FULL/LONG TITLE OF THE TRIAL

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

SHORT TRIAL TITLE / ACRONYM

PEGASUS feasibility study with people with SMI and metabolic syndrome

This protocol has regard for the HRA guidance and order of content.

RESEARCH REFERENCE NUMBERS

IRAS Number:	**326517**
SPONSORS Number:	**ETH2425-0099**
FUNDERS Number:	**NIHR204418**

TRIAL REGISTRY NUMBER AND DATE: To be applied.

PROTOCOL VERSION NUMBER AND DATE

Version 2.0 dated 01.05.2025

Version Control

Version	Date	Author	Reason
V0.1	12th March 2024	Lauren Walker	First Draft (Feasibility Study only)
V0.5	22nd August 2024	Lauren Walker, Victoria Bird, Jacqueline Sin, et al.	Near final
V1.0	3rd September 2024	PEGASUS PMG	Final
V1.1	15th October 2024	PEGASUS PMG	Amended following REC comments
V1.2	4th February 2025	PEGASUS PMG	Amended with changes in PI in site, timeline and measures used
V2.0	1st May 2025	PEGASUS PMG	Amended with changes in outcome measures and extended duration
V2.1	5th of August 2025	Jacqueline Sin	Amended with changes in team staff, minor documentation clarification and welcome letter
V2.2	29th September 2025	Jacqueline Sin, Bethan Hatherall	Amended with minor documentation clarification
V2.3	21st November 2025	PEGASUS PMG	Minor documentation changes

SPONSOR

City St George's, University of London

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

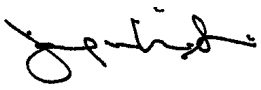
Signature: 

Date: 05/08/2025

Name (please print): Professor Rose McCabe

Position: Trial Sponsor, SHMS, City St George's, University of London

Chief Investigator:

Signature: 

Date: 05/08/2025

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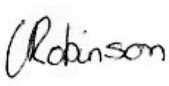
Position: Co-CI, PEGASUS Research Programme, SHMS, City St George's, University of London

Statistician:

Signature: 

Date: 01/05/2025

Name: Dr Clare Robinson

Position: Senior Lecturer in Medical Statistics, QMUL

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Joint-sponsor(s)/co-sponsor(s)	NA
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Trials Pharmacist	NA
Programme Steering Committee (PSC) which also agrees to act as the Data Management Committee (DMC) for the feasibility study	PSC Chair - Dr Emily Peckham e.peckham@bangor.ac.uk Other members – Dr Royes Joseph, Emily Tabb, Dr Gemma Travis-Turner, Professor Sashi Sashidharan, David French, Mona Qassim, Cheryl Garvey, Anne Scott, Paul Fishwick, Gordon Johnston

i. LIST of CONTENTS

ii. LIST OF ABBREVIATIONS

Define all unusual or 'technical' terms related to the trial. Add or delete as appropriate to your trial. Maintain alphabetical order for ease of reference.

AE	Adverse Event
AR	Adverse Reaction
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
CTU	Clinical Trials Unit
CVD	Cardiovascular Disease
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
HDL	High density lipid
ICC	Intracluster correlation coefficient
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.
ISRCTN	International Standard Randomised Controlled Trials Number
NHS R&D	National Health Service Research & Development
LER	Lived Experience Researcher
LDL	Low density lipid
NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
PMG	Programme Management Group
PSC	Programme Steering Committee
PW/PSW	Peer Worker/ Peer Support Worker
QA	Quality Assurance
QC	Quality Control
QP	Qualified Person
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event

SAR	Serious Adverse Reaction
SDV	Source Data Verification
SMI	Severe Mental Illness
SOP	Standard Operating Procedure
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reaction
T2D	Type 2 Diabetes

iii. TRIAL SUMMARY

Trial Title	A peer supported/led group programme for people with severe mental illness to reduce risk of cardiovascular disease (PEGASUS): A feasibility evaluation study	
Internal ref. no. (or short title)	PEGASUS feasibility study with people with SMI and metabolic syndrome	
Clinical Phase	Feasibility testing	
Trial Design	Non-randomised mixed method feasibility study	
Trial Participants	People with Severe Mental Illness (SMI) and metabolic syndrome	
Planned Sample Size	40 service user participants; and up to 16 intervention staff (2 peer workers and 2 mental health nurses (or other mental health professionals or non-registered practitioners with appropriate training per site) for post-intervention focus group study	
Treatment duration	6 months	
Follow up duration	3 and 6 months post baseline	
Planned Trial Period	9 months	
	Objectives	Outcome Measures
Primary	Research aims: To assess the feasibility of the peer-supported group clinic intervention	Section 3.6
	To assess recruitment and retention rates over the study period.	

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR Programme Grant for Applied Research https://www.nihr.ac.uk/explore-nihr/funding-programmes/programme-grants-for-applied-research.htm	Research costs £2,679,253.97

v. ROLE OF TRIAL SPONSOR AND FUNDER

The sponsor (City St George's, University of London) holds overall responsibility for the initiation and management of the study.
The funder (NIHR) plays no role in study design, conduct, data analysis and interpretation, manuscript writing, or dissemination of results. Nor does the funder control the final decision regarding any of these aspects of the study.

vi. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Programme Steering Committee:
The research described in this protocol forms part of a larger research programme. An independent programme steering committee (PSC) will meet at least biannually to provide independent oversight, advice and guidance to the programme. The PSC comprises 11 independent members (see PSC membership), including a chair, an independent statistician, at least one other academic or clinical member with appropriate expertise and two PPI members. For the current feasibility study, the PSC has agreed to take on the role of an independent Data Management Committee (DMC).

The PSC will be attended by Gillard and/or Newman and/or Sin as co-CIs plus other members of the programme team as necessary. The programme team will report to the PSC on progress in delivering the programme as funded. Minutes will be signed off by the PSC chair and submitted to NIHR. The programme team will seek the advice of the PSC on any major amendments to ethical approval.

Lived Experience Advisory Group:
An independent Lived Experience Advisory Group (LEAG) will meet approximately three times per year (15 meetings over 5 years of the entire programme) and will advise the study team on important aspects of undertaking the research, including (but not limited to) development of data collection materials, co-production of the peer-supported group intervention, participant recruitment strategies, interpretation of data, and writing up and dissemination of research outputs.

vii. Protocol contributors

The protocol has been designed by the study team, as named above and was informed by members of the LEAG.

viii. KEY WORDS:	Behaviour change; cardiometabolic risk; co-production; feasibility study; group clinic; peer support; severe mental illness

ix. TRIAL FLOW CHART

A Gantt chart for the current feasibility study (updated for v.2.0):

	2024				2025												2026		
	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
Project Month	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**
PEGASUS Programme Management Group	x	x	x	x	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Programme Steering Committee (and DMC for feasibility study)		x						x			x							x	
Lived Experience Advisory Group (LEAG)	x			x							x				x				x
HRA ethics and site C&C	x	x				x			x										
Co-design workshops	x		x	x							x						x		
SOP/CRF and CSO & researcher training						x	x	x	x	x	x								
Manual development					X	x	x	x	x										
Intervention staff training and supervision									x	x	x	x	x	x	x	x	x		
Staff recruitment							x	x	x	x	x	x							
Service user (SU) participant recruitment									x	x	x	x	x						
Eligibility screening									x	x	x	x	x						
Intervention delivery										x	x	x	x	x	x	x	x		
Data collection									x	x	x	x	x	x	x	x	x		
Interviews/focus group with SU participants and staff												x	x			x	x		
Data analysis											x	x	x	x	x	x	x		
Refining intervention and RCT design													x	x	x	x	x	x	x

See also Figure 1 – Participant flow diagram in Section 7.1.2

STUDY PROTOCOL

A peer supported/led group programme for people with severe mental illness to reduce risk of cardiovascular disease: A feasibility evaluation study

(Short title: PEGASUS feasibility study with people with SMI and metabolic syndrome)

BACKGROUND

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 SMI[1]. People with SMI have approximately 50% increased risk of developing cardiometabolic 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 SMI. There is a 'double disadvantage' for people from racialised communities who can have an elevated risk of poor metabolic health, compounded by higher rates of diagnosis of SMI[6, 7]. People diagnosed with SMI should be offered routine monitoring of weight, and cardiometabolic and metabolic indicators of morbidity and these indicators should be audited in the annual team report. Trusts should ensure compliance with quality standards on the monitoring and treatment of cardiometabolic and metabolic disease in people with psychosis or schizophrenia through board-level performance indicators[8-11]

There is systematic under-recognition and under-treatment of CVD and its risk factors in people with SMI in primary care[12], resulting in one of the greatest multi-morbidity and health inequality gaps in England[13]. People with SMI are three times more likely to attend A&E with an urgent physical health need and almost five times more likely to be admitted as an emergency case compared to people without SMI[14].

