

Supporting Physical Activity through Co-production in people with Severe Mental Illness: Feasibility Trial

Submission date 12/07/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 09/09/2022	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 24/05/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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. Practical issues in establishing such a study will also be examined.

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

Who can participate?

People aged 18 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 on how many people who sign up to the study, the number of people who drop out along the way, and the number of missed sessions for the intervention. We will interview a small group of people about their experience of being part of the study.

What are the possible benefits and risks of participation?

This is considered a low-risk research study.

This is an opportunity for participants to inform the development of future research (larger trial) and 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 July 2022 to December 2024

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)

Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

311668

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 311668, CPMS 53407

Study information

Scientific Title

Supporting Physical Activity through Co-production in people with Severe Mental Illness (SPACES): a randomised feasibility study of an intervention aimed at increasing the physical activity of people with severe mental ill health

Acronym

SPACES

Study objectives

1. People with conditions like schizophrenia, schizoaffective disorder, and bipolar disorder are less physically active than those without these health conditions, and the World Health Organisation has said that being more physically active can have as big an impact on health as stopping smoking
2. To evaluate the acceptability of a bespoke intervention designed to increase physical activity and the critical parameters for the design of a definitive RCT when compared to treatment as usual

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 18/08/2022, West of Scotland 5 Research Ethics Committee (via Zoom; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 22/WS/0101

Study design

Multicentre feasibility randomized controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Increasing physical activity levels in adults with severe mental ill health (SMI)

Interventions

Participants are randomised via block randomisation with a separate schedule for each site /centre to receive either:

1. Usual care alone
2. Usual care plus an 18-week physical activity intervention developed using a synthesis of current evidence and co-produced through public involvement members with SMI and other key stakeholders

Intervention Type

Behavioural

Primary outcome(s)

1. Acceptability of the intervention measured using:
 - 1.1. The Acceptability Intervention Measure (AIM) at 6 months post-randomisation (intervention participants only)
 - 1.2. Intervention uptake, attendance, and attrition throughout the study
 - 1.3. Interviews with intervention participants and intervention facilitators at 6 months post-randomisation
2. Feasibility of a full-scale trial measured using:
 - 2.1. Participant recruitment data at the end of recruitment
 - 2.2. Monitoring the quantity and quality of accelerometer-derived physical activity data collected at baseline, 3 months post-randomisation, and 6 months post-randomisation
 - 2.3. Interviews with intervention participants and intervention facilitators at 6 months post-randomisation

Key secondary outcome(s)

1. Physical activity measured using accelerometer data at baseline, 3, and 6 months post-randomisation
2. Sedentary behaviour measured using accelerometer data at baseline, 3, and 6 months post-randomisation
3. Body mass index (BMI) calculated using height and weight measurements at baseline, 3, and 6 months post-randomisation
4. Severity of depression measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline, 3, and 6 months post-randomisation
5. Severity of generalised anxiety disorder measured using the General Anxiety Disorder-7 (GAD-7) questionnaire at baseline, 3, and 6 months post-randomisation
6. Self-reported physical activity and sedentary behaviour measured using the Simple Physical Activity Questionnaire (SIMPAQ) at baseline, 3, and 6 months post-randomisation
7. Health-related quality-of-life measured using the EuroQoL 5D-5L (EQ5D-5L) questionnaire at baseline, 3, and 6 months post-randomisation
8. Health-related quality-of-life measured using the Short Form Health Questionnaire - 12 (SF-12) at baseline, 3, and 6 months post-randomisation
9. Mental health-related quality-of-life measured using the Recovering Quality of Life (ReQoL) at baseline, 3, and 6 months post-randomisation
10. Healthcare resource use measured using a bespoke healthcare service use questionnaire (collecting participant's use of primary, secondary, and community healthcare services, with special attention paid to physical activity and mental health related services) at baseline, 3, and 6 months post-randomisation

Completion date

31/12/2024

Eligibility

Key inclusion criteria

1. Aged ≥ 18 years
2. Schizophrenia and other non-organic psychoses (ICD F20 -F29 and subcodes or DSM equivalent), and Bipolar Disorder and manic episodes (ICD F30 and F31 and subcodes and DSM equivalent)
3. Able to walk unaided

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

71

Key exclusion criteria

1. Lack capacity to participate
2. Primary diagnosis of drug or alcohol abuse
3. Have a medical contraindication of physical activity
4. Already physically active, defined as currently doing >300 min/week of self-reported moderate to vigorous physical activity
5. Unwilling to wear accelerometer
6. Non-English speakers

Date of first enrolment

26/09/2022

Date of final enrolment

28/04/2023

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**Sheffield Health & Social Care NHS Foundation Trust**

Fulwood House
Old Fulwood Road
Sheffield
United Kingdom
S10 3TH

Study participating centre**South West Yorkshire Partnership NHS Foundation Trust**

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

Study participating centre

Kent and Medway NHS and Social Care Partnership Trust

Farm Villa
Hermitage Lane
Maidstone
United Kingdom
ME16 9PH

Study participating centre

North East London NHS Foundation Trust

West Wing
C E M E Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Study participating centre

South London and Maudsley NHS Foundation Trust

Bethlem Royal Hospital
Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

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

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 stored in a publicly available repository.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/02/2024	19/02/2024	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes

