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

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TITLE PAGE

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

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ABSTRACT

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

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

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

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

Strength and Limitations of this study

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

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

INTRODUCTION

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

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

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

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

The Behaviour Change Wheel (BCW) framework is an overarching model of behaviour which can be used to design and evaluate behaviour change interventions with the view of improving adherence and effectiveness.[23] The BCW identifies nine 'intervention functions' that potentially influence any given target behaviour, and explains behaviour change through the COM-B model, in which capability (C), opportunity (O), and motivation (M) interact to generate behaviour (B).[23] Motivation and Capability are facets of the individual (physical and psychological capabilities; reflective and automatic motivations), and Opportunity encompasses factors outside the individual that prompt or enable the behaviour. Evaluating and comparing different interventions using this theoretical behavioural framework will provide valuable insight into effectiveness and mechanisms of action of interventions designed to promote PA in adults with mental illness.

The range of interventions that might promote PA is diverse, in that different combinations of intervention functions can be used to impact capability, opportunity and motivation. Trials designed to assess the efficacy of exercise on health outcomes for adults with mental illness have typically focused on supervised exercise interventions. Supervised exercise interventions provide opportunity (e.g. access to exercise facility and professional instruction) and motivation (e.g. via first-person mastery) but may not impact psychological capability (e.g. problem-solving barriers) or optimally address motivation. The application of behaviour change techniques may more directly address motivation and capability. Research suggests that, of the multitude of behaviour change techniques,[24] interventions involving self-monitoring of PA combined with other self-regulatory techniques (e.g. goal setting) may be more effective than interventions without these techniques.[25] Self-monitoring using electronic activity monitor systems (commonly known as fitness trackers) can increase PA and assist with weight management,[26] and has potential for use with clinical groups;[27] however, acceptability and effectiveness is yet to be established in adults with mental illness. To our knowledge, no studies have compared interventions to promote PA via supervised exercise or a combination self-monitoring and other behaviour change techniques among adults with mental illness.

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

METHODS AND ANALYSIS

Study design

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

Setting and participants

Participants will be recruited from outpatient clinics of public mental health services in Brisbane, Australia (Metro North Mental Health, and Metro South Addictions and Mental Health). These services provide specialist treatment for approximately two million residents of a catchment encompassing inner city, suburban, and regional areas; approximately 15,000 patients are open to the services each year. The study will be promoted across services at clinical team meetings, and staff will be asked to refer potentially eligible clients to the research team.

Following referral, researchers will contact potential participants to provide information and screen for eligibility. Individuals will be eligible if they are a current outpatient of either mental health service, aged 18-65 years, sufficiently fluent in English to complete consent and study procedures, and willing to provide consent to study participation. Exclusion criteria are: i) receiving treatment for an eating disorder; ii) self-reporting more than 300 minutes of moderate-to-vigorous activity in the previous week; and iii) reporting medical risk factors assessed using the Adult Pre-exercise Screening System (APSS)[28] without clearance for participation from a medical practitioner. Screening will involve assessment of PA using an adapted version of the Active Australia questionnaire,[29] which asks about time spent in walking, moderate and vigorous activities in the previous week.

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

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

Randomisation

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

Intervention procedure

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

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

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/cures 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).

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

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

Motivational intervention (MOT)

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

(1) Attend weekly structured group motivational sessions, comprising a 10-min discussion about progress towards goals in the previous week, 20-min discussion of PA guidelines and a health-related topic, 20-min 'motivational exercise', and 10-min revision of goals for the coming week.

(2) Complete a daily log of step count and 'intensity minutes' as displayed on the Garmin device, and self-reported time spent active in contexts: commuting, solo aerobic exercise, community PA groups, and strength training.

Gym exercise intervention (GYM)

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

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

an intensity such that talking becomes difficult (i.e. 'talk test'), and 30-min of resistance training (two sets of 10-15 reps, for a variety common exercises).

(2) Record variables of completed exercise sessions (weight, sets and repetitions for resistance exercises, heart rate measured using heart rate monitors on exercise machines, and rate of perceived exertion achieved during aerobic exercise).

Intervention consistency

Facilitators will be required to familiarise themselves with the manual, and score 100% on a quiz about content, session structure and style of delivery as applicable for GYM and MOT interventions. Session monitoring sheets specifying content of each group session will be printed on a hardcopy A4 sheet, and facilitators will be required to mark each component completed at each session. They will also be asked to document any challenges to implementation of the manualised intervention and responses/feedback provided by participants. Session monitoring sheets will be reviewed by the study team as a record of the content delivered consistent with the manual.

