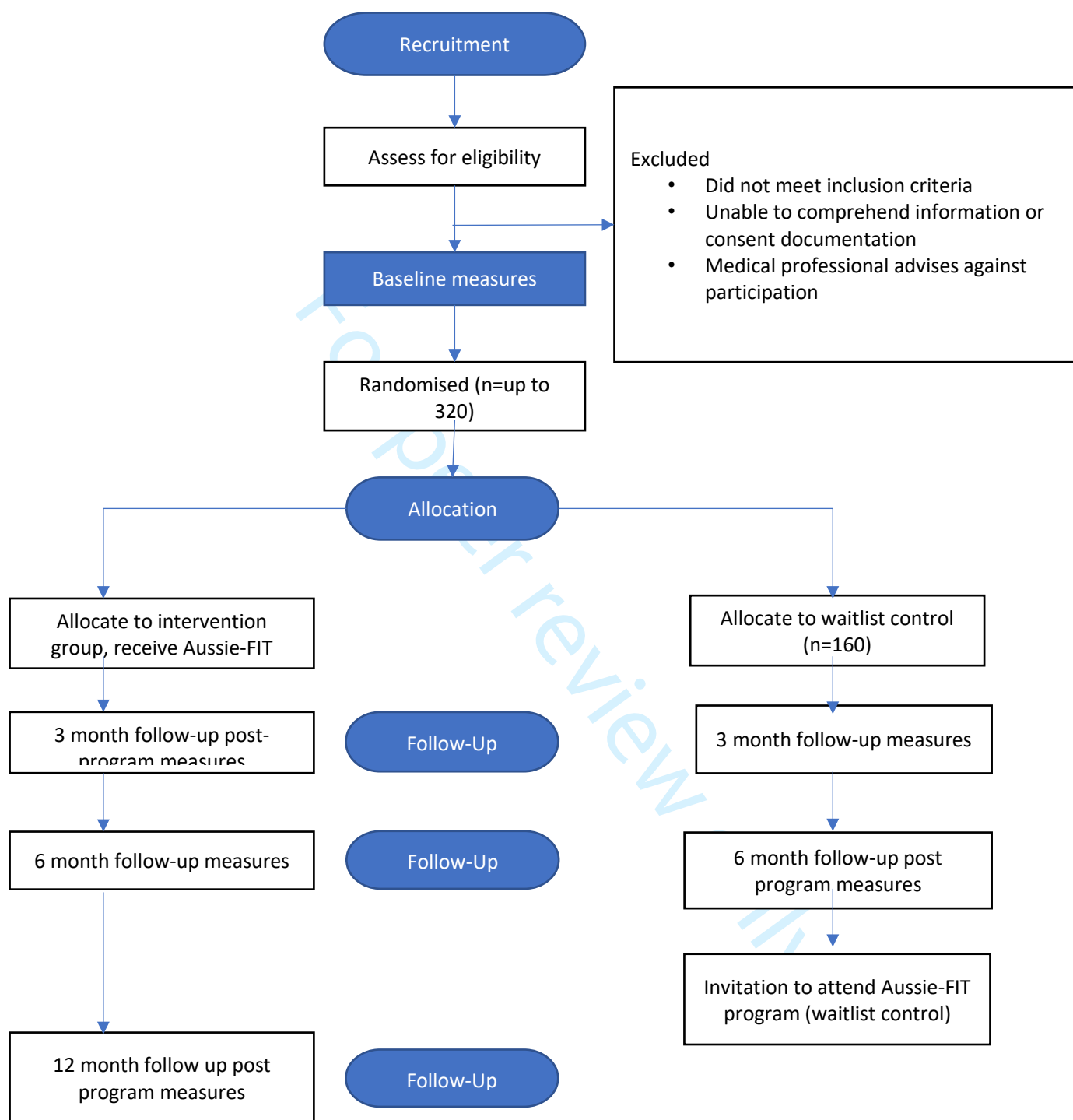
Session 11.	Revision of food diaries; Revision of eating plans; Behaviour control and staying on track; Revision of SMART goals	PA levels, types, positives and challenges	Reviewing steps and alternative activities	Circuit of aerobic, strength, flexibility activities including sport drills
Session 12. Looking ahead towards maintaining a healthy lifestyle	Reviewing progress throughout the program; Celebrating achievements; Determining steps after the program	Tips to maintaining nutrition habits for heart health	Tips to maintaining PA habits	AFL or rugby game

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

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For peer review only

Figure 1. Consort diagram of participant flow through the trial



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



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

Section/item	Item No	Description	Page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	7
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 20-21
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	16

1				
2	Objectives	7	Specific objectives or hypotheses	6
3				
4				
5	Trial design	8	Description of trial design including type of trial (eg,	7
6			parallel group, crossover, factorial, single group),	
7			allocation ratio, and framework (eg, superiority,	
8			equivalence, noninferiority, exploratory)	
9				
10				
11	Methods: Participants, interventions, and outcomes			
12				
13	Study setting	9	Description of study settings (eg, community clinic,	7
14			academic hospital) and list of countries where data will be	
15			collected. Reference to where list of study sites can be	
16			obtained	
17				
18	Eligibility	10	Inclusion and exclusion criteria for participants. If	8-9
19	criteria		applicable, eligibility criteria for study centres and	
20			individuals who will perform the interventions (eg,	
21			surgeons, psychotherapists)	
22				
23				
24	Interventions	11a	Interventions for each group with sufficient detail to allow	10-11, 31-33
25			replication, including how and when they will be	
26			administered	
27				
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29		11b	Criteria for discontinuing or modifying allocated	N/A
30			interventions for a given trial participant (eg, drug dose	
31			change in response to harms, participant request, or	
32			improving/worsening disease)	
33				
34		11c	Strategies to improve adherence to intervention protocols,	14-15
35			and any procedures for monitoring adherence (eg, drug	
36			tablet return, laboratory tests)	
37				
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39		11d	Relevant concomitant care and interventions that are	N/A
40			permitted or prohibited during the trial	
41				
42	Outcomes	12	Primary, secondary, and other outcomes, including the	13-14
43			specific measurement variable (eg, systolic blood	
44			pressure), analysis metric (eg, change from baseline, final	
45			value, time to event), method of aggregation (eg, median,	
46			proportion), and time point for each outcome. Explanation	
47			of the clinical relevance of chosen efficacy and harm	
48			outcomes is strongly recommended	
49				
50				
51	Participant	13	Time schedule of enrolment, interventions (including any	14-15
52	timeline		run-ins and washouts), assessments, and visits for	
53			participants. A schematic diagram is highly recommended	
54			(see Figure)	
55				
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1				
2	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	17
3				
4				
5				
6				
7	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9-10
8				
9				

Methods: Assignment of interventions (for controlled trials)

Allocation:

14	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12-13
15				
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22				
23				
24	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	13
25				
26				
27				
28				
29				
30	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13-14
31				
32				
33				
34	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
35				
36				
37				
38				
39		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
40				
41				
42				

Methods: Data collection, management, and analysis

45	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13-16, 35-38
46				
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56		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	
57				
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1				
2	Data	19	Plans for data entry, coding, security, and storage,	17
3	management		including any related processes to promote data quality	
4			(eg, double data entry; range checks for data values).	
5			Reference to where details of data management	
6			procedures can be found, if not in the protocol	
7				
8	Statistical	20a	Statistical methods for analysing primary and secondary	16-17
9	methods		outcomes. Reference to where other details of the	
10			statistical analysis plan can be found, if not in the protocol	
11				
12				
13		20b	Methods for any additional analyses (eg, subgroup and	17
14			adjusted analyses)	
15				
16				
17				
18		20c	Definition of analysis population relating to protocol non-	17
19			adherence (eg, as randomised analysis), and any	
20			statistical methods to handle missing data (eg, multiple	
21			imputation)	
22				
23	Methods: Monitoring			
24				
25	Data	21a	Composition of data monitoring committee (DMC);	N/A
26	monitoring		summary of its role and reporting structure; statement of	
27			whether it is independent from the sponsor and competing	
28			interests; and reference to where further details about its	
29			charter can be found, if not in the protocol. Alternatively,	
30			an explanation of why a DMC is not needed	
31				
32				
33		21b	Description of any interim analyses and stopping	N/A
34			guidelines, including who will have access to these interim	
35			results and make the final decision to terminate the trial	
36				
37				
38	Harms	22	Plans for collecting, assessing, reporting, and managing	18
39			solicited and spontaneously reported adverse events and	
40			other unintended effects of trial interventions or trial	
41			conduct	
42				
43	Auditing	23	Frequency and procedures for auditing trial conduct, if	N/A
44			any, and whether the process will be independent from	
45			investigators and the sponsor	
46				
47				
48	Ethics and dissemination			
49				
50	Research	24	Plans for seeking research ethics committee/institutional	18-19
51	ethics		review board (REC/IRB) approval	
52	approval			
53				
54	Protocol	25	Plans for communicating important protocol modifications	16
55	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
56			relevant parties (eg, investigators, REC/IRBs, trial	
57			participants, trial registries, journals, regulators)	
58				
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1				
2	Consent or	26a	Who will obtain informed consent or assent from potential	14
3	assent		trial participants or authorised surrogates, and how (see	
4			Item 32)	
5				
6		26b	Additional consent provisions for collection and use of	N/A
7			participant data and biological specimens in ancillary	
8			studies, if applicable	
9				
10	Confidentiality	27	How personal information about potential and enrolled	14-16
11			participants will be collected, shared, and maintained in	
12			order to protect confidentiality before, during, and after the	
13			trial	
14				
15				
16	Declaration of	28	Financial and other competing interests for principal	21
17	interests		investigators for the overall trial and each study site	
18				
19	Access to data	29	Statement of who will have access to the final trial dataset,	18
20			and disclosure of contractual agreements that limit such	
21			access for investigators	
22				
23				
24	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and for	N/A
25	post-trial care		compensation to those who suffer harm from trial	
26			participation	
27				
28	Dissemination	31a	Plans for investigators and sponsor to communicate trial	19
29	policy		results to participants, healthcare professionals, the	
30			public, and other relevant groups (eg, via publication,	
31			reporting in results databases, or other data sharing	
32			arrangements), including any publication restrictions	
33				
34				
35		31b	Authorship eligibility guidelines and any intended use of	N/A
36			professional writers	
37				
38		31c	Plans, if any, for granting public access to the full protocol,	N/A
39			participant-level dataset, and statistical code	
40				
41				
42	Appendices			
43				
44	Informed	32	Model consent form and other related documentation	N/A
45	consent		given to participants and authorised surrogates	
46	materials			
47				
48	Biological	33	Plans for collection, laboratory evaluation, and storage of	N/A
49	specimens		biological specimens for genetic or molecular analysis in	
50			the current trial and for future use in ancillary studies, if	
51			applicable	
52				
53				

*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.



Supplementary File 2.

Standards for Reporting Implementation Studies: the StaRI checklist for completion

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

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

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

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.

The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

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

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

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

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

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For peer review only

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2023-078302.R1
Article Type:	Protocol
Date Submitted by the Author:	21-Sep-2023
Complete List of Authors:	<p>McDonald, Matthew; Curtin University, Physical Activity and Well-being Research Group, enAble Institute; Curtin University, Curtin School of Population Health</p> <p>Brickley, Bryce; Flinders University, College of Medicine and Public Health, Rural and Remote Health</p> <p>Pavey, Toby; Queensland University of Technology, Exercise and Nutrition Sciences</p> <p>Smith, James A ; Flinders University, College of Medicine and Public Health, Rural and Remote Health</p> <p>Maiorana, Andrew; Curtin University, School of Physiotherapy and Exercise Science; Fiona Stanley Hospital, Exercise Physiology Department</p> <p>McCaffrey, Tracy; Monash University, Nutrition, Dietetics and Food</p> <p>Hillis, Graham; Royal Perth Hospital, Department of Cardiology; The University of Western Australia, School of Medicine and Pharmacology</p> <p>Bonson, Jason; Flinders University, College of Medicine and Public Health, Rural and Remote Health</p> <p>Chih, HuiJun; Curtin University, Curtin School of Population Health</p> <p>Gupta, Himanshu; Flinders University, College of Medicine and Public Health, Rural and Remote Health</p> <p>Holmes, Scarlett; Curtin University, Physical Activity and Well-being Research Group, enAble Institute; Curtin University, Curtin School of Population Health</p> <p>Hunt, Kate; University of Stirling, Institute for Social Marketing</p> <p>Kerr, Deborah; Curtin University, Curtin School of Population Health</p> <p>Kwaśnicka, Dominika ; The University of Melbourne, NHMRC CRE in Digital Technology to Transform Chronic Disease Outcomes, Melbourne School of Population and Global Health; SWPS University of Social Sciences and Humanities, Faculty of Psychology</p> <p>Makate, Marshall; Curtin University Bentley Campus, Health Systems and Health Economics, School of Public Health</p> <p>McVeigh, Joanne; Curtin University, Physical Activity and Well-being Research Group, enAble Institute; Curtin University, Curtin School of Allied Health</p> <p>Moullin, Joanna; Curtin University, Curtin School of Population Health</p> <p>Smith, Brendan; Curtin University, Physical Activity and Well-being Research Group, enAble Institute; Curtin University, Curtin School of Population Health</p>

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	Wharton, Lee; Queensland University of Technology Wharton, Neil; Queensland University of Technology Quested, Eleanor; Curtin University, Physical Activity and Well-being Research Group, enAble Institute; Curtin University, Curtin School of Population Health
Primary Subject Heading:	Public health
Secondary Subject Heading:	Cardiovascular medicine, Public health, Sports and exercise medicine
Keywords:	Obesity, Primary Prevention, PUBLIC HEALTH, Randomized Controlled Trial, CARDIOLOGY



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3 **1 Scale-up of the Australian Fans in Training (Aussie-FIT) men's health behaviour**
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5 **2 change program: Protocol for a randomised controlled hybrid effectiveness-**
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7 **3 implementation trial.**
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12 ^{h,i}Hillis, G., ^cBonson, J., ^bChih, H.J., ^cGupta, H., ^bHolmes, S., ^jHunt, K., ^{a,b}Kerr, D.,
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55
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57

58 **Version number and date:** Protocol version 1, date: 28 July 2023
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1
2
3 **26 Abstract**
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5 **27 Introduction**
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7
8 28 Improving physical activity and healthy eating is critical for primary and secondary
9
10 29 prevention of cardiovascular disease (CVD). Behaviour change programs delivered in
11
12 30 sporting clubs can engage men in health behaviour change but are rarely sustained or scaled-
13
14 31 up post-trial. Following the success of pilot studies of the Australian Fans in Training
15
16 32 (Aussie-FIT) program, a hybrid effectiveness-implementation trial protocol was developed.
17
18 33 This protocol outlines methods to: i) establish if Aussie-FIT is effective at supporting men
19
20 34 with or at risk of CVD to sustain improvements in moderate-to-vigorous physical activity
21
22 35 (primary outcome), diet, and physical and psychological health, and ii) examine the
23
24 36 feasibility and utility of implementation strategies to support program adoption,
25
26 37 implementation and sustainment.
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30 **38 Methods and Analysis**
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32
33 39 A pragmatic multi-State/Territory hybrid type 2 effectiveness-implementation parallel group
34
35 40 randomised controlled trial with a 6 month wait-list control arm in Australia. 320 men aged
36
37 41 35-75 years with or at-risk of CVD will be recruited. Aussie-FIT involves 12 weekly face-to-
38
39 42 face sessions including coach-led interactive education workshops and physical activity
40
41 43 delivered in Australian Football League (Western Australia, Northern Territory) and rugby
42
43 44 (Queensland) sports club settings. Follow-up measures will be at 3- and 6-months (both
44
45 45 groups), and at 12 months to assess maintenance (intervention group only). Implementation
46
47 46 outcomes will be reported using the RE-AIM (Reach, Effectiveness, Adoption,
48
49 47 Implementation, Maintenance) framework.
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52 **48 Ethics and Dissemination**
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54
55 49 This multi-site study has been approved by the lead ethics committees in the lead site's
56
57 50 jurisdiction, the South Metropolitan Health Service Human Research Ethics Committee
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1
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3 51 (Reference RGS4254) and the West Australian Aboriginal Health Ethics Committee
4
5 52 (HREC1221). Findings will be disseminated at academic conferences, peer-reviewed journals
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7
8 53 and via presentations and reports to stakeholders, including consumers. Findings will inform
9
10 54 a blueprint to support the sustainment and scale-up of Aussie-FIT across diverse Australian
11
12 55 settings and populations to benefit men's health.
13
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15 56

