

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/08/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/08/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Study website
<https://www.spacesproject.co.uk/>

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Emily Peckham

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
338802

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

IRAS 338802, 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

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention, Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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.

Overall study start date

01/01/2024

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

736

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

28/02/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Sheffield Health and Social Care NHS Foundation Trust

Centre Court, Atlas Way

Sheffield

United Kingdom

S4 7QQ

Study participating centre

Tees, Esk and Wear Valleys NHS Foundation Trust

Trust Headquarters

West Park Hospital

Edward Pease Way

Darlington

United Kingdom

DL2 2TS

Study participating centre

Leeds and York Partnership NHS Foundation Trust

2150 Century Way

Thorpe Park

Leeds

United Kingdom

LS15 8ZB

Study participating centre

South London and Maudsley NHS Foundation Trust

Bethlem Royal Hospital

Monks Orchard Road

Beckenham

United Kingdom

BR3 3BX

Study participating centre

Kent and Medway NHS and Social Care Partnership Trust

Farm Villa

Hermitage Lane

Maidstone

United Kingdom

ME16 9PH

Study participating centre

South West Yorkshire Partnership NHS Foundation Trust

Trust Headquarters
Fieldhead Hospital
Ouchthorpe Lane
Wakefield
United Kingdom
WF1 3SP

Study participating centre

Devon Partnership NHS Trust

Wonford House
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre

Southern Health NHS Foundation Trust

Trust HQ,
Tatchbury Mount
Calmore
Southampton
United Kingdom
SO40 2RZ

Study participating centre

Lincolnshire Partnership NHS Foundation Trust Hq

NHS Foundation Trust
Carholme Court
Long Leys Road
Lincoln
United Kingdom
LN1 1FS

Study participating centre

Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust

St Nicholas Hospital
Jubilee Road
Gosforth

Newcastle upon Tyne
United Kingdom
NE3 3XT

Sponsor information

Organisation

Sheffield Health and Social Care NHS Foundation Trust

Sponsor details

Centre Court
Atlas Way
Sheffield
England
United Kingdom
S4 7QQ
+44 114 2716310
rdu@shsc.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://shsc.nhs.uk/>

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

Publication and dissemination plan

Planned publication of results in a high-impact peer-reviewed journal. Planned publication of the study protocol.

Intention to publish date

31/03/2028

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