

CARMS: Cognitive AppRoaches to coMbatting Suicidality

PARTICIPANT INFORMATION SHEET 2 FOR SERVICE-USER PARTICIPANTS: EXPERIENCES OF NEGATIVE FEELINGS AND BARRIERS AND SOLUTIONS TO IMPLEMENTING CARMS IN NHS MENTAL HEALTH SERVICES.

Version 3.0 06-06-17

This study has been approved by an NHS research ethics committee (REFERENCE NUMBER: 17/NW/0089)

What is the purpose of this project?

Many people with mental health problems experience suicidal thoughts and feelings. This can be very distressing, and it may affect people's lives in all kinds of ways. This project is to see if usual treatment from mental health services is better or worse with the addition of a new talking therapy called CARMS (Cognitive AppRoaches to coMbatting Suicidality). We would like to hear your views about how NHS services can best provide psychological therapies for suicidal thoughts and behaviours.

Invitation:

We would like to invite you to take part in this project. Our project collects information about your thoughts, feelings, and experiences. It is not invasive (e.g., we won't take blood tests). Please read all of the information on this sheet carefully. If you would like any more information or feel that there is anything you don't understand, please contact the members of our CARMS team. Please take your time to think about taking part or not.

Who is organising this project?

This project is being organised by Greater Manchester Mental Health Trust (GMMH), the University of Manchester and the Manchester Academic Health Sciences Centre (MAHSC), Clinical Trials Unit (CTU).

Why have I been asked to take part?

You have been asked to take part because you may have been having mental health problems such as psychosis, (e.g., hearing /seeing things that others don't necessarily hear/see; having unusual thoughts that others don't necessarily have), and also having suicidal thoughts or behaviours.

Do I have to take part?

No. It is your choice to take part or not. If you decide to take part and then change your mind during the project, you can leave at any time without any detriment to yourself. You can also ask that any information you have given us up to that point be withdrawn or destroyed. If you decide not to take part your mental health care will continue as normal and you do not have to give us a reason for your decision.

What will taking part involve from me?

If you agree to take part, we will ask you to meet with a member of the CARMS project team. This CARMS project worker will ask you some questions in an informal interview. This will take about an hour. We are also interested to hear from you about what it was like doing the interview with us. We will ask you about this immediately, and we may follow this up with a short questionnaire about a month later.

We would like to audio record the session you have with the researcher, and then later write-it down. This is so we can look at what people have said and make sure we understand what they mean. Members of the IRAS Reference number: 17/NW/0089 IRAS ID = 201644 ISRCTN Number: ISRCTN17776666 ClinicalTrials.gov Number: NCT03114917



CARMS research team will listen to the recording. Your care team will not listen to the recording. Your name will be removed from what we write down as will any identifying information (e.g., where you live, or who your care co-ordinator is).

If you agree to take part, you will be asked to provide your informed consent by signing a Consent Form at least 24 hours after reading this information sheet.

What sorts of questions will I be asked?

The sorts of things which we will ask include how you've been feeling, how you feel about your future, what makes you feel down, and the sorts of things which have helped to make you feel better. Other things which we will ask include how you think psychological therapies can be rolled-out by the NHS. We will also ask you about any problems that you can see with offering psychological therapies, and how we may be able to get round those problems. Finally, we will also ask you what it was like to take part in suicide research.

Will I be paid?

We recognise the importance of the time that you are giving CARMS. Therefore, you will be paid ± 10 for doing this interview with us.

What are the risks of taking part?

Speaking with the CARMS project worker in this way has no known risks. However, when you meet with the project worker, you will be asked to talk about your views on rolling out psychological treatments. If this makes you think about your own circumstances, then this may be upsetting. You will be able to take a break whenever you like and you can stop the interview at any time. You will be working with a trained project worker who will be able to advise you on where to get help if you do feel upset. We will also call you the day after your interview to see how you are doing. We may follow this up after about a month.

What are the benefits of taking part?

There are no direct benefits for you from this project. However, by telling us what you think, you will be helping us to try and introduce psychological talking therapies in the best way we can. Your views are very important to us.

Will any information I give be kept confidential?

Your care team will be informed that you are taking part in the study. However, any information you give us during the study is confidential to the CARMS research team. All information about you that is shared outside these people will have all identifying information, for example your name and address, removed. We would only share information with your care team if you told us something that we thought would put you or someone else in danger. If we needed to do this, we would talk to you first.

Individuals from the University of Manchester, the host NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data but, all individuals carrying out these auditing and monitoring activities will have a strict duty of confidentiality to you as a research participant.

Your interviews will be written out in full by a specialist company which is external to the CARMS team, and approved by the University of Manchester.

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Your anonymised data will be stored securely at the host NHS trust, at participating NHS trust sites, and at the MAHSC CTU until data entry is complete. We will archive CARMS data for 15 years after which it will be destroyed. We archive the data so that we can return to the this anonymised data so that it can be used in future research projects.

Who can I talk to about how my data will be stored and/or used?

Please contact the project co-ordinator of the CARMS project until December 2020:

Charlotte Huggett : Project Co-ordinator Telephone: 0161 276 3301

Email: charlotte.huggett@manchester.ac.uk

After December 2020, please contact the Principal Investigators (see below).

What if there is a problem?

If you are worried about any part of this project, you can speak to one of the CARMS team members or project workers who will do their best to answer your questions. If they cannot help you or if you would like to make a *minor complaint* about the project, then in the first instance please contact the principal investigators of the project:

PATRICIA GOODING, Coupland 1 Building, University of Manchester, Manchester, M13 9PL.

Telephone: 0161 275 1971 Email: patricia.gooding@manchester.ac.uk

Or

GILLIAN HADDOCK, Zochonis Building, University of Manchester, Manchester, M13 9PL.

Telephone: 0161 275 8485 Email: gillian.haddock@manchester.ac.uk

If you wish to make a *formal complaint* or if you are not satisfied with the response you have gained from the CARMS team in the first instance then please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 2046.

What will happen to the results of this project?

We aim to publish the results in scientific articles and to present the results to other scientists. We will also write the results in a non-scientific way for anyone who is interested. There will be no identifying information in these articles. The results will not be available until the CARMS project is finished (2020).

Contact for further information

If you would like any further information or have any questions, please contact the project co-ordinator of the CARMS project directly:

Charlotte Huggett : Project Co-ordinator Telephone: 0161 276 3301

Email: charlotte.huggett@manchester.ac.uk

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