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# BMJ Open

## A randomised controlled trial of interventions to promote adoption and maintenance of physical activity in adults with mental illness

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Manuscripts

1  
2  
3 1 **TITLE PAGE**

4 2 **Title: A randomised controlled trial of interventions to promote adoption and**  
5 3 **maintenance of physical activity in adults with mental illness**

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33 29

## 30 **ABSTRACT**

31 *Introduction:* Physical activity (PA) has diverse benefits for physical and mental health and  
32 can reduce symptoms of mental illness. Adults with mental illness face practical,  
33 psychosocial and socioeconomic barriers to adopting and maintaining PA, and it is unclear  
34 how to effectively promote PA in this group. Supervised exercise interventions provide high  
35 support but may not promote autonomous motivation, which is important for PA  
36 maintenance. The aim of this study is to compare the effectiveness of two interventions to  
37 promote PA in adults with mental illness.

38 *Methods and analysis:* This is a randomised controlled trial of two interventions to promote  
39 PA: (1) supervised exercise and gym membership (GYM), and (2) motivational discussions  
40 and self-monitoring of PA using fitness trackers (MOT). The intervention duration is 16-  
41 weeks, including 8-weeks of weekly supervised group sessions, and 8-weeks of access to the  
42 gym or fitness tracker unsupervised. Participants are community-dwelling adults recruited  
43 from outpatient clinics of public mental health services. The primary outcome is PA adoption  
44 assessed using GENEActiv accelerometers worn continuously over 8-weeks. Secondary  
45 outcomes measured at baseline, post-intervention (8 weeks) and follow-up (16 weeks),  
46 include exercise motivation, psychological distress and self-reported PA assessed using self-  
47 administered questionnaires, and indicators of physical health measured by a researcher  
48 blinded to allocation (blood pressure, weight, waist circumference, six-minute walk test).  
49 Participant experiences will be assessed using qualitative focus groups with analysis  
50 informed by a theoretical model of behaviour (COM-B).

51 *Ethics and Dissemination:* Ethics approval has been obtained from the Royal Brisbane and  
52 Women's Hospital (HREC/17/QRBW/302).

53 *Registration details:* The trial is registered under the Australian and New Zealand Clinical  
54 Trial Registry (ACTRN12617001017314).

### 55 **Strength and Limitations of this study**

- 56 • This study uses a robust methodological design, and the interventions are based on  
57 theoretical model of behaviour to enhance interpretation and generalisability of  
58 findings.
- 59 • An objective measure of physical activity (PA) is used continuously during the  
60 intervention to allow reliable assessment of PA behaviour change.

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- 61 • Recruitment will be non-probabilistic, so the resulting cohort may not be a
- 62 representative sample of adults receiving public mental health services.
- 63 • Use of a self-report measure of PA during the follow-up period limits assessment of
- 64 PA maintenance.

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## 67 INTRODUCTION

68 The benefits of physical activity (PA) for mental and physical health are widely  
69 recognised.[1] PA and exercise (PA to enhance or maintain fitness) can improve metabolic  
70 risk factors, protect against chronic physical conditions such as cardiovascular disease, and  
71 improve psychosocial wellbeing and longevity.[2, 3] The World Health Organisation PA  
72 guidelines are to accumulate 150-300 minutes per week of moderate-to-vigorous activity.[4]  
73 About a third of the population globally do not meet these guidelines, with inactivity more  
74 prevalent in high income countries.[5] Policy initiatives and public health campaigns to  
75 increase PA can be effective;[6] however, research has highlighted the importance of  
76 targeting campaigns to specific sub-groups,[7] and people experiencing socioeconomic and  
77 psychosocial barriers may need more focused support to adopt and maintain an active  
78 lifestyle.[8]

79 One such population group is adults with mental illness. This group are at higher risk of  
80 developing cardiovascular and metabolic conditions,[9] and have lower levels of PA[10] than  
81 the general population. In addition to the acknowledged physical and psychosocial benefits of  
82 PA, PA can reduce symptoms of depression,[11] anxiety,[12] and schizophrenia,[13] and  
83 improve quality of life in adults with mental illness.[14] Adults with mental illness face  
84 complex barriers to adopting and maintaining an active lifestyle: social isolation, medication  
85 side-effects, and illness symptoms are among many factors that have been described as  
86 hindering PA behaviour change.[15] PA intervention studies have demonstrated  
87 feasibility[16] and are associated with improved health outcomes;[14] however, little is  
88 known about how effective such interventions are at influencing PA outside supervised  
89 sessions, which is important for maintaining health benefits.[17] Given the potential for PA  
90 to improve health and wellbeing in this group, the implementation of interventions to  
91 promote PA in mental health services is increasingly advocated.[18, 19]

92 Research has highlighted the importance of autonomous motivation in adoption and  
93 maintenance of PA for adults with mental illness.[20] Cross-sectional studies indicate that the  
94 motivational mechanisms that influence PA behaviour in adults with mental illness are not  
95 dissimilar to the general population, and are independent of psychiatric diagnosis and  
96 medication use,[21] indicating that established behaviour change theories are generalisable to  
97 this group. However, the importance of tailoring interventions to focus on the specific  
98 barriers and facilitators experienced by adults with mental illness has been emphasised.[8]  
99 The few studies of interventions to improve PA motivation in adults with mental illness have

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3 100 not based their evaluation on a theoretical model of behaviour, which is critical for  
4 101 understanding potential mechanisms of behaviour change, or have not related motivational  
5 102 outcomes to PA behaviour to examine potential causal relationships.[22] There is a need for  
6 103 theory-based empirical evidence on how to positively impact PA motivation and behaviour in  
7 104 adults with mental illness.

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11 105 The Behaviour Change Wheel (BCW) framework is an overarching model of behaviour  
12 106 which can be used to design and evaluate behaviour change interventions with the view of  
13 107 improving adherence and effectiveness.[23] The BCW identifies nine ‘intervention functions’  
14 108 that potentially influence any given target behaviour, and explains behaviour change through  
15 109 the COM-B model, in which capability (C), opportunity (O), and motivation (M) interact to  
16 110 generate behaviour (B).[23] Motivation and Capability are facets of the individual (physical  
17 111 and psychological capabilities; reflective and automatic motivations), and Opportunity  
18 112 encompasses factors outside the individual that prompt or enable the behaviour. Evaluating  
19 113 and comparing different interventions using this theoretical behavioural framework will  
20 114 provide valuable insight into effectiveness and mechanisms of action of interventions  
21 115 designed to promote PA in adults with mental illness.

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30 116 The range of interventions that might promote PA is diverse, in that different combinations of  
31 117 intervention functions can be used to impact capability, opportunity and motivation. Trials  
32 118 designed to assess the efficacy of exercise on health outcomes for adults with mental illness  
33 119 have typically focused on supervised exercise interventions. Supervised exercise  
34 120 interventions provide opportunity (e.g. access to exercise facility and professional instruction)  
35 121 and motivation (e.g. via first-person mastery) but may not impact psychological capability  
36 122 (e.g. problem-solving barriers) or optimally address motivation. The application of behaviour  
37 123 change techniques may more directly address motivation and capability. Research suggests  
38 124 that, of the multitude of behaviour change techniques,[24] interventions involving self-  
39 125 monitoring of PA combined with other self-regulatory techniques (e.g. goal setting) may be  
40 126 more effective than interventions without these techniques.[25] Self-monitoring using  
41 127 electronic activity monitor systems (commonly known as fitness trackers) can increase PA  
42 128 and assist with weight management,[26] and has potential for use with clinical groups;[27]  
43 129 however, acceptability and effectiveness is yet to be established in adults with mental illness.  
44  
45 130 To our knowledge, no studies have compared interventions to promote PA via supervised  
46 131 exercise or a combination self-monitoring and other behaviour change techniques among  
47 132 adults with mental illness.

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3 133 To address limitations of previous research and inform practice, the aim of this study is to  
4 134 compare the effectiveness of two interventions designed to promote PA in adults with mental  
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6 135 illness: a supervised exercise intervention, and a motivational intervention involving self-  
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8 136 monitoring of PA. While both interventions may increase PA, for study purposes, the  
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10 137 hypothesis is that the motivational intervention will have a greater impact on PA adoption  
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12 138 than the supervised exercise intervention. Secondary aims are to evaluate acceptability and  
13  
14 139 participants' experiences of the interventions and explore potential mechanisms of action  
15  
16 140 using the BCW and COM-B behaviour system as a frame.

## 17 141 **METHODS AND ANALYSIS**

### 18 142 **Study design**

19  
20 143 This is a two-arm, parallel group, randomised controlled trial of interventions designed to  
21  
22 144 promote adoption and maintenance of PA among adults with mental illness.

