Title: A peer-group programme for people with severe mental illness to reduce risk of cardiometabolic disease (PEGASUS): protocol for a feasibility study

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Abstract

Background People diagnosed with severe mental illness (SMI) die around 15-20 years prematurely compared with people without these conditions, partially to a 50% increased risk of developing cardiovascular disease (CVD). Treatment and diagnosis rates of CVD and metabolic disease (together called cardiometabolic disease) are lower in people diagnosed with SMI, at a considerable cost to individuals and their families, health services, and society. Previous trials have shown that behaviour change interventions to reduce cardiometabolic risk, when delivered alone, produce modest results at best. PEGASUS aims to co-design a peer-led group intervention with lived experience and which includes social integration and peer support along with behaviour change to reduce cardiometabolic risk in people diagnosed with SMI.

Methods This is a multi-site single arm mixed methods study based in three National Health Service (NHS) Mental Health Trusts in England, aiming to test the feasibility of the PEGASUS intervention and its future evaluation in a large-scale randomised controlled trial. Over six months, participants aged 18-75, with a diagnosis of SMI and enhanced cardiovascular disease risk will attend ten fortnightly support groups led by a peer support worker and a healthcare professional, focusing on physical health, both general and specific to those diagnosed with SMI. Additionally, there are four one-to-one sessions with a peer support worker and a booster session three months after the intervention has ended. Biometric, accelerometer, behavioural and psychometric questionnaire data will be collected at baseline, three months, and six months, accompanied by qualitative interview and focus group data at three and six months. The feasibility and acceptability of each measure will also be measured. Quantitative data will be analysed using STATA and qualitative data will be analysed with NVivo using rapid framework analysis.

Discussion This study will determine the feasibility and acceptability of a peer-led group programme to reduce cardiovascular disease risk in people diagnosed with SMI. The results will inform the PEGASUS randomised controlled trial.

Trial registration This study was approved by the Health Research Authority and Wales Research Ethics Committee (IRAS: 326517) on 3rd September 2024 and was registered with the ISRCTN (29596999) on 18th August 2025.

Keywords cardiovascular disease, cardiometabolic disease, severe mental illness, behaviour change, feasibility study, metabolic syndrome, schizophrenia, bipolar disorder, psychosis, co-production, peer support

1.Introduction

1.1 Background and rationale

People with a diagnosis of severe mental illness (SMI) such as schizophrenia, bipolar disorder and other psychoses, have poorer physical health and die on average 15-20 years younger than people without a diagnosis of SMI (1) . People diagnosed with SMI have approximately 50% increased risk of developing cardiovascular disease (CVD) (2), the single biggest contributor to premature death (3), and a two to threefold risk of developing type 2 diabetes mellitus (T2D) (4, 5) compared to people without a diagnosis of SMI. Furthermore, there is a 'double disadvantage' for people from South Asian, Black African and Black Caribbean communities in the UK who may have both an elevated risk of poor cardiometabolic health and higher rates of SMI (6). There is systematic under-screening (7), under-recognition (7, 8) and under-treatment (9, 10) of CVD and its risk factors in people diagnosed with SMI in primary care (7), resulting in one of the greatest multi-morbidity and health inequality gaps in England (8). Considering that the impact of CVD for the UK economy exceeds £29 billion annually, its under-recognition and under-treatment among people diagnosed with SMI lead to substantial costs for the healthcare system and society (11).

Trials conducted in the UK focusing on physical health of people diagnosed with SMI have not achieved improvements in primary outcomes including total cholesterol (12), weight (13) or health-related quality of life (14). These interventions used established behavioural change techniques, such as goal-setting and action planning, but failed to achieve lifestyle changes necessary to reduce cardiometabolic risk. Other recent studies largely address single risk factors for cardiovascular and metabolic health and evaluate single goal interventions, while for the most part not specifically addressing issues of social isolation and poor social support that compound physical and mental health challenges for people diagnosed with SMI (15-17) . However, there is good evidence indicating that multiple goal interventions are associated with improved cardiometabolic health (18) and that for people diagnosed with SMI, peer-based approaches, which reduce social isolation and increase social support show promise (19). Indeed studies have shown that social support facilitates physical activity and self-management of SMIs through encouragement, practical support and shared experiences (20, 21). There is therefore a strong rationale for developing and evaluating a multi-goal peer-group and peer supported intervention, specifically addressing challenges for people diagnosed with SMI and aimed at reducing risks and subsequent costs of cardiometabolic disease.

Following a comprehensive synthesis of research evidence on group interventions for improving physical health outcomes in people with SMI (22) and a qualitative study with people with SMI (IRAS ID: 336978), we set out to co-design a culturally-responsive lifestyle intervention that combined: a) a self-management programme targeted to address the range of specific challenges faced by people diagnosed with SMI to looking after their physical health; b) peer support to improve social inclusion and self-efficacy; and c) a group model co-led by peer support workers and healthcare professionals. The research described in this protocol will assess the feasibility of the intervention and the evaluation parameters.

1.2 Objectives

The aim is to test the feasibility of PEGASUS, a co-designed peer-support group intervention for people diagnosed with SMI and at risk of cardiometabolic disease. The objectives of this feasibility study are:

- To establish the feasibility of recruitment and retention
- To assess the acceptability of the intervention for individuals diagnosed with SMI and elevated cardiometabolic disease risk and for the facilitators delivering the intervention
- To determine the feasibility of collecting the primary and secondary outcome data needed for a future randomised controlled trial
- To estimate the location (proportion) and variability (confidence intervals) of the primary outcome to refine the power calculations for a full trial
- To refine the content and delivery strategies for the intervention
- To determine the best method of evaluating intervention implementation and fidelity

Data on recruitment and retention will determine progression to the RCT with internal pilot in 2027, using specified progression criteria given in Table 1.

Table 1: Pre-specified progression criteria

Progression criteria	**GREEN status**	**AMBER status**	**RED status**
i) Proportion of potential participants who consent to participate in the study who are screened as eligible	At least 40% of those who consent to participate in the study are screened as eligible	At least 20% of those who consent to participate in the study are screened as eligible	Less than 20% of those who consent to participate in the study are screened as eligible
ii) Adherence measured as: Proportion of	At least 80% of participants attended at least 50% of	At least 50% of participants attended at least 50% of	Less than 50% of participants attended at least 50% of

participants who attended at least 50% of programmed group sessions and at least one 1-to-1 peer support session	programmed group sessions and at least one 1-to-1 peer support session	programmed group sessions and at least one 1-to-1 peer support session	programmed group sessions and at least one 1-to-1 peer support session

1.3 Study design

The study is a multi-site, non-randomised, single arm, mixed methods feasibility study.

2. Methods: participants, interventions, and outcomes

2.1 Study setting

The study will be carried out in up to four National Health Service (NHS) Mental Health Trusts in urban areas in England characterised by high levels of ethnic diversity.

2.2 Eligibility criteria

<u>Inclusion criteria</u>

Participants will be able to join the study if they meet the following criteria:

- Aged 18 to 75 years
- Have capacity to consent to participate in research
- Currently on the caseload of community mental health services or on primary care or Integrated Care Board (ICB) SMI registers
- Current primary diagnosis of schizophrenia-spectrum disorders (ICD-10 diagnoses F20–29) or bipolar disorder (F31) or in Early Intervention for Psychosis Services (EIPS) with formal diagnosis of psychosis (ICD-10 diagnoses of F29)

- If on psychotropic medication, on stable dose for 90 days (N.B. This refers specifically to either adding or changing to a new antipsychotic medication but does not apply to dosage adjustment of a pre-existing antipsychotic medication.)
- Enhanced CVD risk as indicated by any one of:
    - Obesity defined as: waist circumference over 102cm or BMI ≥25 kg/m2 in white men or waist circumference over 90cm or BMI or ≥23 kg/m2 in minority ethnic men, and waist circumference over 88cm or BMI ≥25 kg/m2 in white women or waist circumference over 80cm or ≥23 kg/m2 in minority ethnic women
    - Hypertension defined as: blood pressure over 130/85 mmHg or documented hypertension on medication
    - Dyslipidaemia defined as: fasting triglyceride level over 1.7mmol/l or total cholesterol ≥5.0 mmol/L or on medication for hyperlipidaemia (e.g. statin) or high-density lipoprotein (HDL) cholesterol level less than 0.9mmol/l (men)/1mmol/l (women)
    - Hyperglycaemia defined as: HbA1c > 37 mmol/mol (5.5%) or fasting plasma glucose level ≥5.6 mmol/l or documented type 2 diabetes (T2D)
- If on treatment for T2D, hypertension or hyperlipidaemia, on stable dose medication for at least 90 days

