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Helping people with severe mental illness lower their risk of heart disease through peer support groups

Submission date
06/08/2025

Recruitment status
Recruiting

Registration date
18/08/2025

Overall study status
Ongoing

Last Edited
19/08/2025

Condition category
Mental and Behavioural Disorders

[ ] 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
People living with severe mental illness (SMI), such as schizophrenia or bipolar disorder, often have poorer physical health and can die 15–20 years earlier than the general population. One of the main causes of early death is heart disease. This risk is even higher for people from Black, Asian and minority ethnic communities. The PEGASUS study is testing a new group programme designed to help people with SMI reduce their risk of heart disease. The programme includes support with healthy eating, physical activity, and managing health goals, and is co-led by peer support workers (people with lived experience of mental health difficulties) and healthcare professionals.

Who can participate?
Adults who have a diagnosis of severe mental illness and also have metabolic syndrome (a group of health conditions that increase the risk of heart disease) may be able to take part.

What does the study involve?
Participants will be invited to join a group of 8–12 people for 10 sessions over 6 months. Each session lasts 2 hours and is led by a peer support worker and a healthcare professional. The sessions focus on different aspects of health and wellbeing. Participants will also have an individual ‘onboarding’ session before the group starts, four one-to-one sessions with a peer worker during the programme, and a reunion session after the programme ends. The study will also involve completing questionnaires and health checks at the beginning, middle, and end of the programme. Some participants may be invited to take part in an interview or focus group to share their views on the programme.

What are the possible benefits and risks of participating?
Taking part may help participants improve their physical health, feel more confident about managing their health, and feel more socially connected. There are no major risks, but some people may find it difficult to talk about their health or take part in group sessions. Support will be available throughout.

Where is the study run from?
City St George’s, University of London (UK)

When is the study starting and how long is it expected to run for?
June 2025 to March 2026

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

Who is the main contact?
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Study website
https://city.ac.uk/pegasus

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
326517

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 59641, NIHR204418

Study information

Scientific Title
A peer-led group programme for people with severe mental illness to reduce risk of cardiovascular disease (PEGASUS): A feasibility evaluation study

Acronym
PEGASUS feasibility study

Study objectives
The aim of this research is to feasibility test a trained peer-supported group clinic intervention for people with SMI who have increased risk of CVD. Building on development work, evidence from a systematic review and an experience-based co-design process leading to the development of a co-produced peer-supported group clinic intervention, the objectives of this study are:
1. To establish the feasibility of the intervention for future evaluation in a randomised controlled trial (RCT), specifically:
1.1. Establish the feasibility of recruitment and retention strategies for the main trial
1.2. Assess the acceptability of, and retention to the planned intervention for individuals with SMI and elevated CVD risk
1.3. Determine the feasibility of collecting primary and secondary outcome data for the main trial
2. Estimate the location (proportion) and variability (confidence intervals) of the primary outcome to refine the power calculations for the main trial
3. To refine the content and delivery strategies for the intervention
4. To determine the best method of evaluating intervention implementation and fidelity

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/10/2024, Wales Research Ethics Committee 7 (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2922 940968; Wales.REC7@wales.nhs.uk), ref: 24/WA/0289

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Severe mental illness and metabolic syndrome

Interventions
The PEGASUS intervention is a therapeutic group programme for people with severe mental illness at risk of cardiovascular disease and has been co-produced by peer workers, clinicians, and most importantly people with lived experience. The programme consists of 10 group sessions over the course of 6 months. The duration of each session is 2 hours. Each session consists of the same group of 8-12 people and the same two facilitators; a mental health peer support worker (someone who has lived experience of mental health difficulties and is using such experience in their work to support others) and a health care professional (this might be a nurse, dietician or occupational therapist). Each session will have a focus on different aspects of health and wellbeing that our previous research has identified as important to people with SMI and cardiovascular disease risk. Participants are also offered an ‘onboarding’ session with one of the facilitators in advance of the first group session, and 4 additional one-to-one sessions with the peer support worker over the course of the programme. A reunion session will be offered within 3 months of the programme finishing.

Intervention Type
Behavioural

Primary outcome measure
Acceptability of intervention and study delivery as assessed by focus group/interviews at 3 and 6-months.

Secondary outcome measures
1. Participant recruitment and retention rate is measured using study records at baseline, 3 months, and 6 months
2. Waist circumference is measured using tape measurement at baseline, 3 months, and 6 months
3. Hip circumference is measured using tape measurement at baseline, 3 months, and 6 months
4. Body mass index (BMI) is measured using height and weight measurements at baseline, 3 months, and 6 months