In England, SMI has been estimated to cost £7.9 billion[15], 30% of this direct treatment costs and 70% indirect costs to individuals, informal carers and society in terms of lost productivity and premature mortality. A large proportion of treatment costs is for physical healthcare. For example, in a study of people on the Clinical Practice Research Datalink database, annual healthcare costs in England for T2D and SMI averaged £4059, of which £2745 was for non-mental health related hospital inpatient stays. Costs for those with T2D and SMI were higher than for people with T2D alone by £1930, of which £1207 related to non-mental health related hospital inpatient stays. Comorbid hypertension was one of the key predictors of higher costs among people with T2D and SMI[16].

The range of challenges to improving physical health for people with SMI include antipsychotic induced side-effects including weight gain and sedation, social isolation, low motivation and self-efficacy related to negative symptoms, social stigma, lack of support for behavioural change and difficulties in accessing disjointed physical and mental health care[17-21]. Key determinants of self-management of physical health among people with SMI[22-28] include factors that affect people's motivation to look after their physical health, such as emotional wellbeing, burden of living with SMI, beliefs about ability to self-manage, and having the skills to establish and maintain routines [22, 23]. Social isolation, widespread among people with SMI, is a barrier to physical health self-management[20, 29] while social support facilitates self-management through encouragement, practical support and shared experiences[25, 29]. Residency in areas of higher own-group density for people from racialised communities might buffer against social isolation and be associated with exposure to

stronger health-protective social norms, which may ultimately protect against premature mortality in severe mental illness[30].

Lack of integration between physical and mental health services, including perceived jurisdictional boundaries between sectors, contributes to low confidence among mental health professionals in their skills to manage physical health, and among physical health professionals in their communication skills with patients with SMI[31, 32]. Across healthcare sectors, it is also well established that stigma and diagnostic overshadowing - i.e. misattribution of physical symptoms to mental illness - contribute to under-recognition and treatment of physical health conditions in people with a SMI[33, 34]. Improving the physical health of people with SMI is a healthcare priority. Better integration of physical and mental health services is widely recommended[35], however, optimal models have not yet been found[31, 36].

This research offers a comprehensive intervention to CVD risk reduction specifically targeting people with SMI, using peer-led multi-goals approaches which have proven benefits[37]. Our study has also paid particular attention to the intersecting disadvantages in access, experiences and outcomes faced by people from minority ethnic communities. Therefore, where possible we will attempt to recruit at least one peer worker and/ or nurse to the intervention team at each site who share similar heritage and culture to racialised communities who make up a substantial proportion of the population locally (e.g. the Bengali/ Bangladeshi community in Tower Hamlets in East London).

2 RATIONALE

There is a strong rationale for developing and evaluating an intervention, specifically addressing challenges for people with SMI, aimed at reducing risks and subsequent costs of CVD. Recent UK trials for physical health of people with SMI have not achieved improvements in primary outcomes including total cholesterol[38],weight[39] or health-related quality of life[40]. These interventions used established behavioural change techniques, such as goal-setting and action planning, but failed to achieve lifestyle change necessary to reduce CVD risk. Other recent studies[41-44] largely address single risk factors for cardiometabolic 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 with SMI). There is good evidence indicating that multiple goal interventions, and the achievement of multiple goals, is associated with overall impact on cardiometabolic health[45] but what is most important is the quality of the intervention.

There remains a need for a study that addresses the full range of challenges faced by people with SMI in reducing CVD risk. We are using participatory action research approach[46] to co-produce a culturally responsive lifestyle intervention that combines: a) a self-management programme targeted to address the range of specific challenges faced by people with SMI to looking after their physical health; b) peer support to improve social inclusion and self-efficacy; c) a group clinic model to ensure integration of physical and mental health services. The research described in this protocol will assess the feasibility of the intervention.

2.1 Assessment and management of risk

This feasibility study is categorised as Type A = No higher risk than usual care.

There are few anticipated adverse effects of this structured lifestyle intervention. The development of the intervention ensured that it was tailored to the needs of people with SMI. There is a risk that anxiety about weight and its complications may be increased. If the intervention is unsuccessful this may lead to feelings of poor self-esteem. These risks probably are outweighed by the risk of widening health inequality and worsening health among people with SMI if the intervention is not assessed.

Blood sample collection for anthropometric data analysis is already part of routine physical health checks (at least annually for individuals on the GP Severe Mental Illness List). The risks such as increased anxiety and discomfort over short duration of time incurred is no higher than usual care.

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

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.

3.1 Primary objective

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:

a. To establish the feasibility of the intervention for future evaluation in a randomised controlled trial (RCT), specifically:
- Establish the feasibility of recruitment and retention strategies for the main trial
- Assess the acceptability of, and retention to the planned intervention for individuals with SMI and elevated CVD risk
- Determine the feasibility of collecting primary and secondary outcome data for the main trial
- Estimate the location (proportion) and variability (confidence intervals) of the primary outcome to refine the power calculations for the main trial

b. To refine the content and delivery strategies for the intervention
c. To determine the best method of evaluating intervention implementation and fidelity.

3.2 Secondary objectives

Not applicable for this feasibility study

3.3 Outcome measures/endpoints

The main outcome of this research will be a final, revised content and delivery strategies for the peer-supported group clinic intervention and the best method for evaluating the intervention in a full RCT.

3.4 Primary endpoint/outcome

Described in the table in Section 3.6

3.5 Secondary endpoints/outcomes

Not applicable as this is a feasibility trial.

3.6 Table of endpoints/outcomes

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objectives	▪ Participant recruitment & retention rate ▪ Acceptability (as assessed by focus group/interview ▪ Feasibility of collecting: ▪ Waist and hip circumference ▪ BMI ▪ Triglycerides ▪ HDL-cholesterol ▪ LDL-cholesterol ▪ Total cholesterol ▪ HbA1c ▪ Blood pressure ▪ Questionnaires as listed in Section 7.7 (so to determine mean and standard deviation (SD) of measurements required for the future full RCT)	Baseline (pre-intervention), 3 month and 6-month follow up

4 TRIAL DESIGN

Non-randomised mixed method feasibility study

5 TRIAL SETTING

This is a multi-centre study, which will be conducted at four NHS mental health Trusts with their GP surgery/integrated care systems (ICS), community healthcare NHS Trust and community/voluntary sector partners. The four sites are East London NHS Foundation Trust (ELFT), North East London NHS Foundation Trust (NELFT), Birmingham & Solihull Mental Health NHS Foundation Trust, South West London and St Georges Mental Health NHS Trust.

Participants will be recruited from community mental health services (i.e. community mental health teams, recovery teams, early intervention in psychosis services, enhanced primary care services and their equivalents at each site), in four mental health NHS Trusts in England, and GP surgeries/regional integrated care systems (ICS) in coterminous areas, as well as through community sector organisations identified in our programme equality, diversity, and inclusion (EDI) work.

6 PARTICIPANT ELIGIBILITY CRITERIA

6.1 Inclusion criteria

Service users

Participants will:

- Be aged 18 to 75 years
- Have capacity to consent to participate in research
- Currently on the caseload of mental health services in community settings or on GP/ ICS severe mental illness (SMI) list
- 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) or an aforementioned diagnosis.
  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 not applies to dosage adjustment of a pre-existing antipsychotic medication.)
    - Enhanced CVD risk as indicated byany one of:Obesity defined as: waist circumference over 102cm in men (or >90cm in non-white men) or over 88cm in women (or >80cm in non-white women) or BMI≥25 kg/m^2 (or ≥23 kg/m^2 in non-white people)
    - 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

For the purposes of the feasibility study, we will adopt a purposive sampling approach to identifying participants to ensure diversity in our sample in order that we obtain feedback on the intervention from racialised and other marginalised perspectives.

Intervention staff

Participants will be peer (support) workers and registered mental health nurses (or other healthcare professionals or practitioners with appropriate training) who have been trained and engaged by their

employing organisation (i.e. one of the four sites) to deliver (co-facilitate) the PEGASUS intervention for the purposes of this study.

Where possible we will attempt to recruit at least one peer worker and/or nurse to the intervention team at each site who share similar heritage to racialised communities who make up a substantial proportion of the population locally (e.g. the Bengali/ Bangladeshi community in Tower Hamlets in East London).

6.2 Exclusion criteria

Service users

People who:

- 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 EIPS 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 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 (see secondary outcomes below)
- Blood pressure or hyperlipidaemia managed outside of primary care
- Type 1 diabetes

Intervention staff

Peer (Support) Workers, registered mental health nurses or other healthcare professionals or practitioners who are not trained for delivering the PEGASUS intervention for the purposes of this study.

7 TRIAL PROCEDURES

7.1 Recruitment

Recruitment will be conducted at four NHS mental health Trusts with their GP surgery/integrated care systems (ICS), community healthcare NHS Trust and community/voluntary sector partners.

In each of the four study sites we will recruit and train up to four peer workers and two mental health nurses (or other healthcare professionals/practitioners with appropriate training) to deliver the intervention.

We will recruit 10 (lower limit 8, upper limit 12) participants in each site (n=40 participants), using eligibility criteria as defined in section 6 above, to participate in a group clinic intervention running for four to six months. The intervention will comprise the full intervention model developed in the co-design process, except for any booster sessions after the end of the intervention. All participants will be invited to attend the intervention sessions. This study does not include a control arm.

7.1.1 Participant identification

Service user participants:
Electronic patient record of all people with SMI on the caseload of participating Trusts and SMI registers of participating GP surgeries/ICS will be screened by site clinical studies staff to identify possible presence of metabolic syndrome, as indicated by any one of:

- HbA1c > 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 participants or >23 in non-white people;
- 10-year QRISK3 score ≥ 10%

Potential participants will be identified by a) asking members of the direct care team in community mental health services and GP surgeries, and project leads in community (voluntary) sector organisations (including faith-based and cultural organisations) working with people with mental and physical health needs to give or send people who meet eligibility criteria project information (flyer plus participant information sheet which includes a summary top sheet as suggested by the LEAG) or b) placing flyers in community mental health service and community sector service delivery locations or c) local research staff (clinical studies team) will screen case registers and clinician caseloads in adherence with local Trust privacy notice permissions and consent to contact arrangements. Where potential participants express interest in being involved, they will be able to contact a member of the study team directly using contact information on flyers, or a member of their direct care team/ project team will be able to pass their contact details to the research team, as preferred.

In addition, we will contact people who attended health awareness/wellbeing events/workshops (and any similar events) run by sites outside the context of the study who agreed to be contacted about the research to assess their potential interest in participating in the trial.

All potential participants will be sent study information by email if available or by post (including Participant Information Sheet and any flyers or video-based information about the study that we might develop with the LEAG) and contacted by a member of the site's clinical studies team and invited to meet either in person or remotely by telephone or online videoconferencing application to discuss the study, have any questions answered and then invited to give informed consent to participate in the study (see 7.2). Interpreters will be identified from local providers used by study sites to support, either face-to-face or by telephone or videoconferencing application, to ensure that people with a first language other than English are able to participate in the research and intervention.

Peer worker and health professional participants:
Across the collaborating Trusts, we will work with the site PI and the local research and innovation team, Leads for Wellbeing Hub/Services, PW service, multi-disciplinary professional groups, to promote the study and invite interested PW and clinicians to join the study.

Interested staff members who have been trained to deliver the intervention will be provided with a participant information sheet about the focus group study and a meeting either in person or remotely via online videoconferencing or phone with a researcher to discuss the study and to clarify any outstanding queries. Informed consent will be obtained following at least a period of 24 hours.

7.1.2 Screening

Service user participants
Following informed consent (see 7.2) obtained from identified service users as outlined above, participants will meet a research nurse in person who will go through the eligibility criteria screening (see section 6 for the Inclusion and Exclusion criteria). Demographic data including age, sex, ethnicity, will be collected. Cardio-metabolic risk data will be confirmed by a research nurse using Standard Operating Procedures to measure each indicator as defined above and as follows:

- waist circumference
- body mass index
- blood pressure
- full fasting lipid profile (including triglyceride level, high-density cholesterol, low-density cholesterol, and total cholesterol levels)
- HbA1c
- smoking status, tobacco, and betel nut or paan (or pan as it is also called) use
- alcohol consumption
- All variables collected from primary care records or by research nurse to calculate QRISK3 scores[47]

The following data will be extracted from clinical notes, and further checked with participants:

- current mental health diagnosis
- current co-morbid physical health conditions
- current prescribed medication

Those that are eligible (as per 6.1) will go on to complete baseline data collection (See 7.6), and to be allocated to the intervention.

People identified with uncontrolled hypertension (i.e. either Systolic BP ≥200 mmHg 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. People who are not eligible for the study because they do not fulfil criteria for metabolic syndrome or for other reasons will not continue in the feasibility study. They will be provided with evidence-based healthy lifestyle information by the research nurse and encouraged to make an appointment with their GP for their next annual physical health check.

7.1.3 Payment

Service user participants will receive a payment of £25 per data collection appointment.

7.2 Consent

The Principal Investigator (PI) retains overall responsibility for the conduct of research at their site, this includes the taking of informed consent of participants at their site. They must ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained and competent to participate according to the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki. If delegation of consent is acceptable then details should be provided.

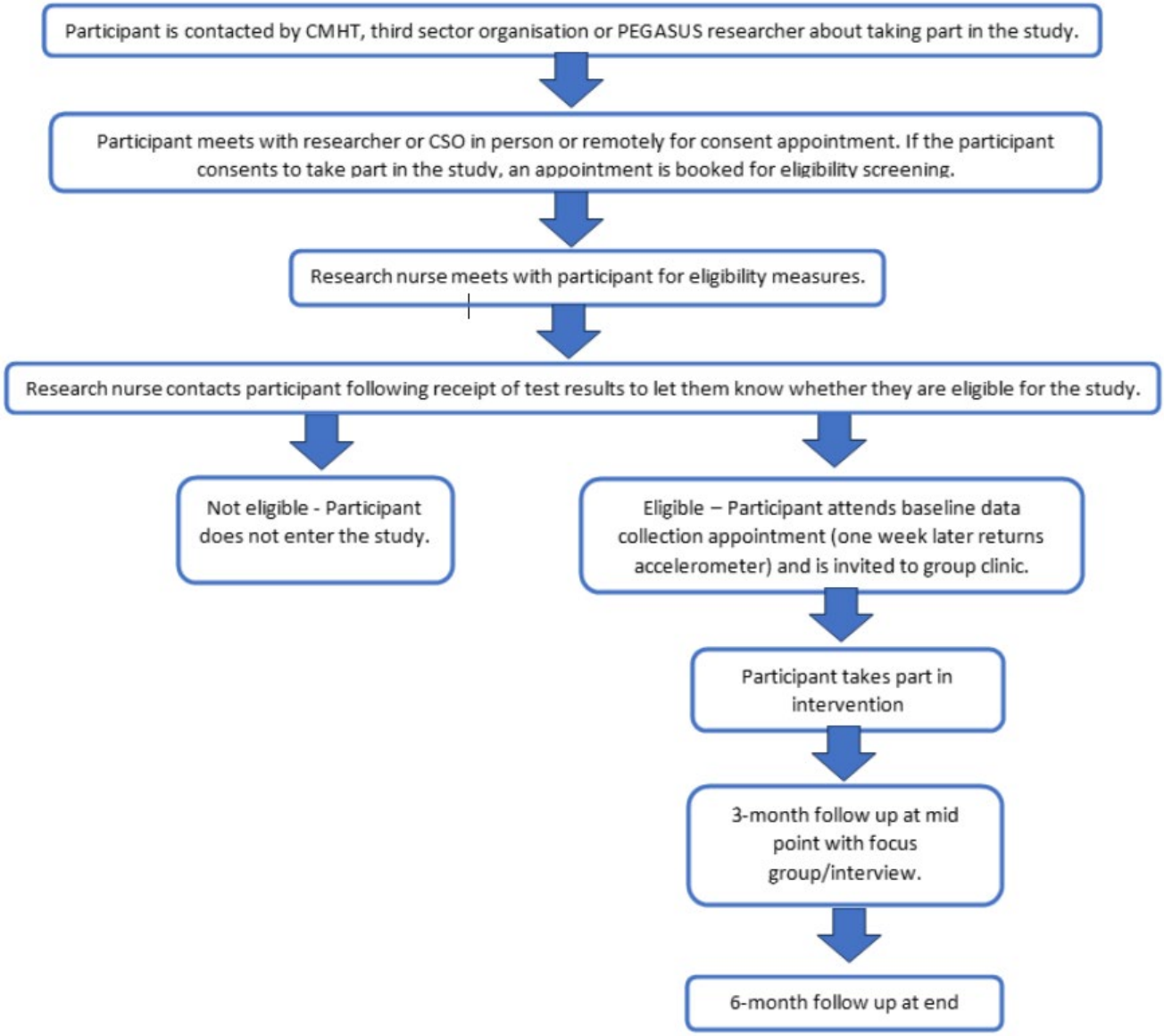
Where a potential participant contacts a member of the research team directly, or where a member of the study team contacts potential participants using their preferred contact information, they will arrange to meet them in person, by telephone or using video-conferencing application. At that meeting the member of the study team will review the Participant Information Sheet with the potential participant and answer any questions they have about the study and go through the eligibility criteria. If the potential participant is still interested in being involved, they will be invited to give informed consent. If the meeting is face-to-face, the Informed Consent Form will be signed and dated by both parties. If the meeting is by telephone or online, oral informed consent will be taken by the member of the study team who will also complete and sign the Informed Consent Form, sending a copy to the participant so that they can sign and keep a copy for their records.