<u>Exclusion criteria</u>

Participants will not be eligible if they meet any of the following criteria:

- Are currently admitted to acute psychiatric care (i.e. inpatient admission or current referral to a Crisis & Home Treatment Team)
- Have a primary diagnosis of alcohol or substance misuse
- Are awaiting/going through assessment with Early Intervention in Psychosis Service but without formal diagnosis

- Have a diagnosis of an organic mental health disorder (e.g. dementia)
- 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 (23)or PRIMROSE (17). 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)
- Blood pressure or hyperlipidaemia managed outside of primary care
- Type 1 diabetes

2.3 Informed consent

Potential participants will be given a Participant Information Sheet (PIS) at least 24 hours before informed consent is given. Informed consent will be obtained in person, over the phone, or via video conferencing, as the participant prefers. If done remotely, the researcher will sign on behalf of the participant and send a copy to the participant so that they can sign and keep a copy for their record.

2.4 PEGASUS Intervention

2.4.1 Intervention design

The PEGASUS lifestyle intervention was developed based on a literature review, focus groups with people with mental health conditions/barriers/diagnoses, input from a Lived Experience Advisory Group and Equality, Diversity, and Inclusion experts, relevant health professionals including specialists in primary care, mental health, behaviour change and metabolic health, and three co-design workshops. It aims to support people diagnosed with SMI to reduce their risk of cardiovascular disease through increasing social support, self-efficacy, behaviour change and health knowledge and skills. It is underpinned by eight principles (referred to as the PEGASUS values) that

emerged from the co-production process with people with lived experience of SMI. These are that the intervention should be fun, social, flexible, safe, empowering, realistic, respectful, and mindful of people's mental health. The core of the intervention comprises ten two-hour sessions over a period of six months with the same group of 8-12 participants held at the NHS Trust. The sessions will be co-facilitated by a peer support worker and a health care professional already employed through the NHS Trust, with an additional peer support worker trained as back up. Facilitators will receive training and a manual on intervention delivery and PEGASUS ethos, followed by ongoing support and supervision from a dedicated member of the research team. Additional health care professionals (e.g. a physiotherapist, dietician, GP, etc.) will be invited as guests to specific sessions to share their expertise. The ten sessions cover a range of topics of relevance to cardiovascular and metabolic health, including physical activity, healthy eating, coping strategies, social activity, understanding blood test results and medication management and side-effects. Each of the ten sessions involves a short educational component, discussions drawing on the group's experiential knowledge, co-designed asset mapping and a fun activity. Participants will be encouraged and supported to set personalised goals for improving their physical health and will receive additional support through four one-to-one sessions with a peer support worker. The intervention is topped and tailed with an onboarding session prior to the first group session and a group reunion or booster session three months after the last of the ten core group sessions. The onboarding session offers participants a chance to meet with one of the facilitators (either in person, online or by phone) before the sessions begin so the facilitator can introduce themselves, answer any questions, discuss any concerns and help participants feel at ease. The booster session will provide a reunion opportunity for participants to meet up and share how they have been getting on, to rebuild motivation and to address any challenges faced in sustaining lifestyle changes to support physical health.

2.4.2 Training and supervision for peer workers and clinical staff

Peer workers and clinicians delivering the PEGASUS intervention will be existing staff employed at the NHS sites. They will draw upon their knowledge and experience of working with people with mental health conditions. They will receive one-day training to deliver the intervention which will focus on the PEGASUS values, intervention structure, session content, behaviour change and group facilitation techniques, followed by monthly site-specific supervision and cross-site online learning and reflection sessions.

2.4.3 Discontinuation and withdrawal

Participants can choose to discontinue participation in the intervention and/or to withdraw from the study at any time for any reason and do not have to disclose reasons if they so choose. A log will be kept of discontinuations, withdrawals and any reasons provided.