17 57 **Strengths and Limitations**

- 19 58 • This is the first multi-State/Territory trial of a 'fans in training' style intervention.
- 21
22 59 • Consumers and other stakeholders contributed to the development of the protocol, in
23
24 60 particular recruitment and data collection methods.
- 25
26 61 • Using a hybrid design will facilitate the concurrent assessment of intervention
27
28 62 effectiveness and implementation outcomes, promoting efficient implementation and
29
30 63 long-term impact of this evidence-based program.
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33 64 • Due to the nature of the intervention, participants will not be blinded to treatment
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35 65 allocation.
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40 67 **Word count:** 4550
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68 Introduction

69 The cardiovascular benefits of physical activity (PA) and eating a healthy diet are well
70 established, however, 55% of people who live in Australia do not meet PA guidelines, most
71 eat an unhealthy diet and 67% are living with overweight or obesity (1). Among those with a
72 cardiovascular disease (CVD) diagnosis, exercise adherence remains low. Most men with
73 CVD fail to initiate or sustain health behaviour changes, decreasing quality of life and
74 increasing risk of future CVD and premature death (2). For instance, only 30% of patients
75 complete outpatient cardiac rehabilitation, and of those, less than 50% are sufficiently active
76 12 months after their cardiac event (2).

77 A patient survey showed many patients lack self-management skills and are too dependent on
78 exercise rehabilitation staff to sustain behaviour changes upon completion of hospital-based
79 exercise programs (3). Recent estimates suggest that increasing participation in cardiac
80 rehabilitation in Australia from 30% to 65% would result in \$36 million in healthcare savings,
81 \$58 million in social and economic benefits, and significantly reduce annual heart attack
82 admissions (4). To reap these health and economic benefits, new strategies are required to
83 increase PA adherence and healthy eating in people with or at-risk of CVD. Gender tailored
84 programs are important, because men and women experience differences in CVDs risks and
85 occurrences (5). Gender-tailored health behaviour change programs for men have been shown
86 to be appealing and effective (6).

87 The internationally recognised 'Football Fans in Training' (FFIT) program, and our
88 Australian adaptation (Aussie-FIT), are effective in engaging men to improve their health
89 behaviours. FFIT (7) and Aussie-FIT (8) capitalise on men's interest in sport to promote weight
90 loss via sustained improvements in diet and PA. These structured 12-week programs include
91 90 minutes of interactive education and group-based PA that aims to develop the skills and

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3 92 confidence of participants to self-regulate and maintain behaviour change long-term. Programs
4
5 93 are delivered to groups of men by trained coaches in professional sport facilities. The
6
7 94 effectiveness and cost-effectiveness of FFIT was established in a Randomised Control Trial
8
9 95 (RCT) (7). Mean between group weight lost at 12 months was 5kg, and average weight loss
10
11 96 maintenance of 2.9kg was observed in the intervention group 3.5 years post-baseline (9) . FFIT
12
13 97 was adapted for the European Fans in Training (EuroFIT) RCT in 5 European countries, where
14
15 98 similar findings were revealed (10).

19
20 99 Kwasnicka et al (2020) demonstrated feasibility of recruitment, engagement, and
21
22 100 retention of men living with overweight and obesity, as well as acceptability of the Aussie-FIT
23
24 101 intervention and research procedures when delivered at top-tier Australian Football League
25
26 102 (AFL) clubs in Western Australia (WA). Promising physical and mental health outcomes were
27
28 103 observed (11). In a single-arm feasibility trial in Queensland (QLD), a version of Aussie-FIT
29
30 104 adapted for rugby league (League-FIT) has engaged men living with overweight and obesity,
31
32 105 and demonstrated promise in supporting positive physical and mental health outcomes (12). In
33
34 106 a feasibility study of the Aussie-FIT program undertaken at second-tier AFL clubs for men
35
36 107 with CVD, Smith et al (manuscript in preparation) demonstrated feasibility of participant
37
38 108 engagement and retention, and acceptability of the intervention and research procedures.
39
40 109 However, recruiting men with CVD was challenging (Smith et al., manuscript in progress).
41
42 110 Recruitment challenges were likely due to the smaller population of men with CVD (6.5% of
43
44 111 men in Australia) (13) compared with 75% of men with overweight and obesity in Australia
45
46 112 (14), and the smaller fanbases of second-tier AFL clubs compared to top-tier clubs. The
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48 113 effectiveness of Aussie-FIT remains to be tested, as do implementation strategies designed to
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50 114 improve the adoption, implementation, sustainment and scale-up of the program to reach
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52 115 diverse populations of at-risk men. This multi-State/Territory trial aims to establish the
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3 116 effectiveness of the Aussie-FIT intervention for men with or at-risk of CVD, whilst allowing
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5 117 for flexibility with club-size (e.g., top-tier or second-tier) across diverse Australian contexts.
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8 118 A recent systematic review of five unique interventions concluded that, whilst FFIT
9
10 119 has been successfully scaled up, not all health promotion interventions delivered through
11
12 120 professional sport have been successfully scaled up, and thus a greater focus on the potential
13
14 121 for scalability of these interventions is required (15). Scalability is the process of increasing
15
16 122 the number of implementers (e.g., sports clubs) that are willing to initiate delivery of
17
18 123 effective interventions to reach a greater proportion of the target population (16). The
19
20 124 potential for intervention scalability is increasingly considered across the research spectrum,
21
22 125 rather than solely positioned at the end of a linear research pipeline after effectiveness testing
23
24 126 (17). One increasingly common approach to considering implementation and scalability
25
26 127 earlier in the research process is the use of hybrid effectiveness-implementation study
27
28 128 designs, which allow for the assessment of intervention effectiveness alongside
29
30 129 implementation outcomes (18). Implementation outcomes that are important for scalability
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32 130 include program costs, fidelity, adaptability, delivery settings, infrastructure, workforce,
33
34 131 reach and acceptability in diverse populations (Milat et al., 2020).
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41 132 This trial adopts a hybrid effectiveness-implementation design (19) to examine the
42
43 133 effectiveness of Aussie-FIT, and in parallel assess the feasibility and utility of
44
45 134 implementation strategies to support program adoption, implementation, sustainment and
46
47 135 scalability, using the RE-AIM framework. We pose two research questions to simultaneously
48
49 136 address both the intervention and the implementation process aims (20): 1) is the Aussie-FIT
50
51 137 program effective in increasing time spent in moderate-to-vigorous physical activity (MVPA);
52
53 138 and improving other secondary outcomes among men with or at-risk of CVD at 6 month
54
55 139 follow up; and 2) what are the facilitators and barriers to implementation, sustainment and
56
57 140 scalability of the Aussie-FIT program?
58
59
60

141 **Method**

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

145 **Study design**

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

153 **Context**

154 The study is set in and around the capital cities of Darwin (Northern Territory), Perth
155 (WA), and Brisbane (QLD). These urban centres have distinct contextual characteristics. QLD
156 and WA make up 20% and 10% of the national population respectively and are far more
157 populated than the Northern Territory (NT) which makes up less than 1% of the national
158 population (22). There is significant cultural diversity across each State/Territory; for example,
159 the proportion of males that identify as Aboriginal and/or Torres Strait Islander in the NT
160 (26.3%) is considerably higher than in QLD (4.6%) and WA (3.3%) (23). Australian Football
161 is the most popular sport in WA and the NT, whereas in QLD, Rugby League is most popular
162 (24).