Data collection

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

Table 2: Schedule of assessments

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

Recommendations for Interventional Trials (SPIRIT) Figure

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

Participant characteristics

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

Outcome measures

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

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

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

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

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

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

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

Process evaluation

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

Data management

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

Data pre-processing

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

Data Analysis

Hypothesis testing

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

Sample size

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

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

Acceptability

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

DISCUSSION

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

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

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

Finally, this study has a strong theoretical basis, which is lacking from most PA interventions studies with adults with mental illness.[2222] The study interventions utilise intervention functions outlined in the Behaviour Change Wheel framework to impact PA behaviour by increasing opportunity, capability and motivation as outlined in the COM-B behavioural model. Participant experiences with the interventions will be evaluated qualitatively using the COM-B model as a frame, which is important for identifying effective intervention components, and ensuring patient acceptability.

Ethics and Dissemination

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

Authors' contributions

JC led the study conceptualisation, development of intervention content, and writing of the protocol. SS edited the protocol. DS, SK and MB contributed to study conceptualisation. JB contributed to intervention content. SP contributed to study conceptualisation and intervention content and edited the protocol. All authors edited the manuscript.

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Competing interests statement

The lead author is employed as a Program Manager at PCYC Queensland where he oversees implementation of the *Healthy Bodies, Healthy Minds* (HBHM) program. The exercise protocol used in the HBHM program is one of the intervention conditions of this study. The authors declare they have no other competing interests.

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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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TITLE PAGE

Title: 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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ABSTRACT

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

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

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

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

Strength and Limitations of this study

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

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

INTRODUCTION

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

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

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

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

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

The range of interventions that might promote PA is diverse, in that different combinations of intervention functions can be used to impact capability, opportunity and motivation. Trials designed to assess the efficacy of exercise on health outcomes for adults with mental illness have typically focused on supervised exercise interventions. Supervised exercise interventions provide opportunity (e.g. access to exercise facility and professional instruction) and motivation (e.g. via first-person mastery) but may not impact psychological capability (e.g. problem-solving barriers) or optimally address motivation. The application of behaviour change techniques may more directly address motivation and capability. Research suggests that, of the multitude of behaviour change techniques,[24] interventions involving self-monitoring of PA combined with other self-regulatory techniques (e.g. goal setting) may be more effective than interventions without these techniques.[25] Self-monitoring using electronic activity monitor systems (commonly known as fitness trackers) can increase PA and assist with weight management,[26] and has potential for use with clinical groups;[27] however, acceptability and effectiveness is yet to be established in adults with mental illness. To our knowledge, no studies have compared interventions to promote PA via supervised exercise or a combination self-monitoring and other behaviour change techniques among adults with mental illness.

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

METHODS AND ANALYSIS

Study design

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

Patient and public involvement

Participant burden of the intervention and research measures was assessed using focus group interviews and informal feedback from patients participating in two pilot rounds. Development of the research question and the intervention content was based on existing community programs developed collaboratively with people recovering from mental health issues. These programs that have been implemented and iteratively improved based on participant feedback since 2015. Patients will not be involved in recruitment of participants or conduct of the study. Results of this study will be disseminated to participants through presentation at consumer and community forums.

Setting and participants

Participants will be recruited from outpatient clinics of public mental health services in Brisbane, Australia (Metro North Mental Health, and Metro South Addictions and Mental Health). These services provide specialist treatment for approximately two million residents of a catchment encompassing inner city, suburban, and regional areas; approximately 15,000 patients are open to the services each year. The study will be promoted across services at clinical team meetings, and staff will be asked to refer potentially eligible clients to the research team.

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

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

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

Randomisation

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

Intervention procedure

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

Table 1: Description of intervention functions[a] and behaviour change techniques[b] used in the interventions

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/cures 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).

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

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

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

Motivational intervention (MOT)

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

(1) Attend weekly structured group motivational sessions, comprising a 10-min discussion about progress towards goals in the previous week, 20-min discussion of PA guidelines and a health-related topic, 20-min 'motivational exercise', and 10-min revision of goals for the coming week.

(2) Complete a daily log of step count and 'intensity minutes' as displayed on the Garmin device, and self-reported time spent active in contexts: commuting, solo aerobic exercise, community PA groups, and strength training.