2.4.4 Improving intervention uptake and attendance

Trusts will devise their own methods of improving attendance—potentially including but not limited to appointment cards and phone call/text reminders to align with what occurs with usual Trust appointments. Learnings will be included in future facilitator manual versions.

Facilitators will take attendance data at each session. If a participant misses a session, they will be offered a catch-up with a facilitator to help them feel comfortable to rejoin.

2.4.5 Concomitant care

Participants will continue to receive their usual care outside of PEGASUS, including any primary or secondary mental or physical health care.

2.5 Outcomes

The primary outcome of this feasibility study is retention of participants. Secondary outcomes will be the final content and delivery of the intervention, statistical measurements of primary and secondary outcomes (e.g. mean and standard deviation (SD)) and evaluation strategies needed for a future randomised controlled trial. The outcome measures will be both quantitative and qualitative and include attendance data, biomarkers, health metrics, and questionnaires at baseline, three- and six-months follow-up, and qualitative interviews/focus groups at three and six months (see Table 2).

Biomarkers/metrics will include waist and hip circumference, Body Mass Index (BMI), blood pressure (measured as the mean of three readings), and a blood test measuring triglycerides, HDL-cholesterol, LDL-cholesterol, total cholesterol and HbA_{1c}. Questionnaires include:

- Psychiatric symptoms using the Modified Colorado Symptom index (24)
- Lifestyle behaviour, measured using:
    - Dietary Instrument for Nutrition Education (DINE) (25), adapted by IMPaCT (26)
    - International Physical Activity Questionnaire - Short Form (IPAQ-SF) (27)
    - Cigarette smoking, tobacco and betel nut or paan (also spelled pan) use (28, 29)
    - Alcohol consumption test (AUDIT-C) (30)
- Health-related quality of life measured using the EQ-5D-5L (31) and Manchester Short Assessment of Quality of Life (MANSA) (32)
- Depression measured using the PHQ9 (33)
- Self-efficacy measured using the Generalised Self Efficacy Scale (34)
- Social network measured using the Lubben Social Network Scale (35)

  Health resource utilisation questionnaire adapted from version developed within the DIAMONDS study (16). Data collected include resources used at primary care, A&E attendances, NHS calls, inpatient stays, outpatient and community-based care appointments, and medications (concomitant care). The DIAMONDS questionnaire was

shared with the PEGASUS study by the DIAMONDS study investigators and is not publicly available.

Participants will also be asked to wear a wrist-worn Axivity AX6 accelerometer (36, 37) for one week prior to the start and in months three and six of the intervention. These measure the amount and intensity of physical activity, sedentary behaviour, and sleep windows but have no display visible to the wearer. After each period of wearing, a researcher will download data from the accelerometer using OMGUI software before secure transfer to the central study team.

Table 2: Participant assessments and time points

Assessment	**Enrolment/ Screening**	**Baseline**	**3 months**	**6 months**
Participant recruitment rate	X			
Participant retention		X	X	X
Acceptability (qualitative interviews/focus groups)			X	X
Height	X		X	X
Weight	X		X	X
Waist circumference	X		X	X
Hip circumference	X		X	X
Triglycerides (fasting)	X		X	X
Cholesterol (HDL/LDL/Total)	X		X	X
HBA_{1C}	X		X	X
Blood pressure	X		X	X

Metabolic syndrome - Modified NCEP ATPIII definition (calculated from the above five measures)	X		X	X
Cardiovascular disease risk – QRISK3		X		
Sociodemographics		X		
Smoking status/tobacco use		X	X	X
Alcohol consumption		X	X	X
Diet - Dietary Instrument for Nutrition Education (DINE), adapted by IMPaCT		X	X	X
Physical Activity - International Physical Activity Questionnaire – Short Form (IPAQ-SF), and Accelerometer worn for one-week		X	X	X
Mood & cognitive symptoms - Modified Colorado Symptom Index		X	X	X
Depression - PHQ9		X	X	X
Self-efficacy - Generalised Self Efficacy scale		X	X	X
Social Network - Lubben Social Network Scale		X	X	X
Health-related Quality of Life - MANSA & EQ5DL		X	X	X
Health and concomitant care - health care survey adapted from the DIAMONDS study		X	X	X
Medication			X	X

