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

PEGASUS FAQ (frequently asked questions)

What is PEGASUS and why are we doing this research?

PEGASUS is a research project that aims to help people with mental and physical health challenges improve their health through peer-led support. To learn more, see pages 2-3

Do I have to take part?

No. Your participation is completely voluntary, and you can stop at any time. Not everyone will be eligible. See page 4.

What happens if I decide to take part?

You will attend a series of peer-led support groups over six months. To see if the groups affected you, we will collect information and measurements (e.g. blood pressure, blood tests, and questionnaires) three times: at the beginning, the middle, and the end. We will also hold a focus group in the middle to find out more about your experience of taking part. To find out more, see pages 5-7

Are there any risks or benefits to taking part?

The PEGASUS project has a low risk of harming you. For each time you allow us to collect information and measurements (three times, at the beginning, middle, and end), you will be given will be given £25 your time. You will also be given £25 for taking part in the focus group.

You may benefit from the support groups. For more information, see page 9.

How will you use my data and keep it safe?

We promise to use any data collected for this study securely and keep it safe. You can find out more on pages 7-10

Where can I get more information?

Please read through this information sheet, and then contact [researcher's name] who can talk through any concerns and answer any questions you might have.

Name: name - I am a Lived Experience Researcher for PEGASUS

Mobile: 07423 637 934

Email: email@city.ac.uk

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

You are invited to take part in a research study

We'd like to invite you to take part in a research study to understand how to improve health improvement programmes for people with severe mental illness and cardiovascular disease. Before you decide whether to participate, we would like to explain why the research is being done and what it would involve for you. One of our team will go through this information sheet together with you, to help you make your decision about participating and answer any questions you may have.This shouldn't take more than 10 minutes. Please feel free to talk to others about the study as well, if you wish. You will be given a copy of this information sheet to keep.

What is the purpose of the study?

A feasibility trial is the first test of a new health intervention. The purpose of this study is to establish the feasibility of PEGASUS, a peer-led group clinic with one-to-one peer support intervention to reduce the risk of cardiovascular disease in people with severe mental illness. Someresearch has shown that people with severe mental illness (SMI) have an increased risk of developing cardiovascular (heart and blood vessel) disease and type 2 diabetes compared to people who don't live with SMI. This risk can be bigger for people whose ethnicity or race is Black, Asian or a Minority Ethnic community, who may be more likely to be diagnosed with SMI and experience other health inequalities. We have developed a peer-led group clinic to test how successful a new programme called PEGASUS is and understand what challenges and aids people experience when joining this kind of group support.

Why have I been invited to take part?

You may have been given this information because a professional involved in your care thought that you might be eligible to take part in this research project. Alternatively, you may have left your contact details with a member of the research team at a community Health Awareness Workshop, or you may have seen the research advertised via a flyer or poster and asked for further information.

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We are inviting people to take part in a feasibility study if they have personal experience of severe mental illness (SMI) and an enhanced cardiovascular disease (CVD) risk (such as having high blood pressure or concerns over body weight). Severe mental illnesses (SMI) include schizophrenia-spectrum disorders, or bipolar disorder, or psychosis.

We are particularly interested in hearing about perspectives on physical and mental health from diverse cultural communities. We welcome interest from people who identify as belonging to ethnically diverse groups, especially (but not only) people from Black and South Asian backgrounds.

If you are unsure whether any of these experiences apply to you, we encourage you to contact the researcher for a conversation (see contact details on the last page of this information sheet).

How is the research being done?

The PEGASUS intervention has been co-produced by peer workers, clinicians, and most importantly people with lived experience. It is informed by evidence from research and focus groups with people with mental health conditions and the PEGASUS lived experience advisory group. A feasibility study tests whether we can recruit enough participants to our study, with the aim of running a larger trial in the future. It also helps us understand what participants think about the peer-led group clinic programme (so that feedback can inform changes to the programme or research that can then be tested in a full trial).

What will happen if I take part?

If you are interested in taking part, you can tell the person who gave you this information that you would like to join the study. You can also contact the researcher directly. Their contact details are at the end of this information sheet). They will arrange for you to meet with a member of the research team who can discuss the research, answer any questions you might have and ask you to give your informed consent. This involves completing a consent form with the team member where you both sign and date the form to say that you have understood all the information you need to decide whether or not to take part.

Once you have given your informed consent, the research team member will collect some sociodemographic data (like age and ethnicity) from/with you and arrange an appointment with you

for some additional tests to check if you are eligible for the study. These will include taking some blood samples, your blood pressure, waist measurement, height and weight. All tests will be performed with someone who is qualified to carry them out. You will be reimbursed for your time completing the tests and questionnaires. Any blood samples taken will be destroyed after the lab tests are done, and we will only keep the results.

We will also ask for your preferred contact details. This is so that we can let you know about your blood test results and whether you are eligible to continue to take part in the study. We will also contact you to arrange any follow up visits for data collection. We can also provide feedback on the results of the study if you would like to hear about them (this is optional).

What if my test results show I am not eligible for the study?

If your test results show that you are not eligible to take part in this feasibility study, then a member of the research team will contact you to let you know. You will also be provided with an information booklet containing details about health services and healthcare resources locally. You will still receive payment for your time taken to complete the tests and we thank you for your time. This will mean that your participation in the study is now complete.

Will anyone be told about my test results?

All data that you provide will be kept confidential and stored securely for 10 years (see data protection section beginning on page 7 for more information). If any of your test results indicated that urgent medical review or treatment is needed, then the study team would make a referral to your GP (and/or treating psychiatrist for those haven't got a GP). We would make sure to keep you informed at all steps in this process.

What if my results show I am eligible for the study?

If your test results show that you are eligible to take part in the feasibility study, then a member of the research team will contact you to ensure that all baseline data - including some questionnaires about mental health and wellbeing which you can complete by yourself or with a Researcher.. You will be invited to take part in a peer-led group clinic for six months. . The Researcher will provide

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further information about how you can attend the PEGASUS peer-led group clinic. You are still entitled to change your mind and do not have to continue with the study if you don't want to. study team will inform your GP (and/or treating psychiatrist if you haven't got a GP) that you are taking part in the PEGASUS trial. This is standard practice to let them know in case you need to talk to them about taking part or they need to provide any extra support.

As mentioned above, if your test results show that you need urgent treatment, we will inform your GP or psychiatrist. We may also have to tell someone if you say something which suggests there is a risk of significant harm to someone (including you). If this happens, we will talk together about what will happen next.

What will happen during the PEGASUS peer supported group clinic?

The group clinic will be delivered over 6 months and you will be invited to attend a support group clinic once every fortnight over these six months. Group clinics will be facilitated by a peer worker (someone who has lived experience of mental health difficulties and is using such experience in their work to support others) and another health professional (this might be a nurse, dietician or occupational therapist). The group will include approximately 10 members. Each session will have a focus on different aspects of health and wellbeing that our previous research has identified as important to people with SMI and cardiovascular disease risk. In addition, each participant will be offered one-to-one sessions with a peer worker who can work with you individually towards your health goals.

What else will the research involve?

At any point in the study, you can decide you no longer want to take part. You don't have to give a reason, and your medical care will not be affected by withdrawing. But if you do decide to take part, this is what will happen.

Start of study (baseline)

If you are eligible for the study, you will be asked to wear an accelerometer on your wrist for one week. This is like a pedometer which counts the number of steps you take each day.

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Approximately half-way (3 months into the group clinic)

You will be asked to wear an accelerometer on your wrist for one week again. We will repeat the tests that were taken at baseline, including blood tests, weight, BMI, and some health and wellbeing questionnaires. There will be reminders at the group clinic about doing this as well as a chance to ask any questions you have. Any blood samples taken will be destroyed after the lab tests are done, and we will only keep the results.

Six-month follow-up (when the group clinic has come to an end)

You will be asked to wear an accelerometer on your wrist for one week for the final time and you will meet with a member of the study team to collect some more data. These will be the same measures that were taken at baseline, including blood tests, weight, BMI, and some health and wellbeing questionnaires. Any blood samples taken will be destroyed after the lab tests are done, and we will only keep the results.

Focus groups to feedback on the group clinic

About half-way through the support group clinics , a researcher will invite you to attend a focus group with the other members of the group clinic to ask everyone for feedback about the experience. We will invite everyone to contribute to the focus groups, even you were unable to attend every session, as we are interested in hearing about all the issues that people had that might have made attending the clinic difficult or easy. If you want to give feedback on your experiences on an individual basis, we will try our best to organise that.