5. Triglycerides are measured using fasting blood sample at baseline, 3 months, and 6 months
6. HDL-cholesterol is measured using fasting blood sample at baseline, 3 months, and 6 months
7. LDL-cholesterol is measured using fasting blood sample at baseline, 3 months, and 6 months
8. Total cholesterol is measured using fasting blood sample at baseline, 3 months, and 6 months
9. HbA1c is measured using blood sample at baseline, 3 months, and 6 months
10. Blood pressure is measured using automated sphygmomanometer at baseline, 3 months, and 6 months
11. Psychiatric symptoms are measured using the Modified Colorado Symptom Index at baseline, 3 months, and 6 months
12. Dietary behaviour is measured using the Dietary Instrument for Nutrition Education (DINE) adapted by IMPaCT at baseline, 3 months, and 6 months
13. Physical activity is measured using the International Physical Activity Questionnaire - Short Form (IPAQ-SF) at baseline, 3 months, and 6 months
14. Tobacco, cigarette, and betel nut or paan use is measured using self-report questionnaire at baseline, 3 months, and 6 months
15. Alcohol consumption is measured using the Alcohol Use Disorders Identification Test - Consumption (AUDIT-C) at baseline, 3 months, and 6 months
16. Health-related quality of life is measured using the EQ-5D-5L at baseline, 3 months, and 6 months
17. Depression is measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline, 3 months, and 6 months
18. Self-efficacy is measured using the Generalised Self-Efficacy Scale at baseline, 3 months, and 6 months
19. Social network is measured using the Lubben Social Network Scale at baseline, 3 months, and 6 months
20. Therapeutic relationship is measured using the Scale to Assess the Therapeutic Relationship (STAR) at baseline, 3 months, and 6 months
21. Progress towards achievement of personalised lifestyle goals is measured using the Goal-Based Outcome Tool at baseline, 3 months, and 6 months
22. Health and social care service use is measured using the DIAMONDS Service Use Survey at baseline, 3 months, and 6 months
23. Physical activity levels are measured using one-week accelerometer wear at baseline, 3 months, and 6 months

Overall study start date
01/06/2025

Completion date
31/03/2026

Eligibility

Key inclusion criteria
Service users participants will:
1. Be aged 18 to 75 years
2. Have capacity to consent to participate in research
3. Service Involvement:
3.1 Currently on the caseload of mental health services in community settings
3.2 Or on GP/ICS severe mental illness (SMI) list
4. Diagnosis:
4.1 Current primary diagnosis of schizophrenia-spectrum disorders (ICD-10 diagnoses F20–29)

4.2 Or bipolar disorder (F31)
4.3 Or in Early Intervention for Psychosis Services (EIPS) with formal diagnosis of the above conditions
5. If on psychotropic medication, must be on a stable dose for 90 days
6. Enhanced Cardiovascular Disease (CVD) Risk as indicated by metabolic syndrome (NCEP ATP III definition), confirmed at screening by any three of the following:
6.1 Waist circumference over 102 cm (men) or 88 cm (women)
6.2 Blood pressure over 130/85 mmHg or documented hypertension on medication
6.3 Fasting triglyceride level over 1.7 mmol/l
6.4 HDL cholesterol level less than 0.9 mmol/l (men), 1 mmol/l (women)
6.5 HbA1c > 37 mmol/mol (5.5%) or documented Type-2 diabetes (T2D) and on medication
6.6 If on treatment for T2D, hypertension or hyperlipidaemia, must be on stable dose medication for at least 90 days

Intervention staff:
1. Peer (support) workers and registered mental health nurses (or other healthcare professionals or practitioners with appropriate training)
2. Based at one of the five sites/Trusts
3. Have been trained and engaged with the PEGASUS programme to deliver (co-facilitate) the PEGASUS intervention for the purposes of this study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Service users who:
1. Are currently admitted to acute psychiatric care (i.e. inpatient admission or current referral to a Crisis & Home Treatment Team)
2. Have a primary diagnosis of alcohol or substance misuse
3. Are awaiting/going through assessment with EIPS but without formal diagnosis
4. Have a diagnosis of an organic mental health disorder (e.g. dementia)
5. Are currently in receipt of a highly structured and/ or multi-goal healthy lifestyle intervention (e.g. an intervention that combines structured diet and exercise goals, or a highly structured research-based intervention such as DIAMONDS or PRIMROSE-A). Note: referral to single goal lifestyle support, as typically provided in the voluntary-sector or as online NHS advice, is considered as part of care as usual and will be assessed in both trial groups

6. HbA1c > 86 mmol/mol
7. Blood pressure or hyperlipidaemia managed outside of primary care
8. Type 1 diabetes

Intervention staff:
Peer (Support) Workers, registered mental health nurses or other healthcare professionals or practitioners who are not trained for nor delivering the PEGASUS intervention for the purposes of this study.

Date of first enrolment
01/06/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
East London NHS Foundation Trust
Robert Dolan House
9 Alie Street
London
United Kingdom
E1 8DE

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
Birmingham and Solihull Mental Health NHS Foundation Trust
Unit 1
50 Summer Hill Road

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B1 3RB

Study participating centre
South West London and St George's Mental Health NHS Trust
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Sponsor type
University/education

Website
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ROR
https://ror.org/04489at23

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 in a peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Study Team, in accordance with the policies and conditions set out by the ethical or legal restrictions.
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IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	15/10/2024	15/08/2025	No	Yes