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The following data on recruitment, questionnaire completion and intervention attendance will be collected during the intervention period:

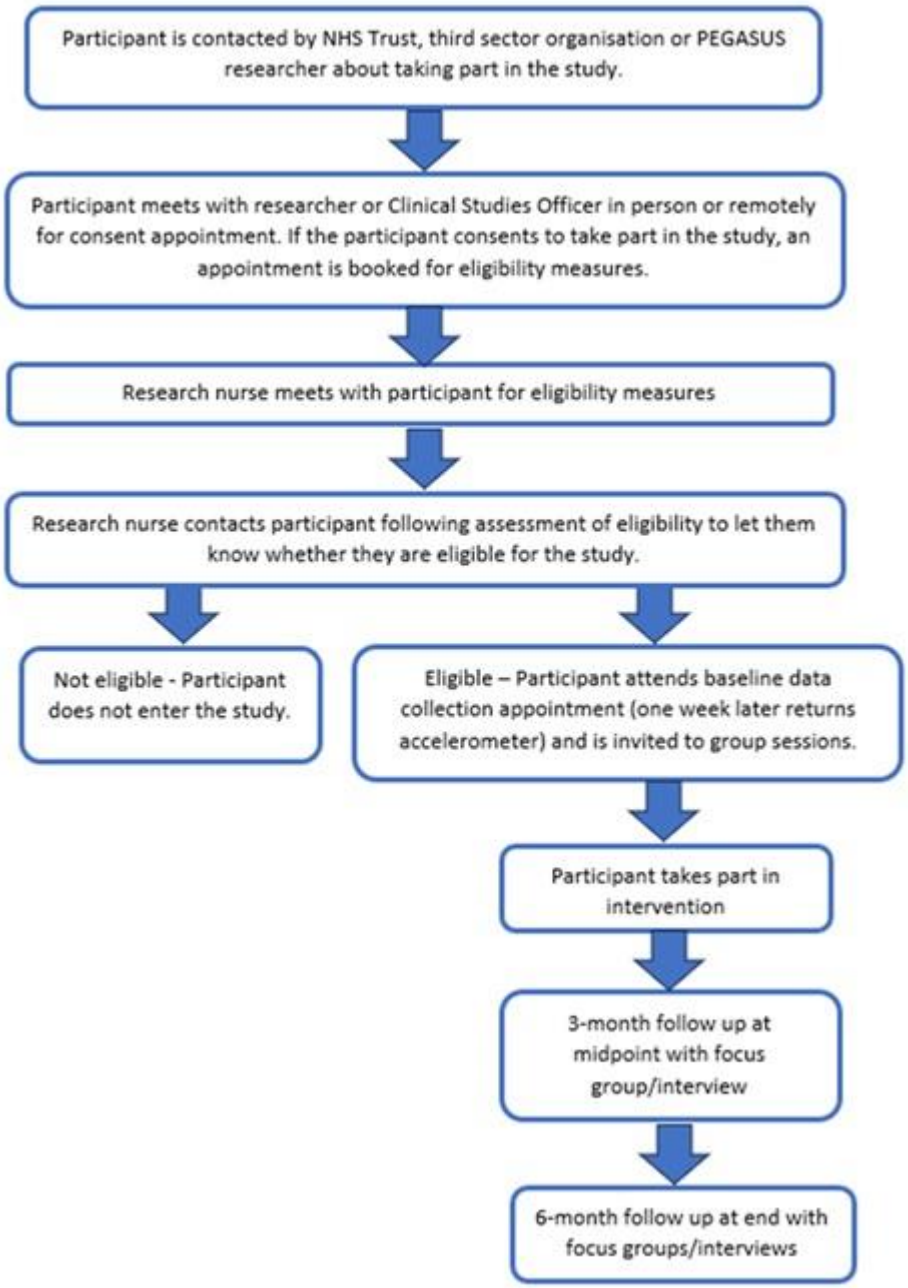
- Number of participants screened
- Number confirmed as eligible after initial clinical assessment and invited to continue to take part in the intervention
- Reason for declining participation where applicable
- Intervention session attendance
- Follow-up data completion rate (questionnaires and clinical data)
- Reason for dropout where applicable

2.6 Participant timeline

The participant schedule through the study including eligibility, consent, screening, baseline, first follow-up and final follow up is shown in Fig. 1.

