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

Submission date
12/07/2022

Recruitment status
No longer recruiting

Registration date
09/09/2022

Overall study status
Completed

Last Edited
24/05/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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

Contact information

Type(s)
Principal Investigator

Contact name
Dr Emily Peckham

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Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
311668

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

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

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 measure
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

Secondary outcome measures
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. Severty 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 edentary 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

Overall study start date
01/07/2022

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
48-72

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
England

United Kingdom

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

Sponsor details
Fulwood House
Old Fulwood Road
Sheffield
England
United Kingdom
S10 3TH
+44 (0)1142716605
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
29/12/2025

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?
HRA research summary			28/06/2023	No	No
Protocol article		17/02/2024	19/02/2024	Yes	No