### 23 145 **Setting and participants**

24  
25 146 Participants will be recruited from outpatient clinics of public mental health services in  
26  
27 147 Brisbane, Australia (Metro North Mental Health, and Metro South Addictions and Mental  
28  
29 148 Health). These services provide specialist treatment for approximately two million residents  
30  
31 149 of a catchment encompassing inner city, suburban, and regional areas; approximately 15,000  
32  
33 150 patients are open to the services each year. The study will be promoted across services at  
34  
35 151 clinical team meetings, and staff will be asked to refer potentially eligible clients to the  
36  
37 152 research team.

38  
39 153 Following referral, researchers will contact potential participants to provide information and  
40  
41 154 screen for eligibility. Individuals will be eligible if they are a current outpatient of either  
42  
43 155 mental health service, aged 18-65 years, sufficiently fluent in English to complete consent  
44  
45 156 and study procedures, and willing to provide consent to study participation. Exclusion criteria  
46  
47 157 are: i) receiving treatment for an eating disorder; ii) self-reporting more than 300 minutes of  
48  
49 158 moderate-to-vigorous activity in the previous week; and iii) reporting medical risk factors  
50  
51 159 assessed using the Adult Pre-exercise Screening System (APSS)[28] without clearance for  
52  
53 160 participation from a medical practitioner. Screening will involve assessment of PA using an  
54  
55 161 adapted version of the Active Australia questionnaire,[29] which asks about time spent in  
56  
57 162 walking, moderate and vigorous activities in the previous week.

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59 163 The researchers will make arrangements to meet eligible individuals who are interested in  
60  
61 164 participation at the intervention venue to obtain written informed consent for study



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3 165 participation, and to complete the baseline assessments. The interventions will be delivered at  
4 166 gymnasium and community facilities of Queensland Police-Citizens Youth Welfare  
5 167 Association (PCYC Queensland). PCYC Queensland is an established state-wide not-for-  
6 168 profit organisation that offers sport and recreational activities and community development  
7 169 initiatives.[30]

#### 11 170 *Randomisation*

12 171 After completing baseline assessments, a researcher not directly involved with study delivery  
13 172 (MB) will allocate participants in a 1:1 ratio using block randomisation (block size of two),  
14 173 using a random sequence generated at randomizer.org. Participants will be advised of  
15 174 allocation by telephone prior to the first group session.

#### 19 20 21 175 **Intervention procedure**

22 176 The study groups will be manualised motivational (MOT) or gym exercise (GYM)  
23 177 interventions. Both interventions are designed to enhance capability, opportunity and  
24 178 motivation to do PA, using intervention functions identified in the Behaviour Change Wheel  
25 179 (Table 1). Interventions are 16 weeks in duration, comprising two 8-week blocks: a  
26 180 supervised group-based component and an 8-week unsupervised component absent of  
27 181 researcher contact or group sessions.

28 182

**Table 1: Description of intervention functions and behaviour change techniques used in the interventions**

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**Gym exercise intervention (GYM)**

**Capability**

*Physical capability*

- *Training*: Verbal instruction [BCT21] and demonstration [BCT22] of different exercises by the AEP. Participants then complete the exercises with technique correction from the AEP [not coded].

**Opportunity**

*Physical opportunity*

- *Enablement*: Provision of access to exercise facility [not coded] and providing information on where and when to exercise (i.e. at the gym during opening times for supervised and unsupervised sessions) [BCT20].

*Social opportunity*

- *Environmental restructuring*: Exercise sessions delivered in groups.

**Motivation**

*Reflective*

- *Education* about purpose and general health consequences of specific exercises [BCT1], e.g. to improve posture, core stability, interval training.

*Automatic*

- *Environmental restructuring*: Self-monitoring of exercises completed for supervised and unsupervised sessions [BCT16].
- 

**Motivational intervention (MOT)**

**Capability**

*Psychological capability*

- *Training*: Identifying and problem-solving barriers to PA [BCT8]. Problem solving strategies include using: social support [BCT29], prompts/cues such as reminders [BCT23], environmental prompts such as getting exercise clothes ready [BCT24], use of imagery [BCT34], identifying negative self-talk and replacing with positive self-talk [BCT33], establishing routine [not coded].
  - *Education*: Explanation and demonstration of strength training exercises that can be done at home [BCT21&22].
-

- *Education* about the processes of behaviour change [not coded], including stages of change, and internal and external motivation.

### **Opportunity**

#### *Physical opportunity*

- *Environmental restructuring*: Provision of fitness tracker which provides summary feedback about activity.

#### *Social opportunity*

- *Environmental restructuring*: Exercise sessions delivered in groups.

### **Motivation**

#### *Reflective*

- *Education* about: i) the general health consequences of PA and inactivity [BCT1], and ii) health consequences specific to adults with mental illness [BCT2], such as reducing mental illness symptoms, countering medication side-effects, and preventing physical illnesses with high prevalence in this group.
- *Persuasion*: Behavioural goal setting [BCT5] and setting graded weekly tasks [BCT9] in Week 1. Reviewing progress and reassessing goals [BCT10] each week. Refining goals in subsequent weeks, by: identifying preferred available community opportunities (e.g. activity groups; walking routes etc.) [BCT20], and action planning for PA in contexts of commuting, leisure, occupational and incidental activity [BCT7].

#### *Automatic*

- *Environmental restructuring*: Daily self-monitoring of PA behaviour [BCT16] using objective methods (the Garmin device) and self-report (activity log).

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183 Note: Behaviour change techniques have been coded as [BCT] and numbered from the  
184 CALO-RE taxonomy;<sup>[24]</sup> techniques not listed in this taxonomy have been specified as [not  
185 coded].

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3 187 Supervised components of both MOT and GYM interventions involve one 60-minute  
4 188 session/week at a PCYC facility located near recruitment site, in groups of up to 10  
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6 189 participants. The GYM intervention will be delivered by an accredited exercise physiologist  
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8 190 (AEP); the MOT intervention will be delivered by personnel with a tertiary qualification in a  
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10 191 health-related field (e.g. physiology, public health). The AEP and MOT facilitators will  
11  
12 192 attend group sessions for GYM and MOT interventions. Participants will be sent weekly text  
13  
14 193 message reminders about the group session times, with phone follow-up if sessions are  
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16 194 missed without explanation. Structure and content of the interventions is summarised below.

16 195 *Motivational intervention (MOT)*

17  
18 196 Participants will be provided Garmin Vivofit 3 devices for use over the 16-week intervention.  
19  
20 197 This device provides real-time feedback about daily steps, distance walked, energy  
21  
22 198 expenditure and time spent in moderate-to-vigorous activity per week ('intensity minutes'). A  
23  
24 199 printed summary of weekly activity from the Garmin will be provided to participants at group  
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26 200 sessions. During the initial 8-weeks, participants will be asked to:

- 26 201 (1) Attend weekly structured group motivational sessions, comprising a 10-min discussion  
27  
28 202 about progress towards goals in the previous week, 20-min discussion of PA guidelines  
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30 203 and a health-related topic, 20-min 'motivational exercise', and 10-min revision of goals  
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32 204 for the coming week.  
32 205 (2) Complete a daily log of step count and 'intensity minutes' as displayed on the Garmin  
33  
34 206 device, and self-reported time spent active in contexts: commuting, solo aerobic exercise,  
35  
36 207 community PA groups, and strength training.

37 208 *Gym exercise intervention (GYM)*

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39 209 Participants will be provided 16-week gym memberships at no cost. During the initial 8-  
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41 210 weeks, participants will be asked to:

- 42 211 (1) Attend weekly structured group exercise sessions and attend the gym at least once  
43  
44 212 unsupervised to repeat exercises from the supervised session. Sessions are based on  
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46 213 PCYC's 'Healthy Bodies, Healthy Minds' program (HBHM), which progressively  
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48 214 introduces exercises to equip participants with the knowledge and confidence to develop  
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50 215 an exercise program based on personal abilities and preferences, in consultation with an  
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52 216 AEP. The weekly group sessions comprise a 10-min discussion of specified exercise  
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54 217 topics, 20-min of aerobic exercise (continuous or interval training) on machine of  
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56 218 participants' choice (treadmill, stationary bike, elliptical trainer, or rowing machine) at

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3 219 an intensity such that talking becomes difficult (i.e. 'talk test'), and 30-min of resistance  
4 220 training (two sets of 10-15 reps, for a variety common exercises).  
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6 221 (2) Record variables of completed exercise sessions (weight, sets and repetitions for  
7 222 resistance exercises, heart rate measured using heart rate monitors on exercise machines,  
8 223 and rate of perceived exertion achieved during aerobic exercise).  
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#### 11 224 **Intervention consistency**

12  
13 225 Facilitators will be required to familiarise themselves with the manual, and score 100% on a  
14 226 quiz about content, session structure and style of delivery as applicable for GYM and MOT  
15 227 interventions. Session monitoring sheets specifying content of each group session will be  
16 228 printed on a hardcopy A4 sheet, and facilitators will be required to mark each component  
17 229 completed at each session. They will also be asked to document any challenges to  
18 230 implementation of the manualised intervention and responses/feedback provided by  
19 231 participants. Session monitoring sheets will be reviewed by the study team as a record of the  
20 232 content delivered consistent with the manual.  
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#### 26 233 **Data collection**

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28 234 Participant information and outcome measures will be collected as summarised in the  
29 235 schedule of assessments (Table 2). Participants will be offered gift cards for completing  
30 236 assessments at each timepoint: AUD\$20 at baseline, AUD\$30 at post-intervention, and  
31 237 AUD\$40 at follow-up. Post-intervention assessments will be administered by a researcher  
32 238 blind to participant allocation. All participants will be invited to complete the post-  
33 239 intervention assessments regardless of continuation with the intervention.  
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**Table 2: Schedule of assessments**

	Enrolment		Baseline		Post-allocation	
	$-t_3$	$-t_2$	$-t_1$	$t_0$	$t_8$	$t_{16}$
<b>INTERVENTIONS</b>						
Motivation intervention				←→		
Gym exercise intervention				←→		
<b>INTAKE</b>						
<i>Eligibility screen</i>	X					
<i>Informed consent</i>		X				
<i>Participant characteristics</i>		X				
<i>Allocation</i>				X		
<b>ASSESSMENTS</b>						
<i>Accelerometry</i>		←→			←→	
<i>K6</i>			X		X	X
<i>BREQ-3</i>			X		X	X
<i>SIMPAQ</i>			X		X	X
<i>Stage of change</i>			X		X	
<i>Physical health measures</i>			X		X	
<i>Focus groups</i>						X

**241 Recommendations for Interventional Trials (SPIRIT) Figure**

242  $-t_3$  = completed upon referral;  $-t_2$  = initial baseline assessment;  $-t_1$  = final baseline assessment;  $t_0$  =  
243 randomisation (week 0);  $t_8$  = post-intervention assessments (week 8);  $t_{16}$  = follow-up assessments  
244 (week 16); K6 = Kessler-6 scale of psychological distress; BREQ-3 = Behavioural Regulation in  
245 Exercise Questionnaire; SIMPAQ = Simple Physical Activity Questionnaire.

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3 246 *Participant characteristics*

4 247 Mental health clinicians (psychiatrist or case manager) will be asked to provide psychiatric  
5 248 diagnosis (ICD-10 codes obtained from hospital records) at referral. Participant baseline  
6 249 characteristics will be assessed using questionnaire items on health and sociodemographic  
7 250 information (medications, education, employment, income management, sex, gender identity,  
8 251 ethnicity), PA attitudes (preference for PA type and satisfaction with current PA level),  
9 252 current and previous use of PA self-monitoring devices (smartphone health apps, pedometers  
10 253 and fitness trackers). Intervention preference will also be assessed (*'Given what you know  
11 254 about the study conditions, which one would you prefer?'*).

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17 255 *Outcome measures*

18 256 *Accelerometry:* Physical activity will be objectively measured using GENEActiv Original  
19 257 accelerometers (GENEActiv, Activinsights Ltd, Kimbolton, UK). GENEActiv monitors are  
20 258 waterproof devices, similar in appearance to a wristwatch, requiring no user input. They  
21 259 measure motion-related and gravitational acceleration using a triaxial microelectromechanical  
22 260 systems (MEMS) accelerometer, light exposure using a photodiode, and temperature using a  
23 261 thermistor. The sampling frequency will be set at 10Hz to extend the battery life to up to 60  
24 262 days. The monitors do not provide feedback about PA, limiting the potential for  
25 263 reactivity.[31, 32] Participants will be asked to wear monitors on their non-dominant wrist  
26 264 but will be offered waist or upper-arm band as alternatives if wrist-wear is not possible (e.g.  
27 265 because of discomfort or impracticality). To assess baseline habitual PA, participants will be  
28 266 asked to wear GENEActiv monitors 24 hours/day for seven consecutive days prior to  
29 267 beginning the intervention. To assess PA adoption, participants will be asked to wear  
30 268 GENEActiv monitors continually during the 8-week intervention (9 weeks total monitor  
31 269 wear).

32 270 *Behavioural Regulation in Exercise Questionnaire (BREQ-3):* The BREQ-3 comprises 24  
33 271 items to assess amotivation, and external, introjected, identified, integrated and intrinsic  
34 272 behavioural regulations.[33] The BREQ-3 has high test-retest reliability ( $\rho=0.78-0.84$  for  
35 273 regulation constructs), and has been shown to be moderately predictive of exercise  
36 274 participation ( $R^2=0.25$ )[33] consistent with behavioural theory that suggests motivation  
37 275 influences behaviour.

38 276 *Stages of change:* A 5-item stages of change questionnaire based on the transtheoretical  
39 277 model will be used for four activities: active commuting, community activity groups, solo  
40 278 aerobic exercise and strength training. Participants chose one of five options: *I don't do this*

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3 279 *kind of activity and I don't intend to start* (pre-contemplation); *I don't do this kind of activity*  
4 280 *but I'm thinking about starting* (contemplation); *I occasionally do this kind of activity*  
5  
6 281 *(preparation); I do this kind of activity regularly and started in the last 6 months* (action); and  
7  
8 282 *I do this kind of activity regularly and have been for longer than 6 months* (maintenance).

9  
10 283 *Kessler-6 scale (K6)*: The K6 is a self-administered questionnaire assessing frequency of six  
11 284 symptoms of distress (*nervous, hopeless, restless or fidgety, so sad that nothing could cheer*  
12 285 *you up, that everything was an effort, worthless*) experienced in the past month using a 5-  
13 286 point Likert scale. The K6 has been shown to have high internal consistency and reliability  
14  
15 287 (Cronbach's alpha=0.89),[34] and total classification accuracy was 0.92 (SD=0.02) when  
16  
17 288 discriminating cases of serious mental illness from non-cases.[35]

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20 289 *Simple Physical Activity Questionnaire (SIMPAQ)*: SIMPAQ is a researcher-administered  
21 290 self-report questionnaire assessing time spent in bed, sitting or lying down, napping during  
22 291 the day, walking, structured exercise, and incidental activities completed in the previous  
23 292 week.[36] Psychometrics of SIMPAQ are currently being assessed in an international  
24 293 validation study.

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28 294 *Physical health*: Indicators of physical health will be blood pressure measured using an  
29 295 automatic sphygmomanometer (Omron HEM-7302) after at least five minutes rest, waist  
30 296 circumference measured to the nearest 1 cm using a tape measure, height measured to the  
31 297 nearest 0.1 cm using a stadiometer, and weight measured to the nearest 0.01 kg using  
32 298 electronic scales (Charder MS 6111). Physical capacity will be measured using the 6-minute  
33 299 walk test (6MWT) which is a submaximal test to assess functional capacity commonly used  
34 300 with adults with mental illness.[37] Standardised instructions and encouragement will be  
35 301 provided each minute consistent with guidelines.[38]

#### 32 302 *Process evaluation*

33 303 Feasibility and acceptability of the interventions will be examined in an embedded process  
34 304 evaluation. Feasibility of the interventions will be assessed using intervention costs  
35 305 (intervention equipment, staff time), referral and uptake rates, adherence (attendance at group  
36 306 sessions assessed by the researcher; attendance at unsupervised sessions assessed using self-  
37 307 report), completion rate, and reasons for non-completion. Acceptability and potential  
38 308 mechanisms of action will be examined using semi-structured focus group discussions of  
39 309 participants' experiences with the study and interventions.

#### 35 310 **Data management**



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3 311 Questionnaires will be administered electronically using the online survey platform Qualtrics  
4 312 (Qualtrics, Provo, UT); data will be exported into SPSS version 23 (SPSS Inc, Chicago,  
5 313 Illinois) for analysis. GENEActiv accelerometer data will be downloaded at completion of  
6 314 baseline and intervention monitoring periods and analysed in Matlab 2016a (The MathWorks,  
7 315 Inc., Natick, Massachusetts, United States). Garmin Vivofit 3 devices allow access to internet  
8 316 and smartphone accounts which provide detailed feedback, social networking and other  
9 317 functionality; however, participants will not be given access to these accounts.

### 14 318 **Data pre-processing**

15 319 Raw GENEActiv accelerometer data will be converted into 60 second epochs. Data will be  
16 320 considered valid if the accelerometer was worn for at least 80% of waking hours[39] on at  
17 321 least four days of the week including at least one weekend day.[40] Consistent with previous  
18 322 research, non-wear time will be defined as  $\geq 90$  minutes with a 20-minute forward-moving  
19 323 standard deviation  $\leq 0.05$ . [41] Waking hours will be defined using a validated algorithm that  
20 324 uses arm angle inactivity to determine sleep periods.[42] Moderate-to-vigorous activity will  
21 325 be defined using validated thresholds.[43] Accelerometer-derived MVPA at baseline and for  
22 326 each week of the study period will be plotted for visual comparison. Questionnaire data will  
23 327 be scored consistent with the questionnaire guidelines. A relative autonomy index will be  
24 328 calculated from the BREQ-3 questionnaire, indicating the degree to which respondents feel  
25 329 self-determined.

### 34 330 **Data Analysis**

#### 35 331 *Hypothesis testing*

36 332 The hypothesis will be tested using multiple linear regression analyses (MLRA). PA adoption  
37 333 will be calculated as the cumulative change in accelerometer-derived moderate-to-vigorous  
38 334 activity between baseline and post-intervention (e.g. area under curve). PA adoption will be  
39 335 used as the dependent variable. Independent variables will include study condition (MOT or  
40 336 GYM), adherence (high or low attendance), and baseline relative autonomy indices.  
41 337 Participant baseline characteristics will be compared between groups, and analyses adjusted  
42 338 for any significant differences. Analyses will be conducted using an intention-to-treat  
43 339 approach.

#### 44 340 *Sample size*

45 341 We anticipate that a sample of 150 participants will afford the opportunity to robustly test the  
46 342 hypothesis, which is also considered feasible to recruit over a three-year period. Formal

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3 343 analysis of statistical power will be undertaken with a preliminary sample of 30 participants  
4 344 at conclusion of a pilot, and the projected sample size adjusted as appropriate.

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6 345 *Acceptability*

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8 346 Qualitative analysis will employ a framework approach which provides a structure for coding  
9  
10 347 and categorising of data.[44] Both deductive and inductive logic will be used to reduce and  
11 348 synthesise data and develop responses to questions regarding acceptability, experience and  
12 349 mechanisms of action. Data coded as influencing PA participation will be analysed using the  
13 350 components of the COM-B model as a frame.

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17 351 **DISCUSSION**

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19 352 This study is to our knowledge the first randomised trials to compare PA behavioural  
20 353 outcomes for two interventions designed specifically to impact PA motivation in adults with  
21 354 mental illness. A pragmatic approach has been taken in the design: inclusion criteria are  
22 355 broad with no specific diagnostic criteria to enhance potential applicability to other mental  
23 356 health services. Interventions will also be delivered at community facilities, likely the most  
24 357 practical way to implement PA interventions given accessibility and absence of gym facilities  
25 358 in many mental health services.

26  
27 359 A strength of this study is that an objective measure of PA will be used continuously during  
28 360 the intervention period to assess PA adoption. Recently published protocols have outlined the  
29 361 intended use of an objective measure of PA as a primary outcome.[45, 46] Comparing a  
30 362 single week of monitoring pre- and post-intervention to estimate PA change is limited,  
31 363 because the measurement may be influenced by other life circumstances (e.g. a participants  
32 364 may be out of town, or their illness symptoms may be worse during the measurement week).  
33 365 Understanding how PA behaviour changes over the course of an intervention will be  
34 366 instructive for future studies on PA interventions for this group.

35  
36 367 A novel aspect of this study is that the use of fitness trackers for PA self-monitoring will be  
37 368 evaluated for adults with mental illness. Garmin Vivofits have been chosen because of their  
38 369 1-year battery life thus removing the participant burden of regular recharging, which was  
39 370 considered unfeasible for people experiencing chronic mental health issues. The devices  
40 371 provide real-time feedback about activity, and detailed feedback is available by using  
41 372 smartphone or internet accounts; however, this functionality will be specifically restricted  
42 373 because many people with mental illness do not own a smartphone or computer with internet  
43 374 access, and it was considered important to standardise participant interaction with the device.

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3 375 Finally, this study has a strong theoretical basis, which is lacking from most PA interventions  
4 376 studies with adults with mental illness.[2222] The study interventions utilise intervention  
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6 377 functions outlined in the Behaviour Change Wheel framework to impact PA behaviour by  
7  
8 378 increasing opportunity, capability and motivation as outlined in the COM-B behavioural  
9  
10 379 model. Participant experiences with the interventions will be evaluated qualitatively using the  
11  
12 380 COM-B model as a frame, which is important for identifying effective intervention  
13  
14 381 components, and ensuring patient acceptability.

### 15 382 **Ethics and Dissemination**

16  
17 383 Ethics approval has been obtained from the Royal Brisbane and Women's Hospital  
18  
19 384 (HREC/17/QRBW/302). The trial is registered under the Australian and New Zealand  
20  
21 385 Clinical Trial Registry (ACTRN12617001017314).

### 22 386 **Authors' contributions**

23  
24 387 JC led the study conceptualisation, development of intervention content, and writing of the  
25  
26 388 protocol. SS edited the protocol. DS, SK and MB contributed to study conceptualisation. JB  
27  
28 389 contributed to intervention content. SP contributed to study conceptualisation and  
29  
30 390 intervention content and edited the protocol. All authors edited the manuscript.

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32  
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34  
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### 36 394 **Competing interests statement**

37  
38 395 The lead author is employed as a Program Manager at PCYC Queensland where he oversees  
39  
40 396 implementation of the *Healthy Bodies, Healthy Minds* (HBHM) program. The exercise  
41  
42 397 protocol used in the HBHM program is one of the intervention conditions of this study. The  
43  
44 398 authors declare they have no other competing interests.

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# BMJ Open

## Protocol for a randomised controlled trial of interventions to promote adoption and maintenance of physical activity in adults with mental illness

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SCHOLARONE™  
Manuscripts

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2  
3 1 **TITLE PAGE**

4 2 **Title: Protocol for a randomised controlled trial of interventions to promote adoption**  
5 3 **and maintenance of physical activity in adults with mental illness**

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## 30 **ABSTRACT**

31 *Introduction:* Physical activity (PA) has diverse benefits for physical and mental health and  
32 can reduce symptoms of mental illness. Adults with mental illness face practical,  
33 psychosocial and socioeconomic barriers to adopting and maintaining PA, and it is unclear  
34 how to effectively promote PA in this group. Supervised exercise interventions provide high  
35 support but may not promote autonomous motivation, which is important for PA  
36 maintenance. The aim of this study is to compare the effectiveness of two interventions to  
37 promote PA in adults with mental illness.

38 *Methods and analysis:* This is a randomised controlled trial of two interventions to promote  
39 PA: (1) supervised exercise and gym membership (GYM), and (2) motivational discussions  
40 and self-monitoring of PA using fitness trackers (MOT). The intervention duration is 16-  
41 weeks, including 8-weeks of weekly supervised group sessions, and 8-weeks of access to the  
42 gym or fitness tracker unsupervised. Participants are community-dwelling adults recruited  
43 from outpatient clinics of public mental health services. The primary outcome is PA adoption  
44 assessed using GENEActiv accelerometers worn continuously over 8-weeks. Secondary  
45 outcomes measured at baseline, post-intervention (8 weeks) and follow-up (16 weeks),  
46 include exercise motivation, psychological distress and self-reported PA assessed using self-  
47 administered questionnaires, and indicators of physical health measured by a researcher  
48 blinded to allocation (blood pressure, weight, waist circumference, six-minute walk test).  
49 Participant experiences will be assessed using qualitative focus groups with analysis  
50 informed by a theoretical model of behaviour (COM-B).

51 *Ethics and Dissemination:* Ethics approval has been obtained from the Royal Brisbane and  
52 Women's Hospital (HREC/17/QRBW/302). We plan to submit a manuscript on protocol  
53 development from pilot work, and a manuscript of the results to a peer-reviewed journal.  
54 Results will be presented at conferences, community and consumer forums and hospital  
55 grand rounds.

56 *Registration details:* The trial is registered under the Australian and New Zealand Clinical  
57 Trial Registry (ACTRN12617001017314).

### 58 **Strength and Limitations of this study**

- 59 • This study uses a robust methodological design, and the interventions are based on  
60 theoretical model of behaviour to enhance interpretation and generalisability of  
61 findings.

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- 62 • An objective measure of physical activity (PA) is used continuously during the  
63 intervention to allow reliable assessment of PA behaviour change.
- 64 • Recruitment will be non-probabilistic, so the resulting cohort may not be a  
65 representative sample of adults receiving public mental health services.
- 66 • Use of a self-report measure of PA during the follow-up period limits assessment of  
67 PA maintenance.