163 **Patient and Public Involvement**

1
2
3 164 Patient and public engagement has been central to the development of the Aussie-FIT
4
5 165 program since its ' inception and in previous pilot studies in which the intervention was
6
7 166 developed based on patient priorities. In preparation for and in the design of this trial,
8
9
10 167 community advisory groups consisting of consumers (i.e., men with or at-risk of CVD, and
11
12 168 former Aussie-FIT participants) and stakeholders (e.g., Aussie-FIT coaches, sporting club or
13
14 169 community representatives) have been formed in each State/Territory. These groups include
15
16
17 170 representation of Aboriginal and/or Torres Strait Islander men. The first of these groups met in
18
19 171 December 2022. Community advisory groups have helped identify potential barriers and
20
21 172 enablers of project success and have co-designed responsive implementation strategies. These
22
23 173 groups will continue to work in partnership with the research team throughout the lifespan of
24
25 174 this project. This will include providing input on culturally appropriate recruitment strategies,
26
27 175 retention strategies, involvement in dissemination planning, and if the effectiveness of the
28
29 176 intervention is established, providing advice on the sustainment and scalability of Aussie-FIT.
30
31
32 177 The outcomes of our cross-site consumer and stakeholder involvement activities during the
33
34 178 trial set-up period, and at later stages in the trial, will be reported in future publications.
35
36 179 Presentations and reports for consumers and stakeholders will be co-designed with consumers
37
38 180 and stakeholders and disseminated to participants and other consumer and community
39
40 181 audiences.

41 42 43 44 45 182 **Participants**

46 47 48 183 Inclusion criteria

49
50
51
52 184 Men aged 35-75 in WA (n=128), NT (n=96) and QLD (n=96) that self-report meeting
53
54 185 one or more of the following criteria will be recruited:

55
56
57 186 a) CVD diagnosis more than 3 months prior to commencing the study, with no upper
58
59 187 limit on length of time since diagnosis; OR

1
2
3 188 b) $\geq 10\%$ risk of CVD, according to the online calculator created by the Australian
4
5 189 Chronic Disease Prevention Alliance, that assesses CVD 5-year risk
6
7
8 190 (www.cvdcheck.org.au/calculator); OR
9

10
11 191 c) Body mass index $\geq 28\text{kg/m}^2$.

12
13
14 192 To determine whether they are eligible, potential participants will complete an online
15
16 193 form, co-designed with consumers to ensure accessibility for men.

17
18
19 194 Participants from non-English speaking backgrounds will be offered interpreters if
20
21 195 they wish to participate in the study. Men at risk of harm from PA will be excluded from
22
23 196 vigorous PA and will instead undertake light or moderate PA as tolerated (if appropriate
24
25 197 based on GP/cardiologist's advice). Where possible men who have not participated in
26
27 198 previous Aussie-FIT or League-FIT programs will be prioritised.

30 199 ***Exclusion criteria***

31
32
33
34 200 Exclusion criteria are: unable to comprehend information or consent documentation;
35
36 201 unable to attend most of the weekly sessions, diagnosed with CVD less than 3 months prior to
37
38 202 the baseline assessments date; experienced a cardiac event less than 3 months prior to the
39
40 203 baseline assessments date; or a medical professional advises against participation (e.g., due to
41
42 204 having a cardiac condition not suitable for an exercise trial in the community such as severe
43
44 205 aortic stenosis or on-going angina).

47 206 **Recruitment**

48
49
50
51 207 Participants will be selected on a 'first come, first served' basis. Men with CVD will be
52
53 208 identified from medical records at hospitals (WA only), cardiac rehabilitation programs
54
55 209 delivered in hospitals, or in the community, and GP or other primary health care services. Men
56
57 210 with or at-risk of CVD will be recruited from community sources including club members'
58
59
60

1
2
3 211 newsletters, traditional/social media, match-day publicity (e.g., announcements, face-to-face
4
5 212 recruitment), snowball sampling (25), sport publications, and local health councils. Interested
6
7
8 213 individuals who see the program advertised will be directed to complete a web-based
9
10 214 expression of interest (EOI) form. Men who prefer not to use the online EOI form will have
11
12 215 the opportunity to express their interest, ask questions, check their eligibility, and enrol (if
13
14 216 eligible) by contacting the research team directly via phone or email. The online EOI form
15
16
17 217 includes a series of questions to confirm eligibility.

18
19
20 218 This trial will host a nested ‘study within a trial’ (SWAT) (26) to examine the utility of
21
22 219 a self-directed online enrolment in comparison to a phone call enrolment process (27). Eligible
23
24 220 men that complete the online EOI will be randomised via the online form to either immediately
25
26 221 book their enrolment appointment online or to receive a call from a researcher to progress their
27
28 222 enrolment. The SWAT will evaluate the effectiveness (including cost-effectiveness) of the
29
30 223 online approach compared to the standard phone call on enrolment rates (27).
31
32
33

34 35 224 **Intervention (Aussie-FIT Program)**

36
37
38 225 The intervention is described following the Template for Intervention Description and
39
40 226 Replication (TIDieR) guidance (28), see Table 1. In brief, the 12, weekly, 90-minute sessions
41
42 227 will be delivered to groups of 16 men. One coach and one Accredited Exercise Physiologist
43
44 228 (AEP) or equivalent suitable health professional facilitate each group. Coaches and AEPs will
45
46 229 be trained by the research team in the core content (PA and diet education), safe exercise for
47
48 230 men with or at-risk of CVD, and in the use of principles of motivation and behaviour change.
49
50 231 Coaches will lead on the program content delivery and AEPs will be primarily responsible for
51
52 232 exercise safety. Practical activities and discussions are designed to help men understand why
53
54 233 and how to improve PA (e.g., understanding exercise intensities, safe strength training,
55
56 234 decreasing sedentary time) and dietary behaviours (e.g., interpreting food labels, portion sizes,
57
58
59
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1
2
3 235 meal planning, eating out), and incorporate behaviour change techniques to support participants
4
5 236 to adopt positive health behaviours in their daily lives. A range of PA intensities are promoted,
6
7 237 and ball skills and circuit training like those undertaken by professional players but modified
8
9 238 to be safe for each man's limitations (e.g., ball skill drills restricted to walking) undertaken.
10
11
12 239 Men are encouraged to self-monitor walking, gradually increasing steps/day throughout the 12-
13
14 240 weeks. The AEP will co-deliver the sessions and support the coach by monitoring participants
15
16 241 (e.g., blood pressure checks), providing advice on safe exercise and providing first aid, if
17
18 242 required. The waitlist control group (another 16 men from each club) will receive the program
19
20 243 6 months later.
21
22
23
24

25 244 **Description of the implementation strategy**

26
27
28 245 Our consumer advisory groups have supported the development of our implementation
29
30 246 strategies in the study set-up phase of this project, full details of which will be reported
31
32 247 elsewhere. The implementation study is structured by the RE-AIM framework (Reach,
33
34 248 Effectiveness, Adoption, Implementation, and Maintenance) (12).
35
36
37

38 249 Reach: Program recruitment strategies have been co-designed with men with or at risk of
39
40 250 cardiovascular disease (CVD). These strategies will be tailored for each State/Territory in
41
42 251 consultation with community advisory groups.
43
44
45

46 252 Effectiveness: Individual effectiveness outcomes will be tested via the RCT. Negative or
47
48 253 unintended consequences will also be documented.
49
50

51
52 254 Adoption: Clubs will be invited to offer formal commitments to continue deliveries pending
53
54 255 further funding opportunities in each State/Territory. An infrastructure and costing model will
55
56 256 be developed to support clubs in sustaining the program, and preferences for models of
57
58 257 sustained program deliveries will be co-designed with stakeholders.
59
60

1
2
3 258 Implementation: A comprehensive coach delivery package will support fidelity of program
4
5 259 delivery. This package includes 15 hours of training for the coaches, detailed program delivery
6
7
8 260 speaking notes, a timing guide, and rationales. Reusable teaching resources will also be
9
10 261 provided to support high-quality delivery. Implementation costs, such as coaches' time for
11
12 262 delivering and preparing for sessions, have been included in the program costing model.