Figure 1

PEGASUS FEASIBILITY STUDY PARTICIPANT EXPERIENCE FLOW CHART



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2 2.7 Sample size

3 We will recruit and train up to four peer workers and two health care professionals to deliver the
4 intervention at each site. We aim to recruit ten participants in each site (n=40). The sample size is
5 justified based on being able to estimate the rate of retention with specified precision. Assuming
6 four groups of ten participants take place, an intracluster correlation coefficient (ICC) of 0.03, and

the rate of retention is estimated as 85% or higher, the current sample size will allow us to estimate the rate of retention with a margin of error (half the width of the 95% CI) of 14% (38).

2.8 Recruitment

For the purposes of this feasibility study, a purposive sampling approach will be used to recruit participants with a range of characteristics relevant to the intervention. Recruitment will be facilitated through routes such as primary care searches, with the aim of reducing barriers to participation.

Potential participants will be identified primarily in two ways: a) through reviewing Trust and GP electronic patient records of people diagnosed with SMI and b) Trust research staff screening case registers/clinician caseloads. Both will be done in accordance with Trust privacy notice permissions and consent to contact arrangements. From these records, Trust staff will aim to identify people who have one or more indicators of elevated cardiovascular risk as follows:

- HbA_{1c} > 37mmol/mol (5.5%), documented Impaired Glucose Tolerance or T2D;
- Blood Pressure > 130/85 or established hypertension;
- HDL level less than 0.9mmol/l (men), 1mmol/l (women);
- Fasting triglyceride level over 1.7mmol/l or prescribed with statin;
- BMI>25 in white people or >23 in people from ethnic minorities (39);
- 10-year QRISK3 score ≥ 10%

Those identified as potential participants will be provided with a participant information sheet and an opportunity to speak with a research team member for any further information or questions. If the potential participant agrees to take part in the study, informed consent will be sought for both screening and, if eligibility is confirmed, enrolment in the study. Following screening, which includes

a blood test and anthropometric measures to confirm eligibility to proceed in the study (see inclusion criteria above), participants will either be enrolled into the PEGASUS intervention if eligible, or they will be provided with evidence-based healthy lifestyle information and encouraged to make an appointment with their GP for their next annual physical health check.

Following screening, those identified with uncontrolled hypertension (i.e. either Systolic BP ≥200mmHg or a diastolic BP >115 mmHg) or suspected of familial hypercholesterolaemia will be referred to their GP and will not continue in the feasibility study.

Those enrolled will be contacted by the peer support worker or health professional delivering the intervention for the initial onboarding appointment. This will be followed by the ten group sessions and four one-to-one peer support sessions over the subsequent six months. All participants found eligible to take part in the PEGASUS intervention will be invited to take part in qualitative interviews and/or focus groups halfway through the six-month intervention and at the end.

Interpreters will be identified from local providers used by study sites, either face-to-face or by telephone or videoconferencing application, to support those not fluent in English with the completion of questionnaires.

3: Methods: Data collection, management, and analysis

3.1 Data collection methods

Quantitative data will be collected at four time points: screening, baseline, follow-up at three months and follow-up at six months. Participants will be offered a £25 voucher for each time point and travel expenses for data collection appointments can be reimbursed. At screening and both follow-up time points, a blood sample will be taken by a research nurse or other phlebotomy-trained

staff member to provide a full fasting lipid profile and HbA_{1c} measure, and blood pressure, body mass index (height/weight), and waist and hip circumference will be measured following standard operating procedures (SOP). In addition, the following will be extracted from clinical notes and further checked with participants: current mental health diagnosis; current co-morbid physical health conditions; and current prescribed medication. A self-completion questionnaire will be used to collect sociodemographic data, as well as data on alcohol consumption and tobacco use. The data collected at screening will allow us to calculate QRISK3 scores (40) which indicate a person's risk of developing a heart attack or stroke over the next ten years.