68

For peer review only

## 69 INTRODUCTION

70 The benefits of physical activity (PA) for mental and physical health are widely  
71 recognised.[1] PA and exercise (PA to enhance or maintain fitness) can improve metabolic  
72 risk factors, protect against chronic physical conditions such as cardiovascular disease, and  
73 improve psychosocial wellbeing and longevity.[2, 3] The World Health Organisation PA  
74 guidelines are to accumulate 150-300 minutes per week of moderate-to-vigorous activity.[4]  
75 About a third of the population globally do not meet these guidelines, with inactivity more  
76 prevalent in high income countries.[5] Policy initiatives and public health campaigns to  
77 increase PA can be effective;[6] however, research has highlighted the importance of  
78 targeting campaigns to specific sub-groups,[7] and people experiencing socioeconomic and  
79 psychosocial barriers may need more focused support to adopt and maintain an active  
80 lifestyle.[8]

81 One such population group is adults with mental illness. This group are at higher risk of  
82 developing cardiovascular and metabolic conditions,[9] and have lower levels of PA[10] than  
83 the general population. In addition to the acknowledged physical and psychosocial benefits of  
84 PA, PA can reduce symptoms of depression,[11] anxiety,[12] and schizophrenia,[13] and  
85 improve quality of life in adults with mental illness.[14] Adults with mental illness face  
86 complex barriers to adopting and maintaining an active lifestyle: social isolation, medication  
87 side-effects, and illness symptoms are among many factors that have been described as  
88 hindering PA behaviour change.[15] PA intervention studies have demonstrated  
89 feasibility[16] and are associated with improved health outcomes;[14] however, little is  
90 known about how effective such interventions are at influencing PA outside supervised  
91 sessions, which is important for maintaining health benefits.[17] Given the potential for PA  
92 to improve health and wellbeing in this group, the implementation of interventions to  
93 promote PA in mental health services is increasingly advocated.[18, 19]

94 Research has highlighted the importance of autonomous motivation in adoption and  
95 maintenance of PA for adults with mental illness.[20] Cross-sectional studies indicate that the  
96 motivational mechanisms that influence PA behaviour in adults with mental illness are not  
97 dissimilar to the general population, and are independent of psychiatric diagnosis and  
98 medication use,[21] indicating that established behaviour change theories are generalisable to  
99 this group. However, the importance of tailoring interventions to focus on the specific  
100 barriers and facilitators experienced by adults with mental illness has been emphasised.[8]  
101 The few studies of interventions to improve PA motivation in adults with mental illness have

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3 102 not based their evaluation on a theoretical model of behaviour, which is critical for  
4 103 understanding potential mechanisms of behaviour change, or have not related motivational  
5 104 outcomes to PA behaviour to examine potential causal relationships.[22] There is a need for  
6 105 theory-based empirical evidence on how to positively impact PA motivation and behaviour in  
7 106 adults with mental illness.

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11 107 The Behaviour Change Wheel (BCW) framework is an overarching model of behaviour  
12 108 which can be used to design and evaluate behaviour change interventions with the view of  
13 109 improving adherence and effectiveness.[23] The BCW identifies nine ‘intervention functions’  
14 110 that potentially influence any given target behaviour (Table 1, footnote (a)), and explains  
15 111 behaviour change through the COM-B model, in which capability (C), opportunity (O), and  
16 112 motivation (M) interact to generate behaviour (B).[23] Motivation and Capability are facets  
17 113 of the individual (physical and psychological capabilities; reflective and automatic  
18 114 motivations), and Opportunity encompasses factors outside the individual that prompt or  
19 115 enable the behaviour. Evaluating and comparing different interventions using this theoretical  
20 116 behavioural framework will provide valuable insight into effectiveness and mechanisms of  
21 117 action of interventions designed to promote PA in adults with mental illness.

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30 118 The range of interventions that might promote PA is diverse, in that different combinations of  
31 119 intervention functions can be used to impact capability, opportunity and motivation. Trials  
32 120 designed to assess the efficacy of exercise on health outcomes for adults with mental illness  
33 121 have typically focused on supervised exercise interventions. Supervised exercise  
34 122 interventions provide opportunity (e.g. access to exercise facility and professional instruction)  
35 123 and motivation (e.g. via first-person mastery) but may not impact psychological capability  
36 124 (e.g. problem-solving barriers) or optimally address motivation. The application of behaviour  
37 125 change techniques may more directly address motivation and capability. Research suggests  
38 126 that, of the multitude of behaviour change techniques,[24] interventions involving self-  
39 127 monitoring of PA combined with other self-regulatory techniques (e.g. goal setting) may be  
40 128 more effective than interventions without these techniques.[25] Self-monitoring using  
41 129 electronic activity monitor systems (commonly known as fitness trackers) can increase PA  
42 130 and assist with weight management,[26] and has potential for use with clinical groups;[27]  
43 131 however, acceptability and effectiveness is yet to be established in adults with mental illness.  
44 132 To our knowledge, no studies have compared interventions to promote PA via supervised  
45 133 exercise or a combination self-monitoring and other behaviour change techniques among  
46 134 adults with mental illness.

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3 135 To address limitations of previous research and inform practice, the aim of this study is to  
4 136 compare the effectiveness of two interventions designed to promote PA in adults with mental  
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6 137 illness: a supervised exercise intervention, and a motivational intervention involving self-  
7  
8 138 monitoring of PA. While both interventions may increase PA, for study purposes, the  
9  
10 139 hypothesis is that the motivational intervention will have a greater impact on PA adoption  
11  
12 140 than the supervised exercise intervention. Secondary aims are to evaluate acceptability and  
13  
14 141 participants' experiences of the interventions and explore potential mechanisms of action  
15  
16 142 using the BCW and COM-B behaviour system as a frame.

## 17 143 **METHODS AND ANALYSIS**

### 18 144 **Study design**

19  
20 145 This is a two-arm, parallel group, randomised controlled superiority trial of interventions  
21  
22 146 designed to promote adoption and maintenance of PA among adults with mental illness.

### 23 147 **Patient and public involvement**

24  
25 148 Participant burden of the intervention and research measures was assessed using focus group  
26  
27 149 interviews and informal feedback from patients participating in two pilot rounds.  
28  
29 150 Development of the research question and the intervention content was based on existing  
30  
31 151 community programs developed collaboratively with people recovering from mental health  
32  
33 152 issues. These programs that have been implemented and iteratively improved based on  
34  
35 153 participant feedback since 2015. Patients will not be involved in recruitment of participants or  
36  
37 154 conduct of the study. Results of this study will be disseminated to participants through  
38  
39 155 presentation at consumer and community forums.

### 40 156 **Setting and participants**

41  
42 157 Participants will be recruited from outpatient clinics of public mental health services in  
43  
44 158 Brisbane, Australia (Metro North Mental Health, and Metro South Addictions and Mental  
45  
46 159 Health). These services provide specialist treatment for approximately two million residents  
47  
48 160 of a catchment encompassing inner city, suburban, and regional areas; approximately 15,000  
49  
50 161 patients are open to the services each year. The study will be promoted across services at  
51  
52 162 clinical team meetings, and staff will be asked to refer potentially eligible clients to the  
53  
54 163 research team.

55  
56 164 Following referral, researchers will contact potential participants to provide information and  
57  
58 165 screen for eligibility. Individuals will be eligible if they are a current outpatient of either  
59  
60 166 mental health service, aged 18-65 years, sufficiently fluent in English to complete consent

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3 167 and study procedures, and willing to provide consent to study participation. Exclusion criteria  
4 168 are: i) receiving treatment for an eating disorder; ii) self-reporting more than 300 minutes of  
5 169 moderate-to-vigorous activity in the previous week; and iii) reporting medical risk factors  
6 170 assessed using the Adult Pre-exercise Screening System (APSS)[28] without clearance for  
7 171 participation from a medical practitioner. Screening will involve assessment of PA using an  
8 172 adapted version of the Active Australia questionnaire,[29] which asks about time spent in  
9 173 walking, moderate and vigorous activities in the previous week.

14 174 The researchers will make arrangements to meet eligible individuals who are interested in  
15 175 participation at the intervention venue to obtain written informed consent for study  
16 176 participation, and to complete the baseline assessments. The interventions will be delivered at  
17 177 gymnasium and community facilities of Queensland Police-Citizens Youth Welfare  
18 178 Association (PCYC Queensland). PCYC Queensland is an established state-wide not-for-  
19 179 profit organisation that offers sport and recreational activities and community development  
20 180 initiatives.[30]

#### 26 181 *Randomisation*

28 182 Allocation concealment will be ensured by performing allocation after completing all  
29 183 baseline assessments. A researcher acting on the Data Safety Monitoring Board and not  
30 184 directly involved with study delivery (MB) will allocate participants in a 1:1 ratio using block  
31 185 randomisation (block size of two), using a random sequence generated at randomizer.org.  
32 186 Participants will be advised of allocation by telephone prior to the first group session by the  
33 187 researcher (JC).

#### 38 188 **Intervention procedure**

40 189 The study groups will be manualised motivational (MOT) or gym exercise (GYM)  
41 190 interventions. Both interventions are designed to enhance capability, opportunity and  
42 191 motivation to do PA, using intervention functions identified in the Behaviour Change Wheel  
43 192 (Table 1). Interventions are 16 weeks in duration, comprising two 8-week blocks: a  
44 193 supervised group-based component and an 8-week unsupervised component absent of  
45 194 researcher contact or group sessions. There will be no restrictions from participating in other  
46 195 therapies or programs outside the intervention.

51 196



**Table 1: Description of intervention functions<sup>a</sup> and behaviour change techniques<sup>b</sup> used in the interventions**

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**Gym exercise intervention (GYM)**

**Capability**

*Physical capability*

- *Training*: Verbal instruction [BCT21] and demonstration [BCT22] of different exercises by the AEP. Participants then complete the exercises with technique correction from the AEP [not coded].

**Opportunity**

*Physical opportunity*

- *Enablement*: Provision of access to exercise facility [not coded] and providing information on where and when to exercise (i.e. at the gym during opening times for supervised and unsupervised sessions) [BCT20].

*Social opportunity*

- *Environmental restructuring*: Exercise sessions delivered in groups.

**Motivation**

*Reflective*

- *Education* about purpose and general health consequences of specific exercises [BCT1], e.g. to improve posture, core stability, interval training.

*Automatic*

- *Environmental restructuring*: Self-monitoring of exercises completed for supervised and unsupervised sessions [BCT16].
- 

**Motivational intervention (MOT)**

**Capability**

*Psychological capability*

- *Training*: Behavioural goal setting [BCT5] and setting graded weekly tasks [BCT9] in Week 1. Reviewing progress and reassessing goals [BCT10] each week. Refining goals in subsequent weeks, by: identifying preferred available community opportunities (e.g. activity groups; walking routes etc.) [BCT20], and action planning for PA in contexts of commuting, leisure, occupational and incidental activity [BCT7].
  - *Training*: Identifying and problem-solving barriers to PA [BCT8]. Problem solving strategies include using: social support [BCT29], prompts/cues such as reminders
-

[BCT23], environmental prompts such as getting exercise clothes ready [BCT24], use of imagery [BCT34], identifying negative self-talk and replacing with positive self-talk [BCT33], establishing routine [not coded].

- *Education*: Explanation and demonstration of strength training exercises that can be done at home [BCT21&22].
- *Education* about the processes of behaviour change [not coded], including stages of change, and internal and external motivation.

### **Opportunity**

#### *Physical opportunity*

- *Environmental restructuring*: Provision of fitness tracker which provides summary feedback about activity.

#### *Social opportunity*

- *Environmental restructuring*: Exercise sessions delivered in groups.

### **Motivation**

#### *Reflective*

- *Education* about: i) the general health consequences of PA and inactivity [BCT1], and ii) health consequences specific to adults with mental illness [BCT2], such as reducing mental illness symptoms, countering medication side-effects, and preventing physical illnesses with high prevalence in this group.

#### *Automatic*

- *Environmental restructuring*: Daily self-monitoring of PA behaviour [BCT16] using objective methods (the Garmin device) and self-report (activity log).

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197 <sup>a</sup> Nine possible intervention functions are specified in the Behaviour Change Wheel  
198 framework: *Education, Persuasion, Incentivisation, Coercion, Training, Restriction,*  
199 *Environmental restructuring, Modelling, Enablement.*[23]

200 <sup>b</sup> Behaviour change techniques have been coded as [BCT] and numbered from the CALO-RE  
201 taxonomy;[24] techniques not listed in this taxonomy have been specified as [not coded].

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2  
3 203 Supervised components of both MOT and GYM interventions involve one 60-minute  
4 204 session/week at a PCYC facility located near recruitment site, in groups of up to 10  
5 205 participants. The GYM intervention will be delivered by an accredited exercise physiologist  
6 206 (AEP); the MOT intervention will be delivered by personnel with a tertiary qualification in a  
7 207 health-related field (e.g. physiology, public health). The AEP and MOT facilitators will  
8 208 attend group sessions for GYM and MOT interventions. Participants will be sent weekly text  
9 209 message reminders about the group session times, with phone follow-up if sessions are  
10 210 missed without explanation. Structure and content of the interventions is summarised below.

11 211 *Motivational intervention (MOT)*

12 212 Participants will be provided Garmin Vivofit 3 devices for use over the 16-week intervention.  
13 213 This device provides real-time feedback about daily steps, distance walked, energy  
14 214 expenditure and time spent in moderate-to-vigorous activity per week ('intensity minutes').  
15 215 During the initial 8-weeks, participants will be asked to:

- 16 216 (1) Attend weekly structured group motivational sessions, comprising a 10-min discussion  
17 217 about progress towards goals in the previous week, 20-min discussion of PA guidelines  
18 218 and a health-related topic, 20-min 'motivational exercise', and 10-min revision of goals  
19 219 for the coming week.  
20 220 (2) Complete a daily log of step count and 'intensity minutes' as displayed on the Garmin  
21 221 device, and self-reported time spent active in contexts: commuting, solo aerobic exercise,  
22 222 community PA groups, and strength training.

23 223 *Gym exercise intervention (GYM)*

24 224 Participants will be provided 16-week gym memberships at no cost. During the initial 8-  
25 225 weeks, participants will be asked to:

- 26 226 (1) Attend weekly structured group exercise sessions and attend the gym at least once  
27 227 unsupervised to repeat exercises from the supervised session. Sessions are based on  
28 228 PCYC's 'Healthy Bodies, Healthy Minds' program (HBHM), which progressively  
29 229 introduces exercises to equip participants with the knowledge and confidence to develop  
30 230 an exercise program based on personal abilities and preferences, in consultation with an  
31 231 AEP. The weekly group sessions comprise a 10-min discussion of specified exercise  
32 232 topics, 20-min of aerobic exercise (continuous or interval training) on machine of  
33 233 participants' choice (treadmill, stationary bike, elliptical trainer, or rowing machine) at  
34 234 an intensity such that talking becomes difficult (i.e. 'talk test'), and 30-min of resistance  
35 235 training (two sets of 10-15 reps, for a variety common exercises).

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3 236 (2) Record variables of completed exercise sessions (weight, sets and repetitions for  
4 237 resistance exercises, heart rate measured using heart rate monitors on exercise machines,  
5  
6 238 and rate of perceived exertion achieved during aerobic exercise).  
7

8 239 **Intervention consistency**

9  
10 240 Facilitators will be required to familiarise themselves with the manual, and score 100% on a  
11 241 quiz about content, session structure and style of delivery as applicable for GYM and MOT  
12 242 interventions. Session monitoring sheets specifying content of each group session will be  
13 243 printed on a hardcopy A4 sheet, and facilitators will be required to mark each component  
14 244 completed at each session. They will also be asked to document any challenges to  
15 245 implementation of the manualised intervention and responses/feedback provided by  
16 246 participants. Session monitoring sheets will be reviewed by the study team as a record of the  
17 247 content delivered consistent with the manual.  
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23 248 **Adverse event reporting**

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25 249 Participants will be asked to report pain or injuries from the previous week at each session;  
26 250 any adverse events will be reported to the data safety monitoring board and ethics committee.  
27 251 Participants experiencing pain related to exercise, pre-existing conditions, or unrelated injury  
28 252 may be required to discontinue the intervention until medical clearance can be obtained.  
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32 253 **Data collection**

33  
34 254 Participant information and outcome measures will be collected as summarised in the  
35 255 schedule of assessments (Table 2). Participants will be offered gift cards for completing  
36 256 assessments at each timepoint: AUD\$20 at baseline, AUD\$30 at post-intervention, and  
37 257 AUD\$40 at follow-up. Post-intervention assessments will be administered by a researcher  
38 258 blind to participant allocation. All participants will be invited to complete the post-  
39 259 intervention assessments regardless of continuation with the intervention.  
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**Table 2: Schedule of assessments**

	Enrolment		Baseline		Post-allocation	
	$-t_3$	$-t_2$	$-t_1$	$t_0$	$t_8$	$t_{16}$
<b>INTERVENTIONS</b>						
Motivation intervention				←————→		
Gym exercise intervention				←————→		
<b>INTAKE</b>						
<i>Eligibility screen</i>	X					
<i>Informed consent</i>		X				
<i>Participant characteristics</i>		X				
<i>Allocation</i>				X		
<b>ASSESSMENTS</b>						
<i>Accelerometry</i>		←————→		←————→		
<i>K6</i>			X		X	X
<i>BREQ-3</i>			X		X	X
<i>SIMPAQ</i>			X		X	X
<i>Stage of change</i>			X		X	
<i>Physical health measures</i>			X		X	
<i>Focus groups</i>						X

**261 Recommendations for Interventional Trials (SPIRIT) Figure**

262  $-t_3$  = completed upon referral;  $-t_2$  = initial baseline assessment;  $-t_1$  = final baseline assessment;  $t_0$  =  
263 randomisation (week 0);  $t_8$  = post-intervention assessments (week 8);  $t_{16}$  = follow-up assessments  
264 (week 16); K6 = Kessler-6 scale of psychological distress; BREQ-3 = Behavioural Regulation in  
265 Exercise Questionnaire; SIMPAQ = Simple Physical Activity Questionnaire.