13
14
15 263 Maintenance: Our nested SWAT will evaluate an automated enrolment strategy, designed to
16
17 264 improve program sustainability when fewer resources are available compared to the trial phase.
18
19 265 Resource sharing agreements will be developed, if required, to ensure the intervention
20
21 266 materials can continue to be used post-trial. Sustainability action plans will be developed with
22
23 267 stakeholders, including identifying suitable charities as delivery partners for ongoing program
24
25 268 deliveries. Indications of individual participant-level behaviour change maintenance will be
26
27 269 assessed at 12-months follow-up in the intervention group.

28
29
30 270 Throughout the implementation process, barriers and facilitators to implementation will be
31
32 271 identified (by stakeholders, including consumers and researchers) and targeted in future
33
34 272 modifications to the program. Interviews with stakeholders will be conducted to identify these
35
36 273 barriers and facilitators. Contextual adaptations required for the different States and Territories
37
38 274 will be documented and evaluated. These adaptations will be co-designed with our consumer
39
40 275 advisory groups to ensure contextual fit while preserving fidelity.

41 42 43 44 45 46 47 276 **Blinding and Randomisation**

48
49
50 277 It is not possible to blind participants to condition due to the nature of the intervention.
51
52 278 Data collectors will be blinded as far as possible. Questionnaire data will be completed online,
53
54 279 PA data will be device measured, and participants will be asked not to reveal whether they are
55
56 280 in the intervention or waitlist control arm, when objective measures of weight and blood
57
58 281 pressure are taken.

1
2
3 282 Aligned with the EuroFIT trial, we propose an individual randomisation for each club,
4
5 283 given the FFIT study confirmed that the minimal between-group contamination effects did not
6
7 284 warrant higher sample size and costs of a cluster trial. (10) Participants from each club (10
8
9 285 clubs, 32 participants per club) will be individually randomised (1:1 randomisation, in blocks
10
11 286 of 8 to reduce prediction of group allocation). A statistician generated the randomisation list
12
13 287 using the RANDBETWEEN (1,2) function using Excel. The statistician, who is not
14
15 288 involved in data collection, will not be told if group 1 or group 2 is the intervention arm to
16
17 289 assure blindness during the analyses. Following completion of baseline measures, trained
18
19 290 research assistants will use opaque, sealed envelopes to assign participants to intervention or
20
21 291 control arms.
22
23
24
25

26 292 **Primary outcome: Physical Activity**

27
28
29 293 Participants will also be asked to wear an Actigraph GTX9 (ActiGraph LLC, Pensacola,
30
31 294 FL) monitor continuously for 7-days on their non-dominant wrist at each data collection time-
32
33 295 point to provide a valid and reliable assessment of MVPA (29). The GT9X is a small
34
35 296 (3.5 × 3.5 × 1 cm), lightweight (14 g), and waterproof tri-axial accelerometer. The monitors
36
37 297 will be initialised to collect data at a 30hz sampling rate. Men will be provided with written
38
39 298 instructions for wearing the Actigraph.
40
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44 299 **Secondary Outcomes**

45
46
47 300 Secondary outcomes include dietary intake, weight, blood pressure, cholesterol, self-
48
49 301 esteem, affective states, quality of life, motivation for physical activity, and use of behaviour
50
51 302 change strategies targeted in the program. A full list of variables assessed and measurement
52
53 303 tools is included in Table 2.
54
55
56

57 304 **Implementation Outcomes**

1
2
3 305 Implementation outcomes will be reported using the RE-AIM (Reach, Effectiveness,
4
5 306 Adoption, Implementation, Maintenance) framework (21). Reach: we will report on the
6
7 307 number of participants interested and recruited; descriptive statistics of their
8
9 308 representativeness, using demographics (e.g., comorbidities, weight, socioeconomic status,
10
11 309 ethnicity) of those recruited in each locality; Effectiveness: as per description of intervention
12
13 310 outcomes and for effectiveness of implementation outcomes, with qualitative interview
14
15 311 findings; Adoption: records of adaptation to the intervention and implementation strategies
16
17 312 (between clubs, locations etc); Implementation: fidelity to key content (e.g., educational
18
19 313 messages) and functions (e.g., appropriate use of behaviour change techniques) via coding of
20
21 314 a subsample of deliveries; adaptations to delivery in each location, ascertained from
22
23 315 coach/participant interviews; barriers and facilitators to program implementation from
24
25 316 perspectives of coaches, administrators, and participants via interviews; Maintenance:
26
27 317 intentions to continue delivering the program (for clubs in this trial) and intentions to initiate
28
29 318 program delivery when further funding secured (new clubs),
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35

36 **Procedure**

37
38
39 320 Participants will book an appointment to attend baseline measures (detailed in Table 2)
40
41 321 at the football or rugby club. Measurement sessions will be led by a team of trained research
42
43 322 assistants. Participants will be asked to complete a survey, which will be presented to them on
44
45 323 an iPad using Qualtrics software. The self-administered survey will ask men demographic
46
47 324 questions including their age, ethnicity, education, marital status, current employment status,
48
49 325 income, and housing status. Weight, height and waist measurements will be taken by a trained
50
51 326 researcher. Cholesterol will be checked using a finger-prick test that measures non-fasting
52
53 327 cholesterol immediately. Participants will undertake a 24-hour dietary recall using the
54
55 328 Intake24, an open-source self-completed computerised dietary recall system based on multiple-
56
57 329 pass 24-hour recall. A trained interviewer will assist participants to complete the recall. The
58
59
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1
2
3 330 self-administered survey will also include items assessing alcohol content, and participants will
4
5 331 also be asked to respond to questions assessing their emotions (i.e., positive and negative
6
7
8 332 affect), quality of life, self-esteem, motivation to for PA and use of behaviour change strategies
9
10 333 taught in Aussie-FIT (automaticity, goal conflict, goal facilitation, coping planning, action
11
12 334 planning). Participants are asked to respond on Likert scales of 1-5 or 1-7. Participants can skip
13
14 335 questions if they prefer not to answer them. All questions have established psychometric
15
16 336 properties and have been used by the research team in studies with similar populations. The
17
18 337 questionnaire pack should take less than 30 minutes to complete. A trained research assistant
19
20 338 will be available to explain to participants how to complete the survey and to answer any
21
22 339 questions they may have during completion of the questionnaire. All participants will be
23
24 340 required to complete the Exercise and Sport Science Australia (ESSA): Adult Pre-Exercise
25
26 341 Screening System (APSS) (30) at the baseline measures session. ESSA stipulates that all
27
28 342 participants who answer 'yes' to a screening question should see an Allied Health Professional
29
30 343 or their general practitioner (GP). To reduce burden on participants of the need to attend a GP
31
32 344 appointment, an Accredited Exercise Physiologist (AEP) (or other equivalent allied health
33
34 345 professional) will review every participant's APSS form and discuss medical history with every
35
36 346 participant, to determine whether they are at risk from physical activity. Waitlist control group
37
38 347 participants will be re-screened at the assessment they attend prior to starting the program in
39
40 348 case of any change in health status from baseline.

