# Participant Information Sheet

**Study title:** Cognitive Bias Modification Utilized to Rectify Errors for Depression (CURED): A randomised double-blind feasibility trial

**Study site:** Institute of Psychiatry, Psychology & Neuroscience (IoPPN)
King's College London
De Crespigny Park
Denmark Hill
London SE5 8AF

**Site investigator:** Professor Jenny Yiend

**Lead researcher** (main study contact)**:** Kaan Alp Karamanli kaan.karamanli@kcl.ac.uk

**REC reference:** 24/LO/0855

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You are being invited to take part in a research study designed by a team at the IoPPN. Before you decide whether you would like to take part or not, it is important that you understand why the research is being done and what taking part will involve. Please read this information sheet carefully and decide if you would like to take part or not.

## What is the study about?

We know that some people experience distress when they have depressive thoughts. This study is testing a procedure for depression called 'CURED' to see whether it is effective in reducing this distress. Prior research has suggested that therapies similar to the one we are testing have sometimes been found to reduce distress due to depression. However, none of these therapies have been tested with people who specifically experience depression.

CURED is a self-administered procedure that has been developed by combining research on biases in depression with tried and tested techniques that can change these biases. However, it is important you understand that ***the name of the study (CURED) <u>does not</u> imply a promise to "cure" depression***. This study is the first stage of trying to understand whether there are any benefits of this procedure and, if so, how long they last.

CURED involves reading text that could be understood in a negative way (such as interpreting a colleague's short reply as a sign of their dislike and disinterest). The procedure encourages people to make a different meaning (such as thinking the reason for the short reply is the colleague being busy) by using word tasks and questions.

At the end of this study, you may also be approached to take part in a further study which would involve a separate interview about your experiences of taking part in the CURED study and your views about the procedures involved. If approached, you would receive a separate information sheet and consent form about this other study and you can choose not to take part without giving a reason.

**Why have you been invited?**

You have been invited because you are 18 years of age or over and experience depressive thoughts and mood. You may have been told about the study by your mental health team or you may have read about the study and got in touch.

**Do I have to take part?**

No. Participation is entirely voluntary, which means it is up to you to decide whether you wish to take part. If you do decide to take part, but later change your mind, you are free to withdraw at any time, without giving a reason, but we will keep information about you that we already have. If you decide not to take part in the study, or later withdraw from the study, this will not in any way affect the normal care you receive.

**How do I know if I can take part in the study?**

If you are 18 years of age or older and experience depressive thoughts and mood, then you may be eligible to take part. We will check this with you by asking you a few questions about your mood, current treatment, if applicable, and symptoms. Also, even though the sessions will be completed on paper which will be sent to you in the post, you will need to have either a mobile phone, tablet or computer/laptop that is connected to the internet to access and complete the questionnaires.

**What will happen if I take part?**

1. ***Consent***. If you are interested in taking part, you will first be asked to sign a consent form (you will be given a copy to keep along with this information sheet).
2. ***Completing a Depression Questionnaire.*** Next, we will email you a depression questionnaire to measure your symptoms. If your scores meet the criteria, we will arrange a follow-up call to discuss further details.
3. ***Eligibility call.*** This call (conducted via phone or online) involves a **semi-structured clinical interview**. This means we will ask you questions based on previous research to ensure your eligibility and the safety of your participation, which will take about 45 mins-1 hour. During this call, we will try to understand:
    - the type and extent of any psychological problems you may have;
    - if you have any mental or physical conditions that mean you would be unable to complete the study tasks (e.g., cancer, dementia);
    - if you have had psychotherapy or changed your mental health medication (e.g., dosage or changes in type) within the last month;
    - if you have had a previous head injury that resulted in a loss of consciousness;
    - if you are experiencing any suicidal thoughts;
    - if you are currently participating or are planning to participate in another study aiming at improving your mental health during the trial.
4. ***Initial ('baseline') assessment***. Next you will complete the first research assessment, completing questionnaires about your current difficulties, your levels of depression and anxiety, and thinking patterns. This should take around one hour.

5. ***Random allocation***. If you are eligible to participate in the study, you will be randomly allocated to one of the two study procedures, the CURED procedure or control procedure. Random allocation means by chance, a bit like flipping a coin. This means that you have a 1 in 2 (50%) chance of receiving either procedure. This is to make sure the study is a fair test. Neither you nor the researcher who contacts you will know which group you have been allocated to until you complete your participation in the study to ensure neither of you are influenced by this information. This is called 'double-blinding'.
6. ***Procedures.*** In the sessions, you will be presented with 40 scenarios consisting of 3 sentences each, describing a daily ambiguous event. After reading each scenario, you will complete a missing word task and answer a question about that scenario. The scenarios will be different in content depending on which procedure you are randomly allocated to. The sessions for both groups will be delivered once a week for 6 weeks, in a self-administered format using paper booklets. The booklets will be sent by post to your preferred address in advance, and we will provide you with a pre-paid envelope to return the booklets to us at the end of the study. After completing each session, you will also be asked to complete a short online questionnaire straight away, which will be sent to you via email. We expect each weekly session to take 45 minutes and the questionnaires to take an additional 15 minutes to complete. Together, this would mean allocating one hour per week for 6 weeks for this part of study.
7. ***Final assessment and 12-week follow-up.*** After you have finished the six sessions, the researcher will ask you to complete the same questionnaires and tasks that you did during the initial assessment. We will then contact you again 6 weeks later to complete the questionnaires one final time.
8. ***The treatment and care that you receive will not change if you take part in the study.*** Throughout your involvement in the study all the other care and treatments that you receive will remain the same unless changed by your care team.

**Will I be compensated for my time?**

Yes, as a reimbursement for your time you will be paid £80 in total; Specifically, you will receive £20 on each of the following occasions:

- After completing the initial ('baseline') assessment
- After completing the questionnaires at the end of session 3
- After completing the assessment at the end of week 6
- After completing the 12-week follow-up

Payments will be in the form of Vex eGift cards.

**What if I change my mind about taking part?**

You are free to withdraw at any point before or during the study, without having to give a reason. Withdrawing from the project will not affect you in any way. You will not have to return any payments made to you. We will ask for your permission to keep any data we have already collected and use it in the final analysis, but you are free not to give your consent for this, in which case we will destroy the data we already collected. You will be asked specifically, in the consent form, if you wish to give your consent for us to keep and use your anonymised data in our analysis, should you withdraw from the study.

**What type of information will be collected?**

We will collect data on depressive and anxious symptoms, negative thinking patterns, and your experience regarding your assigned group. Your data will be protected by the research team in a password-protected secure cloud system provided by King's College London and will not be shared with any other institutions or individuals before it has been anonymised.

**What are the possible disadvantages and risks of taking part?**

The main disadvantage is the possible inconvenience and time commitment required to take part. In addition, the procedures themselves may not be helpful. The procedures will involve talking or thinking about feelings, thoughts or experiences which may be upsetting at times. This is a completely normal part of assessment, and our researchers are very experienced in

keeping this to a level you can manage. There are no right or wrong answers and you do not have to answer any