266 *Participant characteristics*

267 Mental health clinicians (psychiatrist or case manager) will be asked to provide psychiatric  
268 diagnosis (ICD-10 codes obtained from hospital records) at referral. Participant baseline  
269 characteristics will be assessed using questionnaire items on health and sociodemographic  
270 information (medications, education, employment, income management, sex, gender identity,  
271 ethnicity), PA attitudes (preference for PA type and satisfaction with current PA level),  
272 current and previous use of PA self-monitoring devices (smartphone health apps, pedometers  
273 and fitness trackers). Intervention preference will also be assessed (*'Given what you know  
274 about the study conditions, which one would you prefer?'*).

275 *Outcome measures*

276 *Accelerometry*: Physical activity will be objectively measured using GENEActiv Original  
277 accelerometers (GENEActiv, Activinsights Ltd, Kimbolton, UK). GENEActiv monitors are  
278 waterproof devices, similar in appearance to a wristwatch, requiring no user input. They  
279 measure motion-related and gravitational acceleration using a triaxial microelectromechanical  
280 systems (MEMS) accelerometer, light exposure using a photodiode, and temperature using a  
281 thermistor. The sampling frequency will be set at 10Hz to extend the battery life to up to 60  
282 days. The monitors do not provide feedback about PA, limiting the potential for  
283 reactivity.[31, 32] Participants will be asked to wear monitors on their non-dominant wrist  
284 but will be offered waist or upper-arm band as alternatives if wrist-wear is not possible (e.g.  
285 because of discomfort or impracticality). To assess baseline habitual PA, participants will be  
286 asked to wear GENEActiv monitors 24 hours/day for seven consecutive days prior to  
287 beginning the intervention. To assess PA adoption, participants will be asked to wear  
288 GENEActiv monitors continually during the 8-week intervention (9 weeks total monitor  
289 wear).

290 *Behavioural Regulation in Exercise Questionnaire (BREQ-3)*: The BREQ-3 comprises 24  
291 items to assess amotivation, and external, introjected, identified, integrated and intrinsic  
292 behavioural regulations.[33] The BREQ-3 has high test-retest reliability ( $\rho=0.78-0.84$  for  
293 regulation constructs), and has been shown to be moderately predictive of exercise  
294 participation ( $R^2=0.25$ )[33] consistent with behavioural theory that suggests motivation  
295 influences behaviour.

296 *Stages of change*: A 5-item stages of change questionnaire based on the transtheoretical  
297 model will be used for four activities: active commuting, community activity groups, solo  
298 aerobic exercise and strength training. Participants chose one of five options: *I don't do this*

299 *kind of activity and I don't intend to start* (pre-contemplation); *I don't do this kind of activity*  
300 *but I'm thinking about starting* (contemplation); *I occasionally do this kind of activity*  
301 *(preparation); I do this kind of activity regularly and started in the last 6 months* (action); and  
302 *I do this kind of activity regularly and have been for longer than 6 months* (maintenance).

303 *Kessler-6 scale (K6)*: The K6 is a self-administered questionnaire assessing frequency of six  
304 symptoms of distress (*nervous, hopeless, restless or fidgety, so sad that nothing could cheer*  
305 *you up, that everything was an effort, worthless*) experienced in the past month using a 5-  
306 point Likert scale. The K6 has been shown to have high internal consistency and reliability  
307 (Cronbach's  $\alpha=0.89$ ),[34] and total classification accuracy was 0.92 (SD=0.02) when  
308 discriminating cases of serious mental illness from non-cases.[35]

309 *Simple Physical Activity Questionnaire (SIMPAQ)*: SIMPAQ is a researcher-administered  
310 self-report questionnaire assessing time spent in bed, sitting or lying down, napping during  
311 the day, walking, structured exercise, and incidental activities completed in the previous  
312 week.[36] Psychometrics of SIMPAQ are currently being assessed in an international  
313 validation study.

314 *Physical health*: Indicators of physical health will be blood pressure measured using an  
315 automatic sphygmomanometer (Omron HEM-7302) after at least five minutes rest, waist  
316 circumference measured to the nearest 1 cm using a tape measure, height measured to the  
317 nearest 0.1 cm using a stadiometer, and weight measured to the nearest 0.01 kg using  
318 electronic scales (Charder MS 6111). Physical capacity will be measured using the 6-minute  
319 walk test (6MWT) which is a submaximal test to assess functional capacity commonly used  
320 with adults with mental illness.[37] Standardised instructions and encouragement will be  
321 provided each minute consistent with guidelines.[38]

#### 322 *Process evaluation*

323 Feasibility and acceptability of the interventions will be examined in an embedded process  
324 evaluation. Feasibility of the interventions will be assessed by comparing intervention costs  
325 (intervention equipment, staff time) with referral and uptake rates, adherence (attendance at  
326 group sessions assessed by the researcher; attendance at unsupervised sessions assessed using  
327 self-report), completion rate, and reasons for non-completion. Acceptability and potential  
328 mechanisms of action will be examined using semi-structured focus group discussions of  
329 participants' experiences with the study and interventions.

#### 330 **Data management**

1  
2  
3 331 Questionnaires will be administered electronically using the online survey platform Qualtrics  
4 332 (Qualtrics, Provo, UT); data will be exported into SPSS version 23 (SPSS Inc, Chicago,  
5 333 Illinois) for analysis. GENEActiv accelerometer data will be downloaded at completion of  
6 334 baseline and intervention monitoring periods and analysed in Matlab 2016a (The MathWorks,  
7 335 Inc., Natick, Massachusetts, United States). Garmin Vivofit 3 devices allow access to internet  
8 336 and smartphone accounts which provide detailed feedback, social networking and other  
9 337 functionality; however, participants will not be given access to these accounts. Hardcopy  
10 338 consent forms will be stored in locked filing cabinets, and electronic data will be stored on  
11 339 password protected drives accessible to study investigators.

### 18 340 **Data pre-processing**

19 341 Raw GENEActiv accelerometer data will be converted into 60 second epochs. Data will be  
20 342 considered valid if the accelerometer was worn for at least 80% of waking hours[39] on at  
21 343 least four days of the week including at least one weekend day.[40] Consistent with previous  
22 344 research, non-wear time will be defined as  $\geq 90$  minutes with a 20-minute forward-moving  
23 345 standard deviation  $\leq 0.05$ . [41] Waking hours will be defined using a validated algorithm to  
24 346 determine sleep periods.[42] Moderate-to-vigorous activity will be defined using validated  
25 347 thresholds.[43] Accelerometer-derived MVPA at baseline and for each week of the study  
26 348 period will be plotted for visual comparison. Questionnaire data will be scored consistent  
27 349 with the questionnaire guidelines. A relative autonomy index will be calculated from the  
28 350 BREQ-3 questionnaire, indicating the degree to which respondents feel self-determined.

### 36 351 **Data Analysis**

#### 37 352 *Hypothesis testing*

38 353 The hypothesis will be tested using multiple linear regression analyses (MLRA). PA adoption  
39 354 will be calculated as the cumulative change in accelerometer-derived moderate-to-vigorous  
40 355 activity between baseline and post-intervention (e.g. area under curve). PA adoption will be  
41 356 used as the dependent variable. Independent variables will include study condition (MOT or  
42 357 GYM), adherence (high or low attendance), and baseline relative autonomy indices.  
43 358 Participant baseline characteristics will be compared between groups, and analyses adjusted  
44 359 for any significant differences. Missing data will be handled using multiple imputation.  
45 360 Analyses will be conducted using an intention-to-treat approach.

#### 52 361 *Sample size*

53 362 We anticipate that a sample of 150 participants will afford the opportunity to robustly test the  
54 363 hypothesis, which is also considered feasible to recruit over a three-year period. Formal



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2  
3 364 analysis of statistical power will be undertaken with a preliminary sample of 30 participants  
4 365 at conclusion of a pilot, and the projected sample size adjusted as appropriate.