41
42
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46
47
48 349 The full assessment process will usually take about 90 minutes. Following
49
50 350 randomisation, participants will be informed as to whether they will receive the 12-week
51
52 351 intervention immediately (i.e., the intervention arm) or ~6 months later (i.e., the waitlist control
53
54 352 group). Once the intervention arm participants have completed the program, the assessment
55
56 353 package will be repeated for both the control and intervention groups (3 months post baseline)
57
58 354 and then at 6 months post baseline. After the 6 months measures, the waitlist control arm will
59
60

1
2
3 355 complete the 12-week program. Finally, the intervention arm will be asked to attend one final
4
5 356 assessment, 12 months post baseline.
6
7
8

9 357 Where applicable, information regarding the participants' CVD diagnosis will be self-
10
11 358 reported or obtained from medical records. Participant attendance at the program will also be
12
13 359 recorded. At baseline, participants will be asked to tick yes or no to the question "in the future
14
15 360 we may wish to contact you to join a group or individual interview to talk about your
16
17 361 experiences in the program. Do you consent for us to contact you? Yes/No". Approximately
18
19 362 20 of those who tick 'yes', will be contacted by telephone or email at 6 months and/or 12
20
21 363 months, and invited to take part in an interview, which will be conducted on Microsoft Teams
22
23 364 videoconference or in person at the football/rugby club (depending on the person's preference).
24
25 365 Interview questions will be developed in collaboration with PhD candidates and an ethics
26
27 366 amendment will be submitted for approval prior to undertaking any interviews. Any changes
28
29 367 to protocol will be reported on the study Open Science Framework page (<https://osf.io/ev8px/>).
30
31
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33
34

35 368 **Treatment of Waitlist Control Arm**

36
37
38 369 All men will be directed to review evidence-based resources (i.e., Heart Foundation
39
40 370 online material) regarding PA and healthy eating after completion of the baseline assessments
41
42 371 and men in the waitlist control arm will be invited to participate in Aussie-FIT after the 6-
43
44 372 month post baseline assessment.
45
46
47

48 373 **Data Analyses**

49
50
51 374 Physical activity data will be downloaded via the ActiLife software (version 6.13.4),
52
53 375 where the raw accelerometer data will be processed in R using the GGIR V1.5-21 package
54
55 376 (cran.r-project.org/web/packages/GGIR/index.html) (31,32). Physical activity will be
56
57 377 estimated from 5-second epochs, with the average daily activity calculated. To be classified as
58
59
60

1
2
3 378 moderate to vigorous physical activity (MVPA) mean acceleration needs to be ≥ 100 milli-g
4
5 379 (mg) (33). Time in activities lasting at least 1 minute, for which 80% of the activity satisfied
6
7 380 the 100 mg threshold criteria, will be calculated. Average acceleration (calculated as the mean
8
9 381 acceleration across the 24-hour day as a proxy for the daily volume of PA) and intensity-
10
11 382 gradient (as a reflection of the distribution of intensity across the 24-hour day) will be
12
13 383 calculated (34,35). We will only include in the analysis those participants with four or more
14
15 384 valid days of accelerometry data, and at least 10 hours of wear time each day.

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19
20 385 De-identified objective measurements, questionnaire data and calculated PA data will
21
22 386 be exported to Stata software for analyses by an independent biostatistician blinded to the group
23
24 387 allocation. Characteristics of the participants will be summarised in mean (and standard
25
26 388 deviation) or median (and interquartile range) or frequency (and percentage), by treatment
27
28 389 groups. Program efficacy will be analysed following the intention-to-treat principle and per-
29
30 390 protocol approaches outlined below. Changes in the post-intervention outcomes will be
31
32 391 analysed using linear mixed effect regression models whilst controlling for the baseline
33
34 392 measures. Sensitivity analyses will also be performed to include covariates such as age, BMI,
35
36 393 types of comorbidities in the model to compare the beta coefficient of the models with and
37
38 394 without the covariates. If group sizes permit, sub-group analyses will be performed to examine
39
40 395 differences in intervention effects on primary and secondary outcomes between i)
41
42 396 States/Territories; ii) men diagnosed with and without a CVD diagnosis, iii) men with BMI
43
44 397 ≥ 25 and men with BMI < 25 ; and iii) men who identify as Aboriginal and Torres Strait Islander
45
46 398 and men who do not. Further details are available regarding data management and statistical
47
48 399 analysis plans on the project page of the Open Science Framework (<https://osf.io/ev8px/>).

400 **Sample Size Calculations**

1
2
3 401 320 men will be recruited: in WA (n=128), NT (n=96) and QLD (n=96), 160 per arm. This
4
5 402 estimate is based on observed changes in moderate-to-vigorous PA (MVPA) in the Aussie-FIT
6
7 403 pilot (11) and provides 90% power to detect a mean difference of 11-minutes/day (standard
8
9 404 deviation:27-minutes/day) of MVPA at 6-months (primary endpoint). The sample size
10
11 405 powered on MVPA because PA reduces CVD risk independently, and mitigates other risk
12
13 406 factors, such as high blood pressure (36). Change in MVPA of 5 minutes per day is considered
14
15 407 the minimum clinically important difference.(37) We allow for a trial attrition rate of 20%.

20 408 **Economic Evaluation**

23 409 We will use an economic model of the type developed in the Aussie-FIT pilot (11). The cost-
24
25 410 effectiveness analysis will be performed from a health system perspective. Costs will include
26
27 411 direct costs associated with the programme (including setting up and promotion) as well as
28
29 412 self-reported healthcare resource use. In terms of outcome measurement, we will include
30
31 413 short-term outcomes that will allow us to look at the cost per clinically relevant change in
32
33 414 MVPA (5 minutes per day, (37)) and cost per quality-adjusted life years (QALYs). The
34
35 415 QALY is the most widely used approach in economic evaluations for quantifying quality of
36
37 416 life gains (38). The EQ-5D-5L questionnaire will be used to assess quality of life (39), which
38
39 417 is a standardized measure of health status widely adopted in economic evaluations (40). The
40
41 418 EQ-5D-5L responses will be converted into a utility score using the most recent preference-
42
43 419 weights generated from an Australian general population sample (41). Self-reported data
44
45 420 relating to the number and type of health resources used will be collected at each
46
47 421 measurement point. Unit costs for visits to health professionals (GP, practice nurses,
48
49 422 physiotherapists etc) will be sourced from the Medical Benefits Schedule (42). Unit costs for
50
51 423 any inpatient stays and outpatient visits will be sourced from standard Australian public
52
53 424 sector hospital costs (43). Unit costs for prescriptions will be sourced from Pharmaceutical
54
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3 425 Benefits Schedule (PBS) (44). Given uncertainty around parameters such as unit costs and
4
5 426 utility values for calculating QALYs, we will undertake sensitivity analysis to check the
6
7 427 robustness of the estimates.
8
9

10 428 **Data Management**

11
12
13
14 429 Locked cabinets in the participating Universities will be used to store hard copy data and no
15
16 430 identifying information will be included. A file aligning ID codes with participants' identifying
17
18 431 information will be stored on the University server in a password-protected computer file. Only
19
20 432 members of the research team will be able to access the physical and electronic data files.
21
22
23

24 433 **Adverse Events**

25
26
27 434 Coaches will be instructed to report any adverse events during the program sessions to
28
29 435 the local trial co-ordinator, using a standardised form. Serious adverse events will be defined
30
31 436 as a medical event believed by the investigators to be attributable to participation in the Aussie-
32
33 437 FIT program, based on the participant's previous medical conditions and clinical presentation.
34
35
36 438 Participants will also be asked to report any adverse events to the coach.
37
38
39

