Remote Approaches to Psychosocial Intervention Delivery (RAPID): a multi-arm multi-stage trial

Please take your time when reading this information sheet. Feel free to ask us if anything is unclear, or if you would like more information. We will be very happy to answer your questions.

We are inviting you to take part in a study that aims to find out if remote psychosocial approaches can help people who experience suicidal thoughts, and if these approaches can reduce psychiatric hospital admissions. A remote approach is one which takes place online or over the telephone.

The study has three groups, each with a different form of support:

- **Group 1:** In addition to your usual mental health care, you will be offered a one-to-one peer support called PREVAIL. Peer support means talking to a peer support worker - a person who has similar experiences of mental health difficulties. If you are asked to take part in PREVAIL, you will receive up to 12 sessions over 12 weeks via telephone or online.
- **Group 2:** In addition to your usual mental health care, you will be asked to take part in a safety planning approach called SAFETEL. This will be delivered one-to-one by an assistant psychologist. You will receive up to 12 sessions over 12 weeks via telephone or online.
- **Group 3:** You will continue receiving your usual mental health care without using a remote form of support.

This study does not involve medicine being prescribed. If you are currently receiving any medical treatments, the study **will not require you to change or stop them**.

This study is funded by the National Institute for Health Research (NIHR) and has been reviewed and approved by the London Stanmore Research Ethics Committee (Reference 22/LO/0326). The Chief Investigator is Professor Tony Morrison from the University of Manchester and Greater Manchester Mental Health NHS Foundation Trust.

Who are we looking for and do I have to take part?

We are looking for people who:

- Are over the age of 16
- Have experience of a serious mental health problem
- Are currently being seen, or have been seen in the past 14-days by the Home-Based Treatment Team/ Crisis Team
- Are experiencing suicidal thoughts

It is completely up to you if you would like to be involved in the study and you should not feel under any pressure to decide.

What will happen if I choose to take part?

Consent and research assessment: You will meet with a research assistant (RA) to discuss the study and ask any questions you might have. If you would like to take part in the study, you will then be asked to sign a consent form[1]. Depending on covid-19 restrictions this appointment might be in person or via the telephone or MS Teams, so if we cannot give you a paper form to sign, we will audio record the appointment to show the RA has taken you through the consent form correctly.

If you do decide to take part in the study, the RA will complete one brief interview to ask you some questions about suicidal thoughts and behaviours to check whether the study is right for you. They will support you through this assessment and make sure you have the time you need to answer the questions with as many breaks as you want. If the study is right for you, then you will be asked to complete a brief interview about the services you have accessed recently and invited to complete 7 short questionnaires[2] about your wellbeing. This can either be during the same appointment or at a later time. The assessments and questionnaires can take up to one hour to complete, but this can be split across more than one appointment if you prefer.

You can choose how many of the questionnaires to complete and the questions you want to answer. No one will be upset with you if you decide you do not want to complete a questionnaire.

Following this meeting, you will **be allocated by a computer to one of the three groups** listed above. The group you are in will be decided by chance, like flipping a coin.

Follow-up Assessment: Everyone will be asked to do a follow-up assessment at 3 and 6 months to complete the same 2 brief interviews and 7 questionnaires as at the first research assessment. At the final assessment, you will be invited to complete an additional questionnaire regarding your experiences of the study. These follow-up meetings are to see if anything has changed for you over time. They might be in person or via telephone/ MS Teams depending on covid-19 restrictions. Each meeting will take up to one hour.

[1] Consent form – a signed document by participants which outlines informed consent. This means that participants enter the study freely and have been given all the required information prior to entering the study.
[2]Questionnaire – a set of questions with a choice of answers devised for a study.

The two different forms of remote support will not be available after the study ends.

If you do decide to take part but wish to stop using/receiving remote support, you can choose to continue doing the research assessments, or you can choose to stop both. If you decide to stop both, we will ask for your permission to continue to access your medical records for data on hospital admissions for the period of time you would be involved in the study (six months). However, you are free to completely withdraw at any time without having to give a reason and it will not affect the care you receive from mental health services either now or in the future.

Regardless of which group you are asked to take part in, ALL participants are valued for this study. Because everyone's information is equally important, we need to make sure it is all treated the same. As such, we ask that whenever you meet the RA, you do not tell them which of the three groups you have been involved with. However, don't worry if you tell them by accident, no one will be upset with you, and it will not affect what support you receive from the study.

What are the advantages and disadvantages to taking part?

Possible advantages
Although we cannot guarantee it, we hope that people receiving one form of support will find it helpful for coping with distressing thoughts and feelings. The information you share with us may also help us to support other people with similar problems in the future. This is because if any of the two forms of remote support are shown to work, then we will aim to make them more widely available within the NHS.