5  
6 366 *Acceptability*

7  
8 367 Qualitative analysis will employ a framework approach which provides a structure for coding  
9  
10 368 and categorising of data.[44] Both deductive and inductive logic will be used to reduce and  
11 369 synthesise data and develop responses to questions regarding acceptability, experience and  
12  
13 370 mechanisms of action. Data coded as influencing PA participation will be analysed using the  
14  
15 371 components of the COM-B model as a frame.

16  
17 372 **DISCUSSION**

18  
19 373 This study is to our knowledge the first randomised trials to compare PA behavioural  
20  
21 374 outcomes for two interventions designed specifically to impact PA motivation in adults with  
22  
23 375 mental illness. A pragmatic approach has been taken in the design: inclusion criteria are  
24  
25 376 broad with no specific diagnostic criteria to enhance potential applicability to other mental  
26  
27 377 health services. Interventions will also be delivered at community facilities, likely the most  
28  
29 378 practical way to implement PA interventions given accessibility and absence of gym facilities  
30  
31 379 in many mental health services[45, 46].

32  
33 380 A strength of this study is that an objective measure of PA will be used continuously during  
34  
35 381 the intervention period to assess PA adoption. Recently published protocols have outlined the  
36  
37 382 intended use of an objective measure of PA as a primary outcome.[47, 48] Comparing a  
38  
39 383 single week of monitoring pre- and post-intervention to estimate PA change is limited,  
40  
41 384 because the measurement may be influenced by other life circumstances (e.g. a participants  
42  
43 385 may be out of town, or their illness symptoms may be worse during the measurement week).  
44  
45 386 Understanding how PA behaviour changes over the course of an intervention will be  
46  
47 387 instructive for future studies on PA interventions for this group.

48  
49 388 A novel aspect of this study is that the use of fitness trackers for PA self-monitoring will be  
50  
51 389 evaluated for adults with mental illness. Garmin Vivofits have been chosen because of their  
52  
53 390 1-year battery life thus removing the participant burden of regular recharging, which was  
54  
55 391 considered unfeasible for people experiencing chronic mental health issues. The devices  
56  
57 392 provide real-time feedback about activity, and detailed feedback is available by using  
58  
59 393 smartphone or internet accounts; however, this functionality will be specifically restricted  
60  
394 because many people with mental illness do not own a smartphone or computer with internet  
395 access, and it was considered important to standardise participant interaction with the device.

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3 396 Finally, this study has a strong theoretical basis, which is lacking from most PA interventions  
4 397 studies with adults with mental illness.[22] The study interventions utilise intervention  
5  
6 398 functions outlined in the Behaviour Change Wheel framework to impact PA behaviour by  
7  
8 399 increasing opportunity, capability and motivation as outlined in the COM-B behavioural  
9  
10 400 model. Participant experiences with the interventions will be evaluated qualitatively using the  
11  
12 401 COM-B model as a frame, which is important for identifying effective intervention  
13  
14 402 components, and ensuring patient acceptability.

### 14 403 **Ethics and Dissemination**

15  
16 404 Ethics approval has been obtained from the Royal Brisbane and Women's Hospital  
17  
18 405 (HREC/17/QRBW/302). The trial is registered under the Australian and New Zealand  
19  
20 406 Clinical Trial Registry (ACTRN12617001017314). This manuscript is based on approved  
21  
22 407 protocol version 5; any changes to protocol will be updated on the trial registry and outline in  
23  
24 408 future publications. We plan to submit a manuscript on protocol development from pilot  
25  
26 409 work, and a manuscript of the results to a peer-reviewed journal. Results will be presented at  
27  
28 410 conferences, community and consumer forums and hospital grand rounds.

### 27 411 **Authors' contributions**

28  
29 412 JC led the study conceptualisation, development of intervention content, and writing of the  
30  
31 413 protocol. SS edited the protocol. DS, SK and MB contributed to study conceptualisation. JB  
32  
33 414 contributed to intervention content. SP contributed to study conceptualisation and  
34  
35 415 intervention content and edited the protocol. All authors edited the manuscript.

36  
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38  
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42  
43 419 research measures.

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43  
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### 46 423 **Competing interests statement**

47  
48 424 The lead author is employed as a Program Manager at PCYC Queensland where he oversees  
49  
50 425 implementation of the *Healthy Bodies, Healthy Minds* (HBHM) program. The exercise  
51  
52 426 protocol used in the HBHM program is one of the intervention conditions of this study. The  
53  
54 427 authors declare they have no other competing interests.

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

Section/item	Item No	Description	Page No
<b>Administrative information</b>			
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	2,17
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	17
Funding	4	Sources and types of financial, material, and other support	17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 17
	5b	Name and contact information for the trial sponsor	NA
	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	NA
	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)	NA
<b>Introduction</b>			
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	4,5,6
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	6



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1	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6
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3				
4	<b>Methods: Assignment of interventions (for controlled trials)</b>			
5	<b>Allocation:</b>			
6				
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8	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	7
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17	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	7
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22	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
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27	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
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31		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
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35	<b>Methods: Data collection, management, and analysis</b>			
36				
37	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	11, 12, 13, 14
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47		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	11
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2	Data	19	Plans for data entry, coding, security, and storage,	14
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	15
9	methods		outcomes. Reference to where other details of the	
10			statistical analysis plan can be found, if not in the protocol	
11				
12		20b	Methods for any additional analyses (eg, subgroup and	NA
13			adjusted analyses)	
14				
15		20c	Definition of analysis population relating to protocol non-	15
16			adherence (eg, as randomised analysis), and any	
17			statistical methods to handle missing data (eg, multiple	
18			imputation)	
19				
20				
21	<b>Methods: Monitoring</b>			
22	Data	21a	Composition of data monitoring committee (DMC);	7
23	monitoring		summary of its role and reporting structure; statement of	
24			whether it is independent from the sponsor and competing	
25			interests; and reference to where further details about its	
26			charter can be found, if not in the protocol. Alternatively,	
27			an explanation of why a DMC is not needed	
28				
29				
30		21b	Description of any interim analyses and stopping	15
31			guidelines, including who will have access to these interim	
32			results and make the final decision to terminate the trial	
33				
34	Harms	22	Plans for collecting, assessing, reporting, and managing	10
35			solicited and spontaneously reported adverse events and	
36			other unintended effects of trial interventions or trial	
37			conduct	
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40	Auditing	23	Frequency and procedures for auditing trial conduct, if	NA
41			any, and whether the process will be independent from	
42			investigators and the sponsor	
43				
44	<b>Ethics and dissemination</b>			
45				
46	Research	24	Plans for seeking research ethics committee/institutional	2
47	ethics approval		review board (REC/IRB) approval	(abstract)
48				
49	Protocol	25	Plans for communicating important protocol modifications	2, 17
50	amendments		(eg, changes to eligibility criteria, outcomes, analyses) to	(abstract)
51			relevant parties (eg, investigators, REC/IRBs, trial	
52			participants, trial registries, journals, regulators)	
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1	Consent or	26a	Who will obtain informed consent or assent from potential	7
2	assent		trial participants or authorised surrogates, and how (see	
3			Item 32)	
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5		26b	Additional consent provisions for collection and use of	NA
6			participant data and biological specimens in ancillary	
7			studies, if applicable	
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10	Confidentiality	27	How personal information about potential and enrolled	15
11			participants will be collected, shared, and maintained in	
12			order to protect confidentiality before, during, and after the	
13			trial	
14				
15	Declaration of	28	Financial and other competing interests for principal	17
16	interests		investigators for the overall trial and each study site	
17				
18	Access to data	29	Statement of who will have access to the final trial dataset,	15
19			and disclosure of contractual agreements that limit such	
20			access for investigators	
21				
22	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and for	NA
23	post-trial care		compensation to those who suffer harm from trial	
24			participation	
25				
26	Dissemination	31a	Plans for investigators and sponsor to communicate trial	2, 17
27	policy		results to participants, healthcare professionals, the	
28			public, and other relevant groups (eg, via publication,	
29			reporting in results databases, or other data sharing	
30			arrangements), including any publication restrictions	
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33		31b	Authorship eligibility guidelines and any intended use of	NA
34			professional writers	
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36		31c	Plans, if any, for granting public access to the full protocol,	NA
37			participant-level dataset, and statistical code	
38				
39				
40	<b>Appendices</b>			
41	Informed	32	Model consent form and other related documentation	Appendix
42	consent		given to participants and authorised surrogates	A
43	materials			
44				
45	Biological	33	Plans for collection, laboratory evaluation, and storage of	NA
46	specimens		biological specimens for genetic or molecular analysis in	
47			the current trial and for future use in ancillary studies, if	
48			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.