40 439 **Ethics and Dissemination**

41
42
43 440 This multi-site study has been approved by the lead ethics committees in the lead site's
44
45 441 jurisdiction, the South Metropolitan Health Service Human Research Ethics Committee
46
47 442 (Reference RGS4254) and the West Australian Aboriginal Health Ethics Committee
48
49 443 (HREC1221). Reciprocal approvals have been sought from the relevant ethics bodies in the
50
51 444 partner site's jurisdictions. All participants will read an electronic participant information sheet
52
53 445 and offered a hard or electronic copy to keep. They will be asked to electronically indicate
54
55 446 consent before the program enrolment and will be offered a digital or paper copy of their
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3 447 consent form. The study will be disseminated to the academic community, via publication in
4
5 448 peer-review journals, presentations at conferences and reports.
6
7

8 449 **Discussion**

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11
12 450 In 2022, CVD was the leading cause of burden of disease in Australia, and this burden
13
14 451 is higher in males than females (45). Insufficient physical activity and poor diet are key
15
16 452 modifiable behavioural CVD risk factors. Pilot and feasibility studies of Aussie-FIT have
17
18 453 illustrated that the program is acceptable to men in WA, and feasible to deliver in AFL and
19
20 454 West Australian Football League clubs and rugby league clubs in QLD. Scale up of Aussie-
21
22 455 FIT in WA, and out to other States and Territories creates an opportunity to reduce primary
23
24 456 and secondary CVD risk among men with or at risk of CVD via modification of PA and dietary
25
26 457 behaviours. Via this hybrid effectiveness-implementation trial, we will determine whether the
27
28 458 program is effective in improving health and health behaviours in men who take part, and test
29
30 459 strategies to sustain longer term implementation of this program.
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460 **Abbreviations**

461 Aussie-FIT: Australian Fans in Training

462 FFIT: Football Fans in Training

463 BMI: Body mass index

464 CVD: Cardiovascular disease

465 MVPA: Moderate and vigorous physical activity

466 PA: Physical Activity

467 **Trial Registration**

468 The trial has been registered with Australian and New Zealand Clinical Trials Registry
469 (ACTRN12623000437662), prior to recruitment of the first participant (trial registration date
470 28 March 2023). Results will be written up and published and will be available in an open
471 access journal or via the Open Science Framework.

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475 **Author Contributions**

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

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2
3 481 protocols. TP, JMcV, and EQ designed the physical activity data analysis plan. SH, MDM, EQ,
4
5 482 DAK, and DK updated the intervention materials, with input from BB, JB, NW, TP, AM. EQ,
6
7 483 BS, AM, and MDM prepared the main ethics submission. EQ, BB, JS, and JB prepared the
8
9 484 trial procedures and ethics submission for involvement of men who identify as Aboriginal
10
11 485 and/or Torres Strait Islanders. MDM, BB, JS, and JB designed the project consumer
12
13 486 involvement strategies. HC conducted the power analysis and designed the statistical analysis
14
15 487 plan. MM designed the economic evaluation. TP, LW, JS and BB prepared ethics submissions
16
17 488 for reciprocal ethics from local State/Territory committees. EQ and MDM drafted the
18
19 489 manuscript and all authors read, edited, and approved the final version of the manuscript.
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3 **506 Tables and Figures**
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5 507 Table 1 – Intervention description aligned with the Template for Intervention Description
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Table 1. Intervention description aligned with the Template for Intervention Description and Replication (TIDieR) guidance

TIDieR Checklist Item

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

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

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

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

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2	Cholesterol	Cholesterol will be check using handheld point of care device (Accutrend Plus) that	X	X	X
3		measures cholesterol immediately.			
4	Self-reported measures (completed at the measurement sessions at football clubs or online in the participant's own time, depending on preference)				
5	Food intake	Intake24 is an open-source self-completed computerised dietary recall system based	X	X	X
6		on multiple-pass 24-hour recall. A trained interviewer will assist participants who			
7		may request assistance to complete the recall.[14, 15]			
8	Positive and negative	The Short Form of the positive and negative affect scale (PANAS) (46)	X	X	X
9	affect				
10	Self-esteem	The Rosenberg Self-Esteem (RSE) scale (47)	X	X	X
11	Quality of life	The health-related quality of life measured using the EQ-5D-5 L (39)	X	X	X
12					
13	Demographics	Age, ethnicity, education, marital status, current employment status, income, housing	X		
14		status			
15	Motivation	Motivation to be physically active (48)	X	X	X
16	Automaticity	The 'Self-Report Behavioural Automaticity Index' (49)	X	X	X
17	Goal conflict,	Goal conflict and goal facilitation scale (50)	X	X	X
18	facilitation				
19	Action and coping	Action planning and copying planning scale (51)	X	X	X
20	planning				
21	Self-reported programme evaluation measures				
22	Recruitment	How participants found out about the programme; programme uptake (number of	X		
23		people who expressed interest; number of people who fit inclusion criteria)			
24					
25	Programme evaluation:	Attendance to programme sessions and to measurement sessions; fidelity of			
26	via questionnaires and	programme delivery; perceptions of effectiveness and acceptability, assessed using			
27	interviews	the program evaluation questionnaire, which is adapted from the original Aussie-FIT			
28		program. Interviews with participants, coaches and AEPs will also provide further			
29		data on these points.			
30	Training evaluation: via	Coaches will evaluate the training provided to them by completing the coach training			
31	questionnaires and	evaluation questionnaire on completing their training. The interviews will also ask the			
32	interviews	coaches about their training.			
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39	<i>Note.</i> * and 12 months, for intervention group only				
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Table 3. Intervention content

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

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

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

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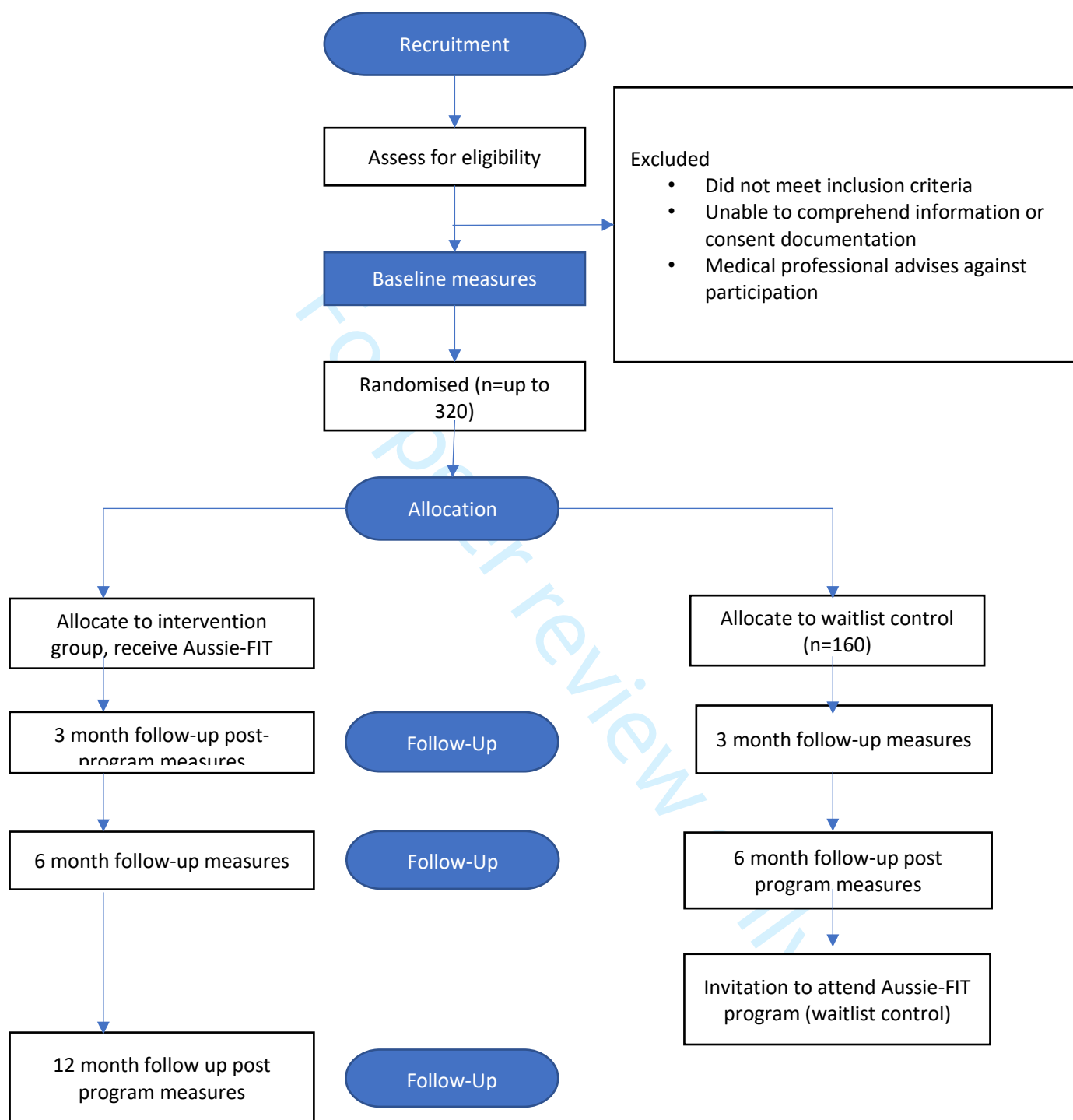
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Figure 1. Consort diagram of participant flow through the trial