Possible disadvantages
It is possible that talking about some of your experiences either during the research assessment or as part of the support sessions may be upsetting. You can decide not to answer a question, stop the meeting or withdraw from the study whenever you wish. **We will always support your choice.**

Will I be paid?
You will receive a payment of £10 for each research assessment meeting (initial meeting, 3-months and 6-months follow-up assessment) to thank you for your time (£30 in total). We can provide these by bank transfer or voucher. If you would prefer to be paid in cash, we will do our best to provide you with this depending on covid-19 restrictions.

How will you use audio recording?
If you do not sign a consent form in person, then we will ask to audio record the consent appointment. This is to show that the researcher has taken informed consent correctly.

We may ask if we can record the research assessment. If you are asked to take part in PREVAIL or SAFETEL, we will also ask for your permission to record some of the sessions; this is so we can check the quality and content of the session to make sure everyone has a similar experience. The recording can be stopped at any time and words can be deleted or replaced. However, it is entirely your choice to have the sessions recorded or not.

To ensure the recording is secure and protects your confidentiality, it will be carried out in-line with policy from the NHS Trust that provides your care. Once the recording has been made, the researcher will transfer it to a secure NHS Drive where it can only be accessed by members of the research team who have permission. Once the recording has been transferred to this secure NHS Drive then it will be deleted from the recording device.

Who will know I am participating and who will have access to information collected about me?

The members of the research team, and those already involved in your mental health care, will know you are taking part. We will write to your GP and inform them you are going to be a participant in the study.

The information that you provide to us will not be shared with your healthcare team unless you say it is okay to do so. The only time that we will share information about you without your permission is if you tell us something that indicates either yourself or another person is at risk of harm. If this happened, then we would need to inform another person, such as your care co-ordinator, psychiatrist, or GP. However, we would always try to discuss this with you beforehand.

Any questionnaires you complete will be coded using an anonymous ID number instead of your name. Any identifiable information about you will be kept safe and secure, then destroyed three years after the study ends (in 2028). The exception to this is the consent form/consent audio recording, which contains your first and last name, as we are required to store this for 7 years after the end of the study (until 2032).

Following each contact with a member of the RAPID team, we will make a contact note in your Health and Social Care Record at the NHS Trust that provides your care to document that either a research assessment, PREVAIL or SAFETEL session has taken place. **The details of the information you provide will NOT be shared in this contact note, unless you tell us that you wish us to share this with your care team.**

How will we use information about you?

The researchers need to use information about you for this research project, this includes your:

- Name
- Contact details (address, telephone number/s and email)
- NHS Number/Electronic Health and Social Care Record number
- Date of birth

This information will be used to run the study and to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure and staff will not be able to access it without permission. Once the study has ended, we will keep some of the data so we can check the results. However, we will write our reports in a way that no-one can work out that you took part in the study.

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (i.e., a specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team.

If you would like to know more about your different rights, or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research: https://documents.manchester.ac.uk/display.aspx?DocID=37095

Will my participation in the study be confidential and my personal identifiable information be protected?

As laid out by data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential, and used only in the way you have been told it will be used.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. This is because we need to manage your records in specific ways for the research to be trustworthy and reliable. You won't be able to see, or change, the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information at: www.hra.nhs.uk/information-about-patients/

You can email the University of Manchester's Data Protection Officer: dataprotection@manchester.ac.uk

What happens if I can no longer decide to take part?

For a variety of reasons people can sometimes lose the capacity to decide for themselves whether or not to continue taking part in a study. For example, this could happen if you become physically or emotionally unwell. Although this is an unlikely event, if it was felt that you were unable to provide consent to take part, we would withdraw you from the study and no further data would be collected. Any data already collected would be kept and used in the study.

What will happen to the results of the study?

At the end of the study, we will write up our findings to submit them for publication in a scientific journal. Presentations may also be given at scientific conferences. All information will be anonymous, and nothing will be shared in public that could identify you. If you wish to know the results of our research, we will be happy to discuss this with you.

Insurance

The insurance arrangements for study management are via The University of Manchester. The insurance arrangements for the design and conduct of the study are via the NHS Indemnity scheme and The University of Manchester where legal liabilities arise from its actions or those of its staff.

Complaints

If you have concerns about any aspect of this study, you can ask to speak to the researchers who will do their best to answer your questions. Please speak to the chief investigator (Professor Tony Morrison) at Greater Manchester Mental Health NHS Foundation Trust, on 0161 358 1395 or tony.morrison@gmmh.nhs.uk

If you wish to make a formal complaint to someone independent of the research team, or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

• The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.ukresearch.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

• If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

• You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information: Tel 0303 123 1113 https://ico.org.uk/make-a-complaint/https://ico.org.uk/make-a-complaint /

Helpful contacts are below.
Thank you for taking the time to read this information

Helpful Contact Details

Research Assistant:
[INSERT NAME]
Contact number [XXXX]
Email [XXXX]

Chief Investigators/ Principal Investigator [delete as appropriate for the site]
NAME
Telephone number
Email address