Where informed consent is being provided by a service user, as part of the informed consent procedure the member of the study team will assess whether the potential participant has, at that time, capacity to give consent to be involved in research. Members of the study team will have received training in assessing capacity to consent to being involved in research.

Informed consent procedures with staff members are described in Section 7.1.1.

See Figure 1 for Service User Participant Flow Diagram.

Figure I – Participant flow diagram



7.3 The randomisation scheme

Not relevant for this study

7.3.1 Method of implementing the randomisation/allocation sequence

Not relevant for this study.

7.4 Blinding

Not relevant for this study

7.5 Emergency Unblinding

Not relevant for this study.

7.6 Baseline data

Following eligibility screening procedures, eligible individuals will then be invited to complete the baseline data collection. Baseline data collection will be scheduled to be within a 2-week window from the eligibility screening where the blood sample forming part of the baseline trial assessment was taken.

7.7 Trial assessments

At baseline only, we will collect participants' sociodemographic data and QRISK3. At baseline, 3-month and 6-month time points, participants will complete further psychometric, anthropometric measures, blood tests, and self-completed assessments, as follows:

- Psychiatric symptoms using the Modified Colorado Symptom index[48]
- Lifestyle behaviour, measured using:
    - Diet - Dietary Instrument for Nutrition Education (DINE)[49], adapted by IMPaCT[50]
    - International Physical Activity Questionnaire - Short Form (IPAQ-SF)[51]
    - Cigarette smoking[52], tobacco and betel nut or paan (also spelled as pan) use – smoking[53] /paan/pan use status and number smoked per day; number of paans chewed per week[53]
    - Alcohol - Alcohol consumption test (AUDIT-C)[54]
- Health-related quality of life measured using the EQ5D-5L[55]
- Depression measured using the PHQ9[56]
- Self-efficacy measured using the Generalised Self Efficacy scale[57]
- Social network measured using the Lubben Social Network Scale[58]
- Therapeutic relationship measured using the STAR[59]
- Progress towards achievement of personalised lifestyle goals, measured with the Goal-based outcome tool[60]
- DIAMONDS Service Use Survey[61]

Service user participants will also be asked to wear a wrist-worn accelerometer[62] for one-week periods prior to the start and in months 3 and 6 of the intervention.

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

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

7.8 Long-term follow-up assessments

Follow-up assessments will take place at 3 and 6 months.

7.9 Qualitative assessments

Within each of the four sites, service user participants (n=40) will be invited to a mid- and post intervention focus group regardless of their levels of engagement with the intervention. The topic guide, developed with our LEAG, and informed by the Theoretical Domains Framework[63], will focus on the acceptability of the intervention. The focus groups will be facilitated by service user researchers and will explore any barriers and enablers of regular intervention session attendance. The focus groups will be recorded and transcribed for analysis. A study ID will be allocated, and any personal data will be removed to protect confidentiality. For individuals who prefer/request to have individual interviews, we will try our best to accommodate that.

Likewise, intervention facilitators will be invited to take part in a focus group/ an interview focusing on their experience of delivering the intervention, content and utility of training, and any barriers or facilitators to intervention delivery. The interview topic guide will be informed by the Theoretical Domains Framework[63] and Normalisation Process Theory[64]. Interviews/focus groups will be conducted by service user researchers. Interviews/focus groups will be audio-recorded and transcribed. A study ID will be allocated, and any personal data will be removed to protect confidentiality.

See Appendix A (16.A) for a Schedule of procedures and data collection

7.10 Withdrawal criteria

No criteria are set for withdrawing participants who have rights to withdraw from the study at any time.

7.11 Storage and analysis of clinical samples

Blood sample from participants will be taken by trained research nurse (or phlebotomist) at the specific NHS Trust/site/hospital phlebotomy service. Storage and analysis for metabolic parameters will be conducted by the laboratory services contracted with each Trust/site according to local policy. Only analysis results for participants identified with study IDs but not any personal data will be sent to the Research Team and such data will be stored together with other research data securely in the Sponsor's database (see Section 11).

The blood sample will be destroyed by the laboratory after completing analysis.

7.12 End of trial

The study will end when data collection and analysis are completed.

8 TRIAL INTERVENTION

8.1 Intervention description

The intervention that is being feasibility-tested in this study has been based on the initial review of the literature and development of the intervention logic model (see Appendix 16.B). The final version of

the intervention will be the main output of the co-production process; however the intervention is likely to comprise:

a. Manualised training for peer workers adapting the ENRICH peer worker training developed by the team[65] along with an adaptation of Manualised Self Management training developed by the team[66], and incorporating the Lester UK Adaptation for positive cardiometabolic health resource for mental health nurses (MHN)/healthcare professionals[67]. There will be a short webinar-type training around personalised goal setting for other healthcare and voluntary sector staff who will contribute to group clinics,

b. 12 fortnightly group clinics over a six-month period (final number, duration and frequency of sessions to be determined), co-facilitated by peer worker and MHN, combining targeted psychoeducation (from GP, community cardiovascular nurse, dietician, occupational therapist, exercise therapist, voluntary sector/ community organisations) with peer-supported self-management skills sessions; (For example - a dietician will attend a clinic towards the beginning of the six-month intervention and provide introductory psychoeducation on healthy eating, and introduce recipe and dietary plan resources. Initial, personalised goals will be agreed between participants, facilitators and dieticians. Participants will complete a dietary record two and four months later with the dietician returning for review sessions to develop and refine individual dietary goals. Each group will potentially build a resource of recipes and diet plans as developed locally and reflecting the cultural identity of group members. Similar personalised goal setting and review work will be undertaken with specialist professionals around exercise, and alcohol, smoking and paan use.)

c. Three one-to-one peer support sessions per participant, bringing experiential knowledge, role modelling and social connection work. Members of this team have piloted a modified, peer-supported version of an established wellbeing mapping intervention, designed to enable and empower connection to people, places and activities that are supportive of each individual in a personalised approach to adopting a more healthy lifestyle;

d. Strategies to build and maintain peer-to-peer support between group clinic members outside of clinic meetings, such as further in-person meetings/drop-in groups utilising local resources (e.g. Park Walk) or a social media group delivered via Whatsapp or closed Facebook group (operated in accordance with participating NHS Trust’s policy) offering fortnightly motivating messages with tips;

e. Monitoring impact of psychotropic medication on cardiovascular risk (e.g. weight gain) with engaging with GP/ psychiatrist to review/ change medication as indicated;

f. Signposting to annual health checks, follow-up with GP for shared care plan consultation and referral to treatment and signposting to community-based support as appropriate; and

g. Group booster session at three months post-clinic to monitor and feedback on maintenance of behaviours/ provide refresher psychoeducation.

8.1.1 Peer worker and clinical staff training

Manualised training will be developed, alongside the co-production of the intervention.

All peer workers and clinicians recruited to deliver the intervention will be trained; followed by regular supervision throughout the feasibility study.

Included within the training and the intervention delivery procedures are measures to ensure safety and maximise wellbeing of all participants. We will pay particular attention to incorporate trauma-informed care in our intervention delivery. We will work with peer workers and clinicians, LEAG, and members of our PMG to develop procedures to identify early signs of psychotic episodes, general plan for support which can be individualized for each participant from the outset of them joining the group.

Some options identified for a stepped model of support include: taking a short break at a quiet space on site; taking medication as needed; requesting an earlier review; informing care coordinator or a named family member or close friend for support; or referring to Home treatment or Crisis support team.