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



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

Section/item	Item No	Description	Page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	7
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 20-21
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
	6b	Explanation for choice of comparators	16

1				
2	Objectives	7	Specific objectives or hypotheses	6
3				
4				
5	Trial design	8	Description of trial design including type of trial (eg,	7
6			parallel group, crossover, factorial, single group),	
7			allocation ratio, and framework (eg, superiority,	
8			equivalence, noninferiority, exploratory)	
9				
10				
11	Methods: Participants, interventions, and outcomes			
12				
13	Study setting	9	Description of study settings (eg, community clinic,	7
14			academic hospital) and list of countries where data will be	
15			collected. Reference to where list of study sites can be	
16			obtained	
17				
18	Eligibility	10	Inclusion and exclusion criteria for participants. If	8-9
19	criteria		applicable, eligibility criteria for study centres and	
20			individuals who will perform the interventions (eg,	
21			surgeons, psychotherapists)	
22				
23				
24	Interventions	11a	Interventions for each group with sufficient detail to allow	10-11, 31-33
25			replication, including how and when they will be	
26			administered	
27				
28				
29		11b	Criteria for discontinuing or modifying allocated	N/A
30			interventions for a given trial participant (eg, drug dose	
31			change in response to harms, participant request, or	
32			improving/worsening disease)	
33				
34		11c	Strategies to improve adherence to intervention protocols,	14-15
35			and any procedures for monitoring adherence (eg, drug	
36			tablet return, laboratory tests)	
37				
38				
39		11d	Relevant concomitant care and interventions that are	N/A
40			permitted or prohibited during the trial	
41				
42	Outcomes	12	Primary, secondary, and other outcomes, including the	13-14
43			specific measurement variable (eg, systolic blood	
44			pressure), analysis metric (eg, change from baseline, final	
45			value, time to event), method of aggregation (eg, median,	
46			proportion), and time point for each outcome. Explanation	
47			of the clinical relevance of chosen efficacy and harm	
48			outcomes is strongly recommended	
49				
50				
51	Participant	13	Time schedule of enrolment, interventions (including any	14-15
52	timeline		run-ins and washouts), assessments, and visits for	
53			participants. A schematic diagram is highly recommended	
54			(see Figure)	
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2	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	17
3				
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6				
7	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9-10
8				
9				

Methods: Assignment of interventions (for controlled trials)

Allocation:

14	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12-13
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24	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	13
25				
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30	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13-14
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32				
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34	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
35				
36				
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39		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
40				
41				
42				

Methods: Data collection, management, and analysis

45	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13-16, 35-38
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56		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	
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2	Data	19	Plans for data entry, coding, security, and storage,	17
3	management		including any related processes to promote data quality	
4			(eg, double data entry; range checks for data values).	
5			Reference to where details of data management	
6			procedures can be found, if not in the protocol	
7				
8	Statistical	20a	Statistical methods for analysing primary and secondary	16-17
9	methods		outcomes. Reference to where other details of the	
10			statistical analysis plan can be found, if not in the protocol	
11				
12				
13		20b	Methods for any additional analyses (eg, subgroup and	17
14			adjusted analyses)	
15				
16				
17				
18		20c	Definition of analysis population relating to protocol non-	17
19			adherence (eg, as randomised analysis), and any	
20			statistical methods to handle missing data (eg, multiple	
21			imputation)	
22				
23	Methods: Monitoring			
24				
25	Data	21a	Composition of data monitoring committee (DMC);	N/A
26	monitoring		summary of its role and reporting structure; statement of	
27			whether it is independent from the sponsor and competing	
28			interests; and reference to where further details about its	
29			charter can be found, if not in the protocol. Alternatively,	
30			an explanation of why a DMC is not needed	
31				
32				
33		21b	Description of any interim analyses and stopping	N/A
34			guidelines, including who will have access to these interim	
35			results and make the final decision to terminate the trial	
36				
37				
38	Harms	22	Plans for collecting, assessing, reporting, and managing	18
39			solicited and spontaneously reported adverse events and	
40			other unintended effects of trial interventions or trial	
41			conduct	
42				
43	Auditing	23	Frequency and procedures for auditing trial conduct, if	N/A
44			any, and whether the process will be independent from	
45			investigators and the sponsor	
46				
47				
48	Ethics and dissemination			
49				
50	Research	24	Plans for seeking research ethics committee/institutional	18-19
51	ethics		review board (REC/IRB) approval	
52	approval			
53				
54	Protocol	25	Plans for communicating important protocol modifications	16
55	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	
56			relevant parties (eg, investigators, REC/IRBs, trial	
57			participants, trial registries, journals, regulators)	
58				
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2	Consent or	26a	Who will obtain informed consent or assent from potential	14
3	assent		trial participants or authorised surrogates, and how (see	
4			Item 32)	
5				
6		26b	Additional consent provisions for collection and use of	N/A
7			participant data and biological specimens in ancillary	
8			studies, if applicable	
9				
10	Confidentiality	27	How personal information about potential and enrolled	14-16
11			participants will be collected, shared, and maintained in	
12			order to protect confidentiality before, during, and after the	
13			trial	
14				
15				
16	Declaration of	28	Financial and other competing interests for principal	21
17	interests		investigators for the overall trial and each study site	
18				
19	Access to data	29	Statement of who will have access to the final trial dataset,	18
20			and disclosure of contractual agreements that limit such	
21			access for investigators	
22				
23				
24	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and for	N/A
25	post-trial care		compensation to those who suffer harm from trial	
26			participation	
27				
28	Dissemination	31a	Plans for investigators and sponsor to communicate trial	19
29	policy		results to participants, healthcare professionals, the	
30			public, and other relevant groups (eg, via publication,	
31			reporting in results databases, or other data sharing	
32			arrangements), including any publication restrictions	
33				
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35		31b	Authorship eligibility guidelines and any intended use of	N/A
36			professional writers	
37				
38		31c	Plans, if any, for granting public access to the full protocol,	N/A
39			participant-level dataset, and statistical code	
40				
41				
42	Appendices			
43				
44	Informed	32	Model consent form and other related documentation	N/A
45	consent		given to participants and authorised surrogates	
46	materials			
47				
48	Biological	33	Plans for collection, laboratory evaluation, and storage of	N/A
49	specimens		biological specimens for genetic or molecular analysis in	
50			the current trial and for future use in ancillary studies, if	
51			applicable	
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*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

Supplementary File 2.

Standards for Reporting Implementation Studies: the StaRI checklist for completion



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

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

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

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

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

Table with 5 columns: Checklist item, Reported on page #, Implementation Strategy, Reported on page #, Intervention. Rows include Title and abstract, Title, Abstract, and Introduction.

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

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

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For peer review only