Gym exercise intervention (GYM)

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

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

(2) Record variables of completed exercise sessions (weight, sets and repetitions for resistance exercises, heart rate measured using heart rate monitors on exercise machines, and rate of perceived exertion achieved during aerobic exercise).

Intervention consistency

Facilitators will be required to familiarise themselves with the manual, and score 100% on a quiz about content, session structure and style of delivery as applicable for GYM and MOT interventions. Session monitoring sheets specifying content of each group session will be printed on a hardcopy A4 sheet, and facilitators will be required to mark each component completed at each session. They will also be asked to document any challenges to implementation of the manualised intervention and responses/feedback provided by participants. Session monitoring sheets will be reviewed by the study team as a record of the content delivered consistent with the manual.

Adverse event reporting

Participants will be asked to report pain or injuries from the previous week at each session; any adverse events will be reported to the data safety monitoring board and ethics committee. Participants experiencing pain related to exercise, pre-exisitng conditions, or unrelated injury may be required to discontinue the intervention until medical clearance can be obtained.

Data collection

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

Table 2: Schedule of assessments

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

Recommendations for Interventional Trials (SPIRIT) Figure

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

Participant characteristics

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

Outcome measures

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

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

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

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

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

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

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

Process evaluation

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

Data management

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

Data pre-processing

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

Data Analysis

Hypothesis testing

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

Sample size

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

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

Acceptability

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

DISCUSSION

This study is to our knowledge the first randomised trials to compare PA behavioural outcomes for two interventions designed specifically to impact PA motivation in adults with mental illness. A pragmatic approach has been taken in the design: inclusion criteria are broad with no specific diagnostic criteria to enhance potential applicability to other mental health services. Interventions will also be delivered at community facilities, likely the most practical way to implement PA interventions given accessibility and absence of gym facilities in many mental health services[45, 46].

A strength of this study is that an objective measure of PA will be used continuously during the intervention period to assess PA adoption. Recently published protocols have outlined the intended use of an objective measure of PA as a primary outcome.[47, 48] Comparing a single week of monitoring pre- and post-intervention to estimate PA change is limited, because the measurement may be influenced by other life circumstances (e.g. a participants may be out of town, or their illness symptoms may be worse during the measurement week). Understanding how PA behaviour changes over the course of an intervention will be instructive for future studies on PA interventions for this group.

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

Finally, this study has a strong theoretical basis, which is lacking from most PA interventions studies with adults with mental illness.[22] The study interventions utilise intervention functions outlined in the Behaviour Change Wheel framework to impact PA behaviour by increasing opportunity, capability and motivation as outlined in the COM-B behavioural model. Participant experiences with the interventions will be evaluated qualitatively using the COM-B model as a frame, which is important for identifying effective intervention components, and ensuring patient acceptability.

Ethics and Dissemination

Ethics approval has been obtained from the Royal Brisbane and Women's Hospital (HREC/17/QRBW/302). The trial is registered under the Australian and New Zealand Clinical Trial Registry (ACTRN12617001017314). This manuscript is based on approved protocol version 5; any changes to protocol will be updated on the trial registry and outline in future publications. We plan to submit a manuscript on protocol development from pilot work, and a manuscript of the results to a peer-reviewed journal. Results will be presented at conferences, community and consumer forums and hospital grand rounds.

Authors' contributions

JC led the study conceptualisation, development of intervention content, and writing of the protocol. SS edited the protocol. DS, SK and MB contributed to study conceptualisation. JB contributed to intervention content. SP contributed to study conceptualisation and intervention content and edited the protocol. All authors edited the manuscript.

The authors would like to thank participants of pilot rounds of this study, and of the community program *Healthy Bodies, Healthy Minds,* for contributing to the study design by providing feedback about their experiences, preferences, and perceived burden of completing research measures.

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Competing interests statement

The lead author is employed as a Program Manager at PCYC Queensland where he oversees implementation of the *Healthy Bodies, Healthy Minds* (HBHM) program. The exercise protocol used in the HBHM program is one of the intervention conditions of this study. The authors declare they have no other competing interests.

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Section/item	Item No	Description	Page No
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	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
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	4,5,6
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	6

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6, 7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7,8,9,10, and Table 1
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	11
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	10
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13, 14 and Table 2
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 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	15

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	7
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
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11, 12, 13, 14
	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

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	NA
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	7
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	15
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	10
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2 (abstract)
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	2, 17 (abstract)

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	17
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	2, 17
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.