For those found to be eligible to proceed with the study, a baseline questionnaire will be administered either in person or by phone/video link with support from the Trust researcher or interpreter if needed. The baseline questionnaire will measure lifestyle behaviour (including diet and physical activity), psychiatric symptoms and depression, self-efficacy, social network, and service use. The data collected via the baseline questionnaire will be collected again, along with alcohol consumption and tobacco use, in a questionnaire administered at the three- and six- month follow-up time points.

An attendance and reflection sheet will be provided to staff delivering the intervention in order to collect attendance data at group and one-to-one sessions and immediate staff reflections post-group session. These reflections will help us identify additional support needs and will inform the final content and delivery of the intervention in a future randomised controlled trial.

At three and six months, focus groups and/or interviews will be conducted with (1.) participants and (2.) facilitators of the PEGASUS intervention., to explore the acceptability, feasibility, and perceived impact of the programme, specifically identifying barriers and facilitators to engagement and delivery. They will be conducted and analysed by researchers with lived experience of mental

distress.. All focus groups/interviews will be audio recorded, transcribed, and analysed using NVIVO software (41).

3.2 Data management

Data will be collected using paper Case Report Forms (CRF) and inputted into a secure database. Hard copy documentation containing identifiable information (e.g. consent forms) will be stored separately to the research data. A spreadsheet with participant identifiable information (contact details) and a corresponding study identification number will be kept in a password-protected file on the secure, password-protected City St George's, University of London network. Hard copies, where applicable, will be kept in a locked filing cabinet in a room in the School of Health & Medical Sciences at City St George's, University of London and/or at NHS study sites to which only members of the research team will have access. Access to the buildings is restricted by swipe card to authorised staff.

In-person interviews and focus groups will be recorded on an encrypted digital recorder which will be transported in a padlocked bag. Within 48 hours the audio file will be uploaded from the encrypted device to the study drive on the secure, password-protected City St George's, University of London network, after which the recording will be deleted from the encrypted device. Online interviews or focus groups will be recorded using the audio only of videoconferencing software used within the secure City St. George's, University of London network. All audio files will be deleted as soon as they have been transcribed and checked by a researcher. Transcripts will be saved on the study drive on the secure, password-protected City St George's, University of London network. All transcripts will be fully anonymised at the point of transcription; any direct or indirect identifying information will be removed or replaced with pseudonyms to protect participant confidentiality. Anonymised direct quotes will be used in study reports and publications to illustrate key findings.

3.3 Statistical methods

There is no formal hypothesis testing in this feasibility study. Quantitative data will be summarised using STATA (42). Categorical data will be presented as counts and percentages and continuous outcomes as mean and standard deviation (or median and IQR as appropriate), with corresponding 95% confidence intervals.

A measure of cardiometabolic risk, such as reversal of metabolic syndrome at end of intervention, is likely to be the primary outcome used within the future randomised controlled trial. As the definition of metabolic syndrome used does not account for increases in blood pressure and cholesterol with age, we set an upper age limit of 75 years in our inclusion criteria. The proportion of participants with a prevalence, reversal and/or reduced severity of metabolic syndrome will be estimated, alongside measures of variability (i.e. confidence intervals). Estimates will be used to inform the design of the definitive study where appropriate, taking into consideration the potential lack of precision inherent in estimates calculated from feasibility studies.

3.4 Methods for qualitative data analyses

Transcripts of qualitative data - interviews and focus groups - will be uploaded to NVivo software for analysis. Rapid framework analysis will be conducted using the intervention logic model, and Theoretical Domains Framework (43) and Normalisation Process Technique domains (44), to identify areas for improvement in intervention delivery.

4. Methods: Monitoring

4.1 Programme Steering Committee:

An independent programme steering committee (PSC) will meet at least biannually to provide independent oversight, advice and guidance to the programme. The PSC has agreed to take on the role of an independent Data Monitoring Committee (DMC) for this feasibility study and includes

eight independent members including a chair, an independent statistician, at least one other academic or clinical member with appropriate expertise, and two lived experience members.