For any service user participants re-joining the intervention after a short break due to ill health reasons, the staff delivering the intervention will organize a catch-up with them to ensure they feel comfortable and sufficiently stable to rejoin.

Peer workers and clinicians – although they were already working in the mental health services and are experienced in working with the service user populations - will be provided with regular supervision and support.

8.2 Trial restrictions

Not applicable.

8.3 Assessment of fidelity against the peer support principles

To ascertain the level of fidelity to the peer support principles framework[65] in delivering the intervention, we will ask the Peer Workers to complete a Peer Support Fidelity Index (PSFI[68] about each individual they support.

9 SAFETY MONITORING

9.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant to whom a trial intervention has been administered, including occurrences which are not necessarily caused by or related to that product.
Adverse Reaction (AR)	An untoward and unintended response in a participant to a trial intervention which is related to any dose administered to that participant. All cases judged by either the reporting medically qualified professional or the Sponsor as having a reasonable suspected causal relationship to the trial intervention qualify as adverse reactions.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect

	Other ‘important medical events’ may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Serious Adverse Reaction (SAR)	An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to the trial intervention, based on the information provided.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	A serious adverse reaction, the nature and severity of which is not consistent with the information about the trial intervention in question set out in the section 9.2.

9.2 Operational definitions for (S)AEs

This is a feasibility study for a low risk intervention.
The following are expected adverse events and serious adverse events for the patient population:
1. Psychiatric hospitalisation
2. Self-harm
3. Suicide attempt
4. Death from suicide

Adverse events will be monitored throughout the study.

9.3 Recording and reporting of SAEs, SARs AND SUSARs

All serious adverse events that are also both ‘unexpected’ (that is, the type of event is not listed in the protocol as an expected occurrence); and ‘related’ (that is, it resulted from administration of any of the research procedures) will be reported by sites to the central team and the sponsor for expedited reporting to the DMC/PSC and the Research Ethics Committee.

Any (S)AEs will be reported to the Programme Manager/CI and DMC (played by the Programme Steering Committee) via email confidentially. A CRF will be filled out and a log maintained to record any SAE, SARs and SUSARs

9.4 Responsibilities

Principal Investigator (PI):

Checking for AEs and ARs when participants attend for treatment / follow-up.

1. Using judgement in assigning seriousness, causality and whether the event/reaction was anticipated using the protocol approved for the trial.

2. Using judgement in assigning seriousness and causality and providing an opinion on whether the event/reaction was anticipated using the protocol approved for the trial.
3. Ensuring that all SAEs are recorded and reported to the sponsor within 24 hours of becoming aware of the event and provide further follow-up information as soon as available. Ensuring that SAEs are chased with Sponsor if a record of receipt is not received within 2 working days of initial reporting.
4. Ensuring that AEs and ARs are recorded and reported to the sponsor in line with the requirements of the protocol.

Chief Investigator (CI) / delegate or PMG members:

1. Clinical oversight of the safety of patients participating in the trial, including an ongoing review of the risk / benefit.
2. Using judgement in assigning the SAEs seriousness, causality and whether the event was anticipated (in line the protocol).
3. Using judgement in assigning whether event/reaction was anticipated or expectedin line with the protocol.
4. Immediate review of all SUSARs.
5. Review of specific SAEs and SARs in accordance with the trial risk assessment and protocol (see Appendix 16.C).

Sponsor: (NB where relevant these can be delegated to CI)

1. Central data collection and verification of AEs, ARs, SAEs, SARs and SUSARs according to the trial protocol onto a database.
2. Reporting safety information to the CI, delegate or independent clinical reviewer for the ongoing assessment of the risk / benefit according to the Trial Monitoring Plan.
3. Reporting safety information to the independent oversight committees identified for the trial (i.e. Data Monitoring Committee (DMC) and Programme Steering Committee (PSC)) according to the Trial Monitoring Plan.
4. Expedited reporting of SUSARs to the REC within required timelines.
5. Notifying Investigators of SUSARs that occur within the trial.
6. Preparing standard tables and other relevant information in collaboration with the CI and ensuring timely submission to the REC.

Programme Steering Committee (PSC):

In accordance with the Trial Terms of Reference for the PSC which has agreed to act as the DMC for the feasibility study, periodically reviewing safety data as the DMC regarding safety issues.

Data Monitoring Committee (DMC):

In accordance with the Trial Terms of Reference for the DMC, periodically reviewing overall safety data to determine patterns and trends of events, or to identify safety issues, which would not be apparent on an individual case basis.

9.5 Notification of deaths

All deaths, including deaths deemed unrelated to the trial protocol, if they occur earlier than expected will be reported to the sponsor within 24 hours of notification.

9.6 Pregnancy reporting

Pregnancy is not considered an AE unless a negative or consequential outcome is recorded for the mother or child/foetus. If the outcome meets the serious criteria, this would be considered an SAE. The pregnant participant will be monitored and followed up in accordance with the schedule previously outlined.

9.7 Overdose

Not relevant for this study.

9.8 Reporting urgent safety measures

If any urgent safety measures are taken the CI/Sponsor shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to the relevant REC of the measures taken and the circumstances giving rise to those measures.

9.9 The type and duration of the follow-up of participants after adverse reactions.

Not relevant for this study.

9.10 Development safety update reports

Not relevant for this study

10 STATISTICS AND DATA ANALYSIS

10.1 Sample size calculation

As this protocol relates to a feasibility study a formal power calculation was deemed inappropriate and hence not conducted. The sample size was justified based on being able to estimate the rate of retention with specified precision. Assuming 4 groups of 10 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 this with a margin of error (half the width of the 95% CI) of 14%[(69)].

10.2 Planned recruitment rate

One of the key objectives of the feasibility study described in this protocol is to estimate recruitment and retention rates for each of the planned sites within the trial.

10.3 Statistical analysis plan

As this is a feasibility study, there will be no formal hypothesis testing, however the analysis plan for all measures collected is summarised below:

Quantitative data will be analysed using STATA. No formal hypothesis testing will be performed. Categorical data will be presented as counts and percentages and continuous outcomes as mean and standard deviation (or median and IQR as appropriate). Corresponding 95% confidence intervals will be calculated for estimates to refine trial parameters as necessary.

Reversal of metabolic syndrome at end of intervention is likely to be the primary outcome used within the future full trial. The proportion of participants with a reversal of metabolic syndrome and/or reduced severity of metabolic syndrome will be estimated, alongside measures of variability (i.e. confidence intervals). Estimates will be used to feed into the design of the definitive trial where appropriate, because they may lack precision and may need to be inflated.

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[63] and Normalisation Process Technique[64] domains, to identify areas for improvement in intervention delivery.

10.3.1 Summary of baseline data and flow of patients

A consort flow diagram (http://www.consort-statement.org/) will be produced to detail the flow of participants through the feasibility study.

Consistent with the aims of the feasibility study, descriptive statistics will be used to summarise data for the outcomes. Means and Standard deviations will be calculated for continuous data, with proportions used for count or dichotomous data.

10.3.2 Primary outcome analysis

Consistent with the aims of the feasibility study, we will be assessing the retention rate of the study, along with the completeness of data and all data collected will be analysed as per section 10.3.

The study will be reported in line with the consort extension[70].

10.3.3 Secondary outcome analysis

Not applicable.

10.4 Subgroup analyses

Subgroup analyses are not applicable. However, for assessing recruitment and retention at each site/Trust, the data will be split into subgroups based on site for such purposes.

10.5 Adjusted analysis

Not applicable.

10.6 Interim analysis and criteria for the premature termination of the trial

No interim analysis is planned for the study.

Safety data will be reported and monitored by the DMEC as described in section X. The DMEC will recommend to the TSC and sponsor whether to modify or stop the study based on the reporting of safety data at the halfway point of the feasibility study. It is the ultimate responsibility of the sponsor to stop the trial.

10.7 Participant population

All participants who are included within the study will be subjected to the study analysis, regardless of whether or not they received the intervention.

10.8 Procedure(s) to account for missing or spurious data

All individuals who are included within the study will be followed up at six months unless the participant has withdrawn from the study. Missing data will be described using descriptive statistics. The proportion of missing data will be collated per measure to assess item completeness.

10.9 Other statistical considerations.

Not applicable to the study.

10.10 Economic evaluation

Not applicable for this study. Nonetheless, in preparation for the future full trial, service use and other data will be assessed and such results will inform the economic evaluation strategies.

11 DATA MANAGEMENT

11.1 Data collection tools and source document identification

Data will be collected using paper Case Report Forms (CRF) and any data collected from Patient MIS will be noted of the CRFs.

11.2 Data handling and record keeping

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, if applicable, will be kept in a fireproofed locked filing cabinet in a room in the School of Health & Medical Sciences at City St George's,

University of London and at NHS premises for the Birmingham Site to which only members of the research team will have access.

In-person or telephone/online interview and focus groups will be recorded on an encrypted digital recorder (password protected work mobile phones and password protected laptops belonging to City St George's, University of London) which will be transported to and from the interview locations in a padlocked bag. Online interviews or groups will be recorded using the audio only of videoconferencing software used within the secure City St George's, University of London network.

Within 48 hours of an in-person or telephone interview or group, 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. The encrypted device will be kept in a locked drawer in a room in the School of Health & Medical Sciences at City St George's if there is time between finishing an interview and deleting the recording from the device (wherever possible, the recording will be uploaded and deleted from the device straight away so this will not be necessary).

Audio files will be saved on the study drive on the secure, password-protected City St George's, University of London network and will be deleted as soon as they are transcribed and checked by the researcher.
Transcripts (identifying information of participants will be left out of the transcript during transcription) will be saved on the study drive on the secure, password-protected City St George's, University of London network.

Hard copy documentation including identifiable information (e.g. consent forms) will be stored in a locked filing cabinet, separately in a different room to the research data. Filing cabinets are stored in offices that are locked when not in use, within the School of Health & Medical Sciences at City St George's or NHS premises at the Birmingham Site. Access to the building is restricted by swipe card to authorized staff.

11.3 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections- in line with participant consent.

11.4 Archiving

Research data will be stored on university network drives at City St George's, University of London for ten years after the study has ended. After this, files will be deleted. In line with City St Geroge's, University of London policies, hard copies of data will be stored in the locked cabinets within a secure research office and then archived after the study has ended for a period of ten years in the university's secure archive facility, subject to compliance with legal, ethical, regulatory and intellectual property protection requirements.

Sufficient metadata shall be recorded and published openly to ensure that research data are both discoverable and can be independently understood without recourse to the creator. Published results

shall always include information on how to access the supporting data and/or the associated metadata. Data and documents will be destroyed in a way that data cannot be recovered. Electronic devices will be fully erased.

Personal data will be stored for 6-12 months and research data for 10 years.

12 MONITORING, AUDIT & INSPECTION

Regular monitoring and audit on study conduct against the protocol will be carried out by the study team, on behalf of the PMG. We will report to the PSC/DMC and the Sponsor.

13 ETHICAL AND REGULATORY CONSIDERATIONS

13.1 Research Ethics Committee (REC) review & reports

Before the start of the study, approval will be sought from a REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements and GP information letters.

Any substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion.

All correspondence with the REC will be retained in the Trial Master File/Investigator Site File

It is the Chief Investigator's responsibility to produce the annual reports as required and the Chief Investigator will notify the REC of the end of the trial

If the trial is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination

Within one year after the end of the trial, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

13.2 Peer review

The overall PEGASUS project plan, including the feasibility study, has been extensively reviewed by multiple subject, lived experience and methodological experts as part of the NIHR funding application and assessment process.

The overall protocol for the programme was peer reviewed internally prior to submission to the funder.

The feasibility study protocol has been co-produced and reviewed by the Project Management Group.

13.3 Public and Patient Involvement

This proposal has been co-produced, which includes:

- distributed decision making and flattened hierarchy in the team

- foregrounding experiential knowledge especially of people from backgrounds including racialised communities and intersecting experiences of disadvantage

-raising awareness of and addressing power differentials within the team

-reflecting critically on multiple perspectives and areas of expertise - experiential, clinical, academic – and how these shape the way research is done

Local PPI

We held discussions with the SUGAR and POPULAR mental health service user research advisory groups in East London in preparing this proposal, with feedback strongly supporting an approach which addresses physical health through a wider social inclusion perspective, a balance of one-to-one and group support, and balancing gender and culturally specific activity with mixed group work.

Co-applicants (Joseph, Gibson, Mark) brought experiential knowledge to developing the proposal, including knowledge of: offering, developing and receiving peer support (group and individual); mental health diagnoses (schizophrenia, bipolar, complex Post Traumatic Stress Disorder, depression, anxiety and neurodiversity (autism/ADHD)); using primary, secondary, inpatient and specialist mental health services; using physical health services relevant to the study (stroke, hypertension, diabetes, weight and lifestyle management); being prescribed and taking psychiatric medications that can cause metabolic conditions; being from racialised communities (Joseph is British African Caribbean and Mark is African Caribbean, South Asian and White British).

The involvement of Gibson, Joseph and Mark has had considerable impact on shaping programme design, including: strengthening co-production/ PPI throughout the programme; strengthening Equality, Diversity & Inclusion (EDI) leading to clear EDI focus across this feasibility trial and a flexible, culturally-informed approach to goal setting in the intervention, including input into the rapid evidence synthesis and Experience Based Co-Design methodology; enhanced involvement of community organisations in enabling people from diverse backgrounds to connect with the programme; greatly strengthened the psychiatric medication monitoring /review aspect of the intervention, supporting self-advocacy and responding to power imbalances around prescribing.

As a co-produced research project, PPI will be woven through every aspect of this feasibility trial and into all other work packages of this project. A Lived Experience Advisory Group (LEAG) of 11 members includes experiential knowledge of:

- diagnosis of Severe Mental Illness and relevant physical health issues
- delivering peer support
- mental and physical health service use
- service user/survivor research, EDI or PPI

LEAG meetings at key time points will assist with co-production of the intervention and feasibility work, refining recruitment processes, developing and testing qualitative interview schedules and interpretation of data. Local PPI groups (e.g. SUGAR in East London, SURESEARCH in Birmingham) will be involved at all sites, supporting us to build relationships with local communities. At each site we will set up a Local Advisory Group (LAG) including service users and carers, peer workers, voluntary sector organisations (including faith and culturally specific groups), and mental and physical health service providers, ensuring that sufficient flexibility is incorporated into the intervention to facilitate implementation locally.

13.4 Regulatory Compliance

The trial will not commence until Favourable REC opinion is obtained.

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place at each site (NHS Trust).

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

13.5 Protocol compliance

Protocol compliance will be monitored strictly by the PEGASUS Program Manager. There will be SOPs created for all study procedures and logs maintained to ensure all processes and procedures are followed as outlined in the protocol.

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

13.6 Notification of Serious Breaches to GCP and/or the protocol

A “serious breach” is a breach which is likely to effect to a significant degree –

- the safety or physical or mental integrity of the participants of the trial; or
- the scientific value of the trial

The sponsor will be notified immediately of any case where the above definition applies during the study

13.7 Data protection and patient confidentiality

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, if applicable, will be kept in a fireproofed locked filing cabinet in a room in the School of Health & Medical Sciences at City St George’s, to which only members of the research team will have access.

Personal addresses, postcodes, email addresses and phone numbers will only be used for contacting participants to arrange interviews/assessments etc.

In-person or telephone interviews and focus groups will be recorded on an encrypted digital recorder. Online interviews or groups will be recorded using the audio only of videoconferencing software used

within the secure City St George's, University of London network. Within 48 hours of an in-person or telephone interview or group, the audio file will be uploaded from the encrypted digital recorder 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 digital recorder. The encrypted recorder will be kept in a locked drawer in a room in the School of Health & Medical Sciences at City St George's in the time between finishing an interview and deleting the recording from the device (wherever possible, the recording will be uploaded and deleted from the device straight away so this will not be necessary).

All interviews and focus groups will be audio-recorded with consent. We will not use visual recording. Personal and research data will be stored on secure university networks and computers.

Audio files will be saved on the study drive on the secure, password-protected City St George's, University of London network and will be deleted at the end of the study. Transcripts (identifying information of participants will be left out of the transcript during transcription) will be saved on the study drive on the secure, password-protected City St George's, University of London network.

Hard copy documentation including identifiable information (e.g. consent forms) will be stored in a locked filing cabinet, separately in a different room to the research data. Filing cabinets are stored in offices that are locked when not in use, within the School of Health & Medical Sciences at City St George's. Access to the building is restricted by swipe card to authorized staff.

Interview and focus groups audio recordings will be transcribed by members of the research team or a professional transcription service with which City St George's, University of London (the sponsor) has a data sharing agreement. Data will be securely transferred and stored during transcription as stipulated in that agreement.

All data (including qualitative data prior to transcription) will be pseudonymised with names of participants will be substituted by individual identification numbers only known to the research team. A password protected spreadsheet linking these codes to the participant will be saved on the study drive on the secure, password protected City St George's, University of London network. During transcription names of individuals and other names (e.g. service names or place names) will be substituted with a descriptive label (e.g. 'mental health service', 'city', or, 'XXX'). Any other identifying information will be substituted 'with 'XXX' during transcription.

Only members of the research team and the transcriber will have access to personal data collected as part of the research, and only with the informed consent of participants. Members of the research team will access data during data collection and analysis; use of a professional transcriber is the most efficient and accurate way to ensure reliable transcription of interview and focus group data. Participants will be told in participant information sheets who will have access to their personal data and why and will be invited to give signed consent to state they have read the participant information sheet and understood the information it contains before any personal data is accessed.

Pseudonymised data will be analysed by members of the research team using either a password-protected desktop university computer at City St George's, University of London or a password-protected and encrypted university laptop. Where data are analysed using a laptop, this will be done in a private space. Data will only be analysed by members of the study team.

Participants can choose to consent to allow de-identified transcripts from interviews or focus groups to be included in secondary data analysis projects by staff or students linked to the research team. This is

completely optional. Direct quotations from participants may be published in publications and reports from this research with consent. These will be anonymised so as not to contain any identifying information.

Reporting of analysis results will contain no personal-identifying information.

Personal data will be stored for 12 months after the study has ended. Research data generated by the study will be stored for 10 years after the study has ended.

The Co-CIs will be the data custodian.

13.8 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

No known competing interests that might influence trial design, conduct, or reporting have been identified. When new personnel at each study site are identified, any information relating to financial and/or other competing interests will be collated and documented.

13.9 Indemnity

The study sponsor (City St George's, University of London) will make all arrangements for insurance and/or indemnity to meet: the potential legal liability of the sponsor for harm to participants arising from the management of the research; the potential legal liability of the sponsor or employer(s) for harm to participants arising from the design of the research; to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research.

13.10 Amendments

The sponsor may make a non-substantial amendment at any time during a trial. If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to REC.

Amendments also need to be notified to the national coordinating function of the UK country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site.

The amendment history will be tracked using the Table provided in Appendix 16.D to identify the most recent version of the protocol.

13.11 Post trial care

Not applicable.

13.12 Access to the final trial dataset

Only the study team will have access to the final dataset.

14 DISSEMINIATION POLICY

14.1 Dissemination policy

We will disseminate our findings through scientific papers as well as publications aimed at PPI and service user audiences, and seminars and conferences at local, national and international levels as well as professional networks including the Royal College of Psychiatry and the Royal College of Nursing. Since COVID-19, webinars aimed at research participants, NHS delivery staff, policy makers and academic audiences have proved well-attended and an effective means of communicating research findings; we will host a series of similar webinars aimed at different audiences for this programme, including clinical, policy and service user/ survivor networks. We will use social media, including individual and institutional twitter accounts, and publicise our study and findings on university and participating Trust websites, working with organisations including The Mental Elf to help disseminate accessible findings. We will run workshops with our stakeholders and work with charities and patient groups to reach a wide audience. We will work closely with the North Thames ARC's mental health, multi-morbidity and population health themes to optimise guidance for future upscaling and roll out of the intervention; with the East Midlands ARC (National ARC lead for research on EDI of Underrepresented Groups and Multiple LTCs) in considering how best to ensure that implementation maximises engagement with local communities and successfully addresses health inequalities for marginalised groups; with colleagues in the implementation science team in the South London ARC, bringing collaboration in future implementation research in support of successful knowledge mobilisation and adoption of the intervention. We will liaise with our contacts within NHSE&I and Public Health England, as appropriate, to share findings, help put our research into practice and consider the policy implications as well as future research. We will engage with Health Education England around ongoing evaluation and development in peer support worker training (findings from our ENRICH peer support training programme inform and are well-cited in the current competencies based-training programme produced by HEE).

We will work with our Lived Experience Advisory Panel to produce accessible research briefings for all our participants as well as other interested groups including community-sector organisations and NHS Trusts. We will also make our findings, health awareness workshops and EDI evaluation report available to organisations working with marginalised and racialised communities through workshops and webinars and via social media. To support this, we will work with contacts at local and national organisations such as the Black, African and Asian Therapy Network (BAATN), the Health Inequalities Research Group, Survivor Research Network, National Survivor User Network, the North West London Making A Difference (MAD) Alliance, Caribbean & African Health Network, Diabetes UK, Bipolar UK and the Hearing Voices Network. We anticipate that our health awareness workshops will begin to have an impact on awareness of physical health issues and take up of physical health checks among people from marginalised communities from the end of year one of the programme. We will make the workshop resource freely available to our study sites and other NHS Trusts via ARCs to maximise that impact. Our feasibility study and trial will bring immediate benefit to participants and to other people with SMI at CVD risk in study sites as learning from the research is shared internally, and through improved integration between physical, mental and primary care services that results from

implementing the intervention. If successful and if more widely implemented, we would anticipate the medium-term impacts of the programme to be improved cardiovascular health of people with SMI in terms of improved individual health markers (e.g. blood pressure, weight, cholesterol) with their associated improvement to quality of life. In the medium to long-term, we would anticipate reversal of Type 2 Diabetes (T2D) for some, reduction in progress to T2D and reduction in debilitating complications of T2D for others, all of which would come with improved quality of life, including mental health, and substantial reductions in healthcare resource use. In the long-term we would anticipate seeing less CVD in people with SMI, including heart disease and stroke, with significant reductions in expensive healthcare resource use and reductions in early death in this population. We note that our study is limited by funding to a one-year follow up and as such we can only provide evidence of short-term impacts here and preliminary modelling work on longer term cost benefits, and in particular will not be able to provide a cost-effectiveness evaluation. The data we collect will enable us to apply for further funding for extended follow-up or new research to identify longer term impacts on health, quality of life and cost. Central to our conviction as a team in undertaking this research is to impact on persistent health inequalities for people from marginalised and racialised communities who have SMI and are at CVD risk. We anticipate that a core impact of the programme will be reduced CVD risk for all people with SMI.

14.2 Authorship eligibility guidelines and any intended use of professional writers

The PEGASUS Programme Management Team (comprising all co-investigators and researchers) has set up a Publication Committee with established Terms of Reference.

We have plans to work with our collaborators extensively in disseminating the study results.
There is no intended use of professional writers.

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16. APPENDICES

Appendix A - Schedule of procedures and data collection

	Study period			
Timepoint	Enrolment	Baseline & Allocation	Post-allocation – intervention delivery & research follow-up	
Enrolment	**-1 month**	**0 month**	**3 month**	**6 month**
Informed consent	X			
Eligibility screen including socio-economic data, medical and psychiatric history	X			
Allocation		X		
Intervention Usual care plus peer-group intervention				
Assessments				
Waist and hip circumference	x		X	x
BMI	x		X	x
Fasting blood Triglycerides	x		X	x
Fasting blood HDL, LDL, total-cholesterol	x		X	x
HbA1c	x		X	x
Blood pressure	x		X	x
QRISK3		x (once only)		
Lifestyle behaviour, measured using: DINE; IPAQ-SR; Cigarette smoking, tobacco and betel nut or paan use – smoking/paan use status and number smoked per day; number of paans chewed per week		x	X	x
Alcohol use with AUDIT-C		x	X	x
Modified Colorado Symptom Index		x	X	x
EQ5D-5L		x	X	x
PHQ9		x	X	x
Generalised Self Efficacy scale		x	X	x
Lubben Social Network Scale		x	X	x
STAR		x	X	x
Goal-based outcome tool		x	X	x
DIAMONDS Service Use Survey		x	X	x
Accelerometer x 1 week		x	X	x
Adverse events			X	x
Perceived acceptability			X	x

Appendix B - Provisional logic model underpinning co-production of the peer supported group clinic intervention

Inputs	Barriers	Mechanisms	Process measures	Outcomes
Manualised self-management facilitation for participants co-delivered by peer workers and mental health nurses	Lack of belief that change is possible/ lack of motivation & skills Lack of understanding among clinicians of alternative worldviews/ interpretations of illness and healthy lifestyle	Targeted Behavioural Change Techniques; role modelling; social learning; goal setting and monitoring Strong 'patient/provider' relationship	Improved health behaviours (activity/ achievement of personalised goals relating to exercise, diet, alcohol, smoking and paan consumption)	**Primary outcome** Prevalence (reversal) of metabolic syndrome
Group clinic, co-facilitated by peer worker/ nurse; psychoeducation from GP, diabetes nurse, dietician, exercise therapist, etc; psychiatric medication review; shared care planning	Poor access to health checks Lack of integration between physical and mental health services Medication side-effects Mental health symptoms/problem	Integrating physical and mental health services	Uptake of physical health checks/ shared care plan with GP Number of clinic sessions Psychiatric medication review	Change in individual metabolic syndrome indicators Composite risk score
One-to-one peer support	Social isolation Challenges of living with SMI Hopelessness	Role modelling, experiential knowledge, social learning Connecting to community Connecting to services	Number of one-to-one peer support sessions Therapeutic relationship with peer worker Self-efficacy, agency, control Social network Social resource use	Severity of psychological symptoms, self-reported health status, depression
Booster sessions	Sustained change	Health consequences	Number of booster sessions	Cost of resource use Quality of Life

Appendix C – Suicide Risk Protocol including reporting form

Suicide Risk Protocol

(V2.05.08.2025)

If at any time you believe that there is a suicide risk with a participant who is a service user participating in the study that has not been communicated to their GP, psychiatrist or care co-ordinator/CPN, you must contact the participants care co-ordinator/GP. If the care co-ordinator/GP is not available then you must contact the local/site PI.

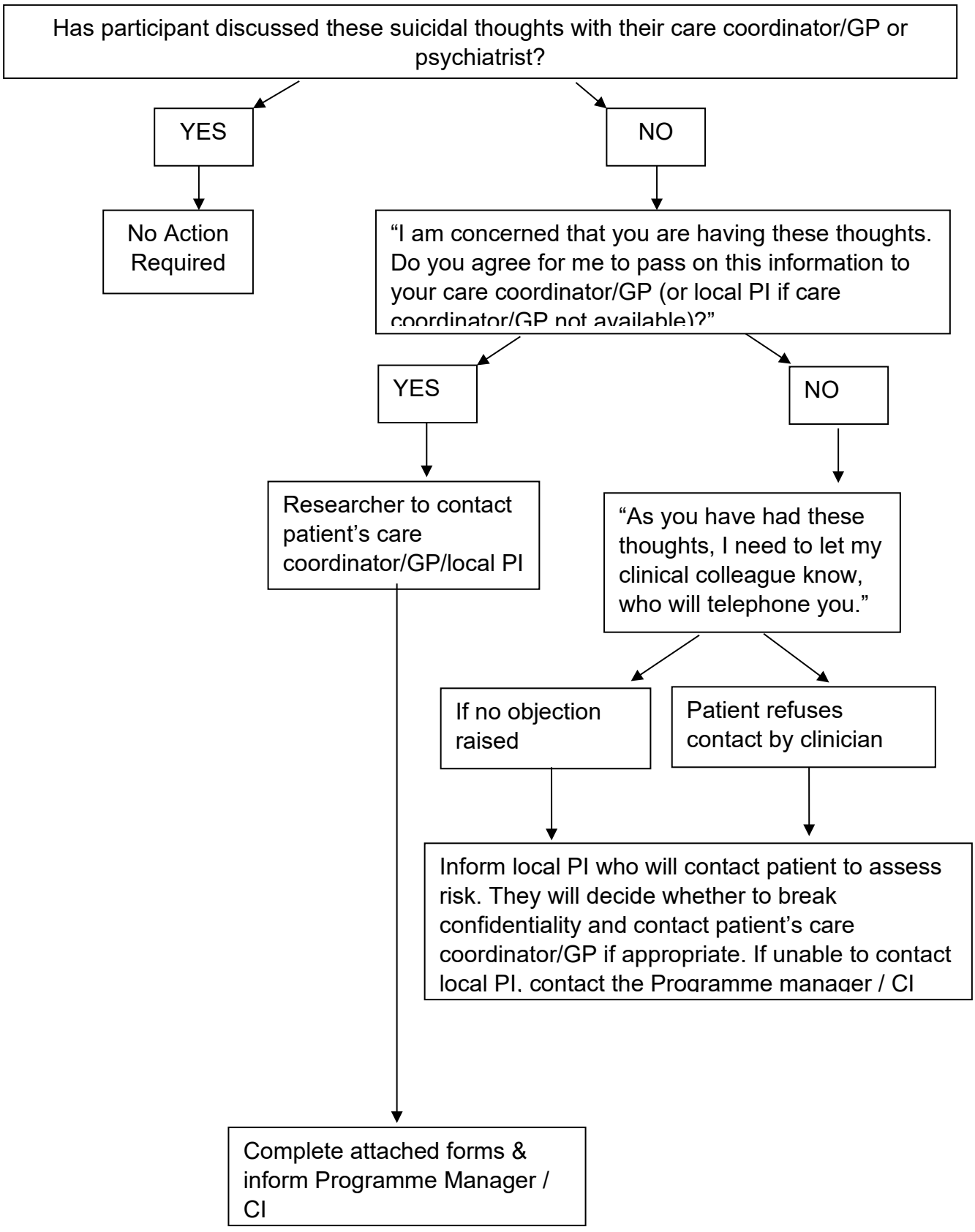
Contact numbers can be found on the back page of this protocol.

Suicide risk identified face-to-face or remotely:

Find a private space to talk to the participant. If there is a clinician available on the research team present, alert the clinician.

If the participant shares with you any thoughts that may suggest they are at risk of suicide or self-harm, then you should ask whether the participant has talked to their GP, psychiatrist or care coordinator/CPN about these feelings. **If the participant has had recent discussions about these thoughts to their GP, care co-ordinator or psychiatrist, then no action is required.**

If not, you should follow the procedure below:


Has participant discussed these suicidal thoughts with their care coordinator/GP or psychiatrist?
YES
NO
No Action Required
"I am concerned that you are having these thoughts. Do you agree for me to pass on this information to your care coordinator/GP (or local PI if care coordinator/GP not available)?"
YES
NO
Researcher to contact patient's care coordinator/GP/local PI
"As you have had these thoughts, I need to let my clinical colleague know, who will telephone you."
If no objection raised
Patient refuses contact by clinician
Inform local PI who will contact patient to assess risk. They will decide whether to break confidentiality and contact patient's care coordinator/GP if appropriate. If unable to contact local PI, contact the Programme manager / CI
Complete attached forms & inform Programme Manager / CI

Non- Suicide risk

If any other areas of risk arise in the focus groups/interviews/feasibility study that are not related to suicide or self-harm but that give cause for concern please complete the non-suicide risk form.

If a non-suicide risk is identified, check whether the participants care coordinator/GP/ psychiatrist is aware of the risk and document this on the non-suicide risk form. If none of the above are aware, contact the site PI for advice and complete the non-suicide risk form. Note the Site PI only needs to sign the non-suicide risk form if the researcher has contacted the site PI.

Reporting Risk Suicidal Intent Form

The participant below has shared thoughts of suicide and the care co-ordinator/GP has been contacted by the researcher.

Date of birth: _____/_____/_____

PEGASUS Participant ID: _____

Action taken

Name of care co-ordinator/GP: _____

Date of contact: _____/_____/_____ Time: ___:___ am/pm

Outcome of contact/Action/Comments: Include verbatim comments from participant where possible

Reporting Risk Suicidal Intent Form: Site PI

PEGAUS Participant ID: _____

Date of birth: _____/_____/_____

Name of PI notified: _____

Date notified: _____/_____/_____

Action taken

Care co-ordinator/GP contacted with Patient's consent? ☐ ☐

Name of care co-ordinator/GP contacted:_____
Date: __/__/___

Outcome of contact/Action/Comments:

Non-Suicide Risk Form

The participant below has been identified as being a risk other than self- harm/ suicide during a PEGASUS focus group/interview/data collection appointment.

Participant ID Code: _____

Date of Assessment: ☐☐ / ☐☐ / ☐☐☐☐

Nature of risk

Summary of how risk protocol implemented:

Researcher Name: ……. Study Site: …….

Research Signature: …… Date: ……...

Name of site PI: …….....

Clinical Contact Signature: ……

Contact Numbers

Local mental health team (general number): TBC

Site PI (name): YBC

Chief Investigators: Steve Gillard / Stan Newman / Jacqueline Sin

Programme Manager: Bethan Hatherall, bethan.hatherall@citystgeorges.ac.uk / 020 7040 5033

Any other relevant numbers: TBC

Appendix D – Template for Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made