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Supporting Physical Activity through Co-production in people with Severe Mental Illness (SPACES): a pragmatic randomised controlled trial

Submission date
25/07/2024

Recruitment status
Recruiting

Registration date
07/08/2024

Overall study status
Ongoing

Last Edited
04/02/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Life expectancy is reduced by around 15 - 20 years for people with severe mental ill health (SMI) compared to people without SMI, and this gap is increasing. The majority of these early deaths are due to physical health problems, which are partly preventable and which are related to factors including health behaviours such as diet, smoking and physical activity. Increasing physical activity can improve physical health in everyone and The World Health Organization has said that encouraging people to be more active can be as beneficial as quitting smoking. People with SMI are less physically active than the general population. Supporting people with SMI to increase their levels of physical activity could help to reduce the life expectancy gap.

Therefore, there is a need to establish whether a physical activity programme (intervention) that is relevant to the needs of people with SMI, is practical, acceptable and useful for people with SMI.

In this study, we will explore the clinical effectiveness and cost effectiveness of a physical activity intervention we have co-designed for people living with severe mental ill health.

Who can participate?
People aged 18 years and over who have a diagnosis of schizophrenia, schizoaffective disorder or bipolar disorder.

What does the study involve?
People who agree to take part in the study will be randomly allocated to usual care, or to the physical activity intervention plus usual care. We will collect information about participants level of physical activity at the outset of the trial and at 3, 6 and 12 months to establish whether the intervention is effective at increasing the amount of physical activity performed by people with SMI. We will also examine the impact of the intervention on other outcomes relating to mental health and quality of life.

What are the possible benefits and risks of participation?
This is considered a low-risk research study.
Participants may enjoy and value contributing to research.
Participants who are randomised into the intervention plus usual care group may experience benefits from the potential increase in physical activity and reduced sedentary behaviour.

Where is the study run from?
Sheffield Health & Social Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
From January 2024 to March 2027

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
Dr Emily Peckham (Chief Investigator), e.peckham@bangor.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
338802

ClinicalTrials.gov (NCT)
Nil known

Central Portfolio Management System (CPMS)
62060

Study information

Scientific Title
Supporting Physical Activity through Co-production in people with Severe Mental Illness (SPACES): a pragmatic randomised controlled trial of a bespoke intervention to increase levels of physical activity in people with SMI compared to usual care

Acronym
SPACES full scale RCT

Study objectives
A bespoke physical activity intervention is more effective at increasing levels of physical activity in people with severe mental illness than usual care

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/05/2024, West of Scotland REC5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, PAISLEY, PA2 7DE, United Kingdom; +44 141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 24/WS/0040

Study design
Multi-center pragmatic randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Increase in physical activity in people with severe mental illness

Interventions
Control and intervention groups: Both groups will receive usual care.

Intervention group only: The intervention comprises of two core components, weekly group-based sessions and one-to-one sessions with the physical activity coordinator. All participants allocated to the intervention, will be offered up to 18 weekly group-based sessions and up to 10 one-to-one sessions delivered by a trained physical activity coordinator.
The weekly group-based session will be up to two hours in length and include three components (up to 60 minutes of physical activity, a 30-minute themed discussion and 30 minutes of social time). The physical activity component will be made up of either an outdoor walk, an indoor circuit style activity graded to the needs of the participants (e.g., resistance exercises, balance exercises, cardiovascular exercises) or a community taster session (e.g., walking football, yoga). The themed discussions will involve informal information giving/sharing, which will cover relevant topics (e.g., getting started/keeping going with physical activity, benefits of increasing physical activity and reducing sedentary behaviour, overcoming barriers/hurdles to doing physical activity, being active in everyday life, staying motivated, keeping energised, exploring

local indoor and outdoor activities). Time for informal socialising will make up the final portion of the weekly group-based session. The session will be delivered in a suitable NHS or community venue and run weekly for 18 weeks.

Randomisation
Allocation will be through block randomisation (with random permuted blocks of various integer multiple of two size) with a separate schedule for each combination of centre and diagnosis. There will be no additional stratification factors, beside centre, and diagnosis (Schizophrenia (F20 and subcodes) vs. Schizoaffective disorder (F25 and subcodes) vs. Other psychotic and delusional disorders (not of known organic origin) (F21 – F24 and F26 – F29 and subcodes) vs. Bipolar disorder and manic episodes (F30 and F31, and subcodes)) in the randomisation sequence. The study statistician in Sheffield CTRU will generate the randomisation schedule prior to the start of the study using its own web-based in-house CTRU (SCRAM) randomisation system.

Intervention Type
Behavioural

Primary outcome(s)
Objective accelerometer-derived minutes per day of Moderate to Vigorous Physical Activity (MVPA) measured at 6-months post randomisation

Key secondary outcome(s))
1. Data on physical activity (light physical activity and MVPA) and sedentary behaviour will be collected by wrist worn accelerometers at baseline, 3-, 6- and 12-months post randomisation.
2. The Simple Physical Activity Questionnaire (SIMPAQ) will be used to measure self-reported physical activity and sedentary behaviour at baseline, 3-, 6- and 12-months post randomisation.

Other secondary outcomes measured at 3, 6 and 12 months:
3. Health behaviours (diet and smoking)
4. Body mass index (kg/m²)
5. Depression (PHQ-9)
6. Anxiety (GAD-7)
7. Loneliness (UCLA-3 item)
8. Health-related quality of life (EQ5D, REQoL)
9. Healthcare resource use and predictive behavioural questionnaire.

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. ICD-10 or DSM-V diagnosis of SMI as documented in GP or psychiatric notes (schizophrenia (F20 and subcodes); schizoaffective disorder (F25 and subcodes); other psychotic and delusional disorders (not of organic origin) (F21-F24 and F26-F29 and subcodes); bipolar and manic episodes (F30 and F31 and subcodes)).
3. Are able to walk unaided
4. Willing to wear an accelerometer

Participant type(s)
Patient, Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. People who lack capacity to participate
2. Primary diagnosis of drug or alcohol abuse
3. Medical contraindication of physical activity as ascertained by GP or mental health team
4. Already physically active, defined as >300 minutes/week of self-reported moderate-to-vigorous physical activity (MVPA)
5. Non-English speakers
6. People who took part in the feasibility study

Date of first enrolment
01/09/2024

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Health and Social Care NHS Foundation Trust
Centre Court, Atlas Way
Sheffield
England
S4 7QQ

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital
Edward Pease Way
Darlington
England
DL2 2TS

Study participating centre
Leeds and York Partnership NHS Foundation Trust
2150 Century Way
Thorpe Park
Leeds
England
LS15 8ZB

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
England
BR3 3BX

Study participating centre
Kent and Medway NHS and Social Care Partnership Trust
Farm Villa
Hermitage Lane
Maidstone
England
ME16 9PH

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Trust Headquarters
Fieldhead Hospital
Ouchthorpe Lane

Wakefield
England
WF1 3SP

Study participating centre
Devon Partnership NHS Trust
Wonford House
Dryden Road
Exeter
England
EX2 5AF

Study participating centre
Southern Health NHS Foundation Trust
Trust HQ,
Tatchbury Mount
Calmore
Southampton
England
SO40 2RZ

Study participating centre
Lincolnshire Partnership NHS Foundation Trust Hq
NHS Foundation Trust
Carholme Court
Long Leys Road
Lincoln
England
LN1 1FS

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
England
NE3 3XT

Sponsor information

Organisation
Sheffield Health and Social Care NHS Foundation Trust

ROR
https://ror.org/05cn4v910

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/ or analysed during the current study will be available on request from Emily Peckham email: e.peckham@bangor.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes