COPESS STUDY

COMMUNITY OUTPATIENT PSYCHOTHERAPY ENGAGEMENT SERVICE FOR SELF-HARM (COPESS): A FEASIBILITY TRIAL

We are inviting you to take part in a study

Before you decide if you want to take part, it is important that you understand why the research is being done and what it involves. Please take time to read the following information. Ask us if there is anything that is not clear or if you would like more information. Take time to decide if you want to take part or not. Thank you for reading this.

1.Who will conduct the study?

School/Faculty: School of Psychology, Faculty of Health, Liverpool John Moores University.

Collaborating Institutions: Mersey Care NHS Foundation Trust, Liverpool Clinical Commissioning Group, University of Leeds, University of Liverpool and University of Manchester.

2.Who to contact

Name and Contact Details and status of the Principal Investigator: Dr Pooja Saini, Lead Researcher, School of Psychology, Room 3.17 Tom Reilly Building, Byrom Street, Liverpool, L3 3AF
Tel: 0151 231 8121

Email: P.Saini@ljmu.ac.uk

Name and Contact Details of Research Assistant: Miss Anna Hunt, Psychology Department, Faculty of Health, Room 316 Tom Reilly Building, Byrom Street, Liverpool, L3 3AF
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Iras Ref No: **275047**

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LIVERPOOL JOHN MOORES UNIVERSITY · NHS Mersey Care NHS Foundation Trust Community and Mental Health Services · NHS Liverpool Clinical Commissioning Group · MANCHESTER 1824 The University of Manchester · UNIVERSITY OF LIVERPOOL · UNIVERSITY OF LEEDS

3. What is the purpose of this study?

This study is about a new brief talking therapy for people who self-harm and have low mood. We plan to provide this therapy from local communities, as part of a service called COPESS (Community Outpatient Psychotherapy Service for Self-harm).

We want to understand if the therapy could be helpful to people with these difficulties. This study is called a "feasibility trial" and is designed to help us find out if it is practical to conduct this trial (or larger versions of this trial, including more people) about the COPESS therapy.

In particular, we hope to answer the following questions:

- Will people be willing to take part in a trial of COPESS?

- Will people who receive therapy from COPESS find it useful or helpful?

- Will people who receive therapy from COPESS attend all the sessions?

- Will we be able to get the information we need to judge if the therapy is helpful?

In this feasibility trial, the researchers are collecting data that will tell them whether one treatment is better or worse than other. The information collected will show how safe a treatment is, or whether it is making a difference to your health. Different people can respond differently to a treatment. By collecting information from lots of people, researchers can use statistics to work out what effect a treatment is having.

4. Why have I been invited to participate?

You have been invited to take part because you are:

- Aged sixteen years or older
- Have a mild or greater level of depression
- Have engaged in self-harm behaviour at least once in the last six months.

Self-harm refers to intentional harm to yourself, for example taking an overdose or cutting yourself. This might have been done to try and end your life (i.e. a suicide attempt) or for other reasons (e.g. to cope with difficult feelings).

5. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. You can withdraw from this study at any time up until the results of the study have been summarised and reported upon by informing the investigators using the contact details on page one of this Patient Information Sheet.

Please note that you are free to withdraw from this study at any time, without giving a reason and without it affecting your legal rights or clinical care, in any way.

6. What will happen to me if I take part?

If you are interested in taking part in the study we would **first arrange a telephone call or face-to-face meeting to check if you are eligible for the study**. This conversation would also be a chance for you to ask questions about the study. We may also seek verbal consent at this point to check your eligibility to take part in this study with your General Practitioner (GP) or other health professional.

If you are still interested and are eligible to take part, we would **arrange an initial, face-to-face meeting with a researcher**. This could happen at the University, your home, or other convenient, private location, depending upon your preference. The meeting would normally last about 30 - 45 minutes. During this meeting we would explain again what is involved in the study and you would again have the opportunity to ask any questions. We would then ask you to fill in a consent form to confirm that you agree to take part.

Once you complete the consent form, the researcher would then ask you a series of questions about yourself, including information about your experiences and difficulties Example questions will include: "*have you ever actually made a plan to kill yourself*?"; "*Have you ever done something to purposely hurt yourself without intending to die?"*. They would also give you questionnaires to fill in.

Following this first meeting you would be invited to one of two groups:

The **Treatment-As-Usual group** will continue to receive their current treatment from health services.

The **COPESS group** will also continue to receive their current treatment but will also be invited to take part in the new talking therapy.

The decision about which group you are in will be made by a computer and not a person. You will be allocated a study reference number. This number will be included in a computer programme with all study reference numbers for all individuals who have agreed to take part in the study. **The computer programme will then randomly assign you to one of the two study groups mentioned above** by randomly placing your study reference number in one or the other group**. This means that no-one, including the research team, will be able to choose which group you go into.**

We will contact you to tell you which group you are in. This part of the study is really important, but we know it can be difficult if you want to be in a particular group and you are allocated to the other group. This is something the research team will be happy to talk more about with you.

After you have been placed in a group, you would be invited to **three further one-to-one meetings with the researcher**. **These will be like the first meeting and will last around 30 - 45 minutes. These meetings will happen roughly one month, two months and three months after the start of the study**. As with the first meeting you will be asked questions about yourself and asked to fill in some questionnaires.

A leaflet explaining the COPESS intervention in more detail is available from the researcher. Briefly, those individuals who are offered the COPESS intervention will be invited to five, one-to-one sessions with a therapist. These sessions will last about 50 minutes. They will focus on current difficulties, emotions and relationships with others. Individuals may be asked to fill in some extra questionnaires at the end of these sessions.

6. What will happen to me if I take part (continued)

If you are offered the COPESS therapy, the sessions may be audio-recorded with your consent using a password-protected audio-recording device. Audio-recordings will be stored by the therapist to a secure storage within the Mersey Care computer system and deleted from the recording device. Only the therapist and their supervisor who will be listening to how the therapist conducts the session with you, will have access to the recording. The recording will be destroyed once the checking has been completed and within 5 years.

You may also be invited to a further one-to-one meeting with the researcher to complete an interview about the therapy and how you found it. The interview will take place at the University, your home, or other convenient, private location, depending upon your preference. The interview will last about an hour.

Throughout the study you will not have to answer any questions you do not want to. You will also be allowed to take breaks during research meetings if needed.

7.Will I be recorded and how will the recorded media be used?

If you take part in an interview, you will be asked to confirm that you agree for the interview to be audio-recorded using a password-protected audio-recording device. As soon as possible after the interview has finished the audio-recording will be transferred to secure storage within the LJMU computer system and deleted from the recording device. Only members of the research team and those who type up the audio-recordings into written text (i.e. UK Transcription Limited http://www.uktranscription.com/) will be able to listen to these recordings.

However, if you prefer, the researcher will make notes summarising your responses to the interview questions. At the end of the interview you will then be asked to read through these notes and sign to confirm that you agree that the notes reflect your responses. Anonymised quotes from your interview responses may be included in study reports, publications and/or presentations. The audio-recordings and written text will not be used for any other purposes without your written permission. All data will be destroyed after 5 years.

8. What are the possible disadvantages and risks of taking part?

During the study you may be asked about experiences that are difficult to talk about, or asked questions that you find upsetting or uncomfortable to answer. You do not have to answer anything you do not wish to. In addition, you can take a break or pause the meeting at any time if you need to, by letting the researcher know. If you are finding a meeting difficult, the researcher will be able to offer support, and if needed, can help direct you to other possible sources of support such as Samaritans (call 116 123 24-hours a day) or Listening Ear (0151 488 6648 Mon-Thurs 9am-8pm; Fri-Sat 9am-5pm) or Papyrus (01925 572444 Mon-Fri 9am-5pm). As stated earlier, you may leave the study altogether at any point, without this impacting on the usual care you receive from health services.

9. **What are the possible benefits of taking part?**

Although you will not receive reimbursement for the therapy sessions you have, you will receive reimbursement for taking part in this study. You will receive £15 in vouchers for each session completed with the researcher, resulting in a maximum of £60. Your involvement will help us to measure the impact of COPESS therapy as a new treatment for people who struggle with self-harm which could potentially help people with difficulties like yours in the future.

10.What will happen to the data provided and how will my taking part in this project be kept confidential?

For this research study we will use information from you. We will only use information that we need for the research study. Only two people from the research team will know your name or contact details and these will be stored on a secure university server. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. Researchers involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data for up to 5 years but will make sure no-one can work out who you are from the reports we write. For more information please check: www.hra.nhs.uk/patientdataandresearch.

All information will be anonymised to make sure that you cannot be identified (i.e. your name and personal information will be removed and replaced with a study reference number which will be unique to you) and treated confidentially. All questionnaire responses captured via the use of an IPad will be transferred by the researcher as soon as possible to a secure computer server within LJMU. All paper based questionnaires and documents will be securely stored within a locket cabinet in an access restricted office within LJMU.

Interviews will be audio recorded on a password protected audio recording device and as soon as possible after the interview the recording will be transferred to a secure computer server within LJMU and deleted from the recording device. The interview recordings will be only be shared with members of the research team and an independent company (i.e. UK Transcription Limited http://www.uktranscription.com/) who will type up the audio-recordings into written text. In addition, UK Transcription Limited will anonymise the written texts by removing any information that could be used to identify you or other individuals or organisations and replace them with made-up names/references. Anonymised data might be used for additional or subsequent research studies.

Your personal data will be stored separately and confidentially for as long as it is necessary to verify and defend, when required, the study process and outcomes. The time period may be a 5 years. Personal data will be accessible to *the research team only.* Personal data collected from you will be recorded using a study reference number. This study reference number will provide a link to your identity and will be stored securely and separately from any other study data and documents

11.Limits to confidentiality

The information you share with us would normally be kept confidential and not shared with others. In circumstances where we are concerned that you or others may be at significant risk of harm, we may need to share this information with others, such as your GP or other clinician. In these cases we would usually talk with you first about the need to do this. Everyone who takes part in this study will have a history of self-harm and this alone would not be enough for us to break confidentiality. However, if we were concerned that there was an immediate or high risk of harm to yourself (e.g. you were planning to end your own life) then in these situations we would need to break confidentiality and inform others.

12.What will happen to the results of the study?

The results of the study will be made available in academic journals, conference presentations, and talks. The information shared in these talks and papers would not allow anyone who takes part in the study to be identified. You will also have the choice of having a summary of the findings sent to you. If you agree to this then we will store a copy of your contact details up till the end of the study. We would destroy this information once the summary had been sent to you.

13. Who is organising and funding/commissioning the study?

This study is organised by LJMU and grant funded by the National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB).

14.Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the NRES Committee North West.

15.What if something goes wrong?

If you have a concern about any aspect of this study, please contact Dr Pooja Saini (0151 231 8121 or P.Saini@ljmu.ac.uk) who will do their best to answer your query. The investigator should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you wish to make a complaint, please contact the chair of the LJMU Research Ethics Committee (researchethics@ljmu.ac.uk) and your communication will be re-directed to an independent person as appropriate.

16. **Data Protection Notice**

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules. Universities, NHS organisations and companies may use patient data to do research to make health and care better. Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'. If they could do the research without using patient data they would not be allowed to get your data. Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts. The data controller for this study will be Mersey Care NHS Trust and the University conducting the research is Liverpool john Moores University (LJMU).

The Mersey Care NHS Data Protection Office provides oversight of LJMU activities involving the processing of personal data. LJMU can be contacted at secretariat@ljmu.ac.uk. This means that they are responsible for looking after your information and using it properly. LJMU's Data Protection Officer can also be contacted at secretariat@ljmu.ac.uk.

The University will process your personal data for the purpose of research. Research is a task that we perform in the public interest.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained.

You can find out more about how we use your information by contacting secretariat@ljmu.ac.uk. If you are concerned about how your personal data is being processed, please contact LJMU in the first instance at secretariat@ljmu.ac.uk. If you remain unsatisfied, you may wish to contact the Information Commissioner's Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/.

Due to the ongoing COVID-19 pandemic and restrictions all Research and COPESS sessions are currently taking place virtually. This will be reviewed throughout the trial in accordance with Government, University and Mersey Care guidelines. If you have any queries please let the Researcher know.