4.2 Adverse event reporting and harms

This is a feasibility study for a low-risk intervention. Adverse events will be monitored throughout the study and will be assessed to decide whether they are related to either the intervention or study procedures. Adverse events include, but are not limited to, the following expected in this patient population: 1. Psychiatric hospitalisation, 2. Self-harm, 3. Suicide attempt, 4. Death from suicide. Adverse events will be evaluated by the Principal Investigator at each research site and reported to the Programme Manager/CI via email confidentially. All reported adverse events will be compiled on an ongoing basis into a summary table and presented to the DMEC/PSC. Any serious adverse events that are either unexpected (that is, not listed above) and/or related (that is, resulting from the intervention or administration of any of the research procedures) will be reported by sites to the central team and the sponsor for expedited reporting to the DMEC/PSC and the Research Ethics Committee.

5. Discussion

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This feasibility study is part of a wider programme of research – the PEGASUS programme – which aims to build upon the existing literature to help decrease the societal and individual costs of inequality (45) faced by people diagnosed with SMI. The PEGASUS feasibility study will assess the feasibility of delivering and evaluating a co-designed intervention developed to address the burdens faced by people diagnosed with SMI by effecting lifestyle changes across many aspects of their lives and to create meaningful, enduring, positive change. The intervention will be refined in light of data

from this feasibility study and any relevant developments in the field of cardiovascular health. Recruitment and retention data will determine the feasibility of progressing to a full randomised controlled trial with an internal pilot trial and the processes and parameters of the trial will be informed by lessons learned from this feasibility study.

5.1 List of abbreviations

AUDIT-C: Alcohol Use Disorders Identification Test-Concise

BP: blood pressure

CI: chief investigator

CRF: case report form

CVD: cardiovascular disease

DINE: Dietary Instrument for Nutrition Education

DMEC: data monitoring and ethics committee

EIPS: Early Intervention in Psychosis Service

EQ5D-5L: EuroQol Five Dimension, 5 level

HbA_{1c}: glycated hemoglobin A1c level

HDL: high density lipoprotein

ICC: intracluster coefficient

ICD: International Classification of Disease

ICS/ICB: Integrated Care System/Board

IMPaCT: Improving Physical Health and Reducing Substance Use in Severe Mental Illness

IPAQ-SF: International Physical Activity Questionnaire

IQR: inter-quartile range

IRAS: Integrated Research Application System

ISRCTN: International Standard Randomised Controlled Trial Number

LDL: low density lipoprtein

PHQ9: Patient Health Questionnaire 9

PIS: participant information sheet

PMG: programme management group

PSC: program steering committee

NHS: National Health Service

NIHR: National Institute for Health and Care Research

PGfAR: Programme Grants for Applied Research

RCT: randomised controlled trial

SAE: serious adverse event

SAR: serious adverse reaction

SD: standard deviation

SMI: severe mental illness

SOP: standard operating procedure

SUSAR: suspected unexpected serious reaction

T2D: type 2 diabetes

6. Declarations

6.1 Ethics approval and consent to participate

This study has been approved by the Health Research Authority and Care Research Wales Committee 7 (IRAS: 326517) on 15 October 2024. Any protocol amendments will be reported to and approved by the REC committee. All participants will provide written informed consent to participate.

6.2 Consent for publication

Not applicable.

6.3 Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

6.4 Competing interests

RH has received honoraria for speaker engagements from Boehringer-Ingelheim, Eli Lilly, Novo Nordisk, ROVI Pharma and USV unrelated to this work.

6.5 Funding

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6.6 Author's contributions

All authors are deemed to meet the ICMJE guidelines for roles of authors and contributors. JS, SG, and SN are co-chief investigators. VB, JS, SG, SN, JD-M, SG, SLG, KG, GAH, RH, WL, NM, CR and FR were responsible for its conceptualisation, design, supervision, and funding acquisition, and CR is the lead Statistician. VB, JS, SG, SLG, SN, JC, JD-M, SG, KG, BH, GAH, RH, VK, WL, NM, YO, JP, CR, FR, LW were involved in its methodology. JS, SG, SN, BH, LW, JC, JP, and VK were involved in project administration. JS, BH, CS, LW, VK, JP, and JC were responsible for resources. JC, BH were involved in writing. All authors were involved in reviewing and editing.

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