Lived experience researchers will run the focus groups – these are researchers who have lived experience of mental health difficulties and are there to provide support and encouragement, as well as answer any questions or concerns. Focus groups are usually quite informal, and you are welcome to contribute your thoughts and opinions but are not under any pressure to talk about anything you do not want to.

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The focus group will take around an hour, depending on how much the group wants to say about the topics, and you can take breaks throughout if you need to. We will audio record the focus groups so that they can be transcribed (written out) and used to help us understand what you thought of the PEGASUS programme. We will use direct quotes from the transcript in our research—in discussions, reports, and publications—but we will keep any quotes shared outside of the research team anonymous so that no one can be identified by what they say.

Can I change my mind after the focus group and will you delete my data?

Once a focus group is complete, the audio recording will be **transcribed** (typed out by someone in an external company up into a written format so that the data can be analysed. We have a contract with them to make sure what you say is kept confidential.). After this the data is also **redacted** - this means all information that could identify an individual will be removed, so that the transcript is anonymised.

Once a focus group has been transcribed and redacted, it is difficult (often impossible) to remove one participant's data. This is because for this study, the aim of transcription is to capture everything that has been said by the group, rather than focusing on who has made each statement. This makes it very difficult for the researcher to identify exactly which focus group participant made each statement. Instead, the result is a long transcript of different anonymous speakers making statements. It is important that you consider that once the focus group is conducted, it may not be possible to remove your individual data from the transcript. However, we can remove your sociodemographic questionnaire and delete that data if you request. Please discuss these issues with the researcher if you have any questions or concerns.

The anonymised data that you provide may be used by us in future studies where your anonymity is maintained and where those studies are for patient benefit and have been approved by a Research Ethics Committee.

What if I can no longer take part in the study during its running?

If any participant lost capacity (e.g. taken seriously ill) while the study was underway, they would not be able to continue with the study. In that case, we would retain the data we had

collected with the participant prior to that time, so that we can study these data to consider the feasibility of the intervention.

What other information will you collect about me?

We will also collect data from your Electronic Patient Record (the notes the Trust keeps) at the beginning, when you consent to take part in the study. We will collect the following information: current mental health diagnosis, current physical health conditions, current medication, and medication side-effects. We will not have access to any detailed information a clinician might have written about you in your notes. This information will be provided to us by information services in the Trust and will be identifiable by an anonymous ID number only. We will also ask you about your health and how you feel regarding the medication effects (wanted or unwanted) during the study. You can tell us as much or as little as you feel comfortable with.

Expenses and payments

In recognition of your time taken to complete data collection, you will be given a £25 voucher. By "data collection", we mean the set of physical health measures (blood tests, weight, etc) and questionnaires we will ask you to complete before joining, half way through and at the end of the group clinic and participating in the focus group. This means you will be paid up to £100 in vouchers if you complete each step. You can choose to receive a BACS payment if you prefer.

In addition, reasonable travel expenses you have for attending data collection in person will be reimbursed. We ask that you bring your tickets or receipts with you so that we can take copies for our payment records.

What are the possible benefits of taking part?

Your participation in this research will help us understand how physical health improvement programmes can be successfully introduced into services and how we can improve the likelihood of that support being culturally appropriate. It is possible that you may enjoy the peer-led group clinics or notice health and wellbeing improvements by taking part in them. However, we cannot guarantee that there will be personal benefits of taking part in this study.

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What are the possible disadvantages and risks of taking part?

It is unlikely that there are any risks in taking part that are bigger than the usual care a person living with SMI receives. There is a risk of discomfort or bruising, just like when taking routine blood samples. It might also be that taking part will make you feel anxious or low about your current or future health, but we will take special care to minimise this risk in a supportive way.

Some people may feel that they don't want to take part in all of the peer-led group clinics, and if this is the case, we would encourage you to discuss your concerns with one of the group clinic leaders. It may be possible to make changes to meet your needs. Alternatively, it may be that the group clinic does not meet your needs, and if this is the case you are not under obligation to attend the group meetings. As a research project, we would still be interested in hearing about your experiences and learning about ways to improve. We would still invite you to provide your feedback about the PEGASUS peer-led group clinic (it is important that we can hear about the negative experiences as well as positive ones). However, you do not have to give a reason for not wanting to attend, and your medical care will not be negatively impacted by your decision.

How is the project being funded?

The study is funded the National Institute for Health Research (NIHR) Programme Grants for Applied Research.

Who is running the project?

The Chief Investigators (CIs) are called Professor Steve Gillard, Professor Stanton Newman, and Professor Jacqueline Sin. CI is the title given to the people who are responsible for the project running according to plan.

Data privacy statement

City St George's, University of London is the sponsor and the data controller of this study based in the United Kingdom. This means that we are responsible for looking after your information and using it properly. The legal basis under which your data will be processed is City St George's public task.

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Your rights to access, change or move your information are limited, as we need to manage your information in a specific way in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally identifiable information possible (for further information please see https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/public-task/).

City St George's will use your name and contact details to contact you about the research study as necessary. If you wish to receive the results of the study, your contact details will also be kept for this purpose. The only people at City St George's who will have access to your identifiable information will be members of the research team, and, if appropriate, individuals with responsibility for monitoring and auditing at City St George's, including of research projects. There may be occasions when regulatory authorities may access research data in accordance with their statutory powers. City St George's will keep identifiable information about you from this study for ten years after the study has finished.

You can find out more about how City St George's handles personal data by visiting https://www.city.ac.uk/about/governance/policies/data-protection-policy. You can also read City's general privacy notice by visiting https://www.city.ac.uk/about/governance/policies/general-privacy-notice . You can also email Dataprotection@city.ac.uk for any questions about what data we keep and how we keep it safe. If you are concerned about how we have processed your personal data, you can contact the Information Commissioner's Office (ICO) directly https://ico.org.uk/.

Will my taking part in the study be kept confidential?

Yes, all information held about you will be kept securely and confidentially in locked filing cabinets or on secure computer servers in locked research offices. When people decide they want to take part in the study we assign people an individual Study ID number. Throughout the study we use this number to identify all information about you, and not your name. A single file that links your name, contact details and study ID number is kept securely and separately from all other information about you. We will hold your personal data, securely, for ten years following the end of the research study in line with the principles of the Data Protection Act (2018). This is in case we need to contact you about the study, or if you have any questions for us about your involvement in the research.

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The only people who will have access to your identifiable data (such as informed consent form) are the immediate research team. Once data has been anonymised (e.g. focus group recording has been transcribed and redacted) then audio recordings are permanently deleted from our secure servers. Any excerpts from focus groups that are quoted directly in research papers or any dissemination of findings from this project, or continued research using the data would be anonymised.

What will happen to the results?

We plan to publish reports in peer-reviewed journals about the results of this study. If you would like to receive updates and copies of our publications by email then you can tick the appropriate box in the informed consent form and the researcher will ensure they have your contact details.

Who has reviewed the study?

This study has been approved by the Health Research Authority NHS *[insert which committee here]* Research Ethics Committee.

What if there is a problem?

If you have any problems, concerns or questions about this study, you should ask to speak to a member of the research team. If you remain unhappy and wish to complain formally, you can do this through City St George's complaints procedure. To complain about the study, you need to phone 020 7040 3040. You can then ask to speak to the Secretary to Senate Research Ethics Committee and inform them that the name of the project is PEGASUS

You can also write to the Secretary at:

Anna Ramberg, Research Integrity Manager

City, University of London, Northampton Square

London, EC1V 0HB

Email: Anna.Ramberg.1@city.ac.uk

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Insurance

City St George's University London holds insurance policies which apply to this study, subject to the terms and conditions of the policy. If you feel you have been harmed or injured by taking part in this study, you may be eligible to claim compensation. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for legal action.

Further information and contact details

If you would like any further information about the PEGASUS study or there are problems with any stage of the research you can contact your site researcher who has been making arrangements to meet with you. The researcher's contact details are:

Name: TBC name of Researcher -I am a Lived Experience Researcher for PEGASUS

Mobile: XXXX

Email:

You can also contact the PEGASUS Programme Manager – change to Jacqueline Sin

Name: Lauren Walker

Mobile: XXXX 02070403971

Email: lauren.walker.3@city.ac.uk jacqueline.sin@city.ac.uk

Thank you for taking the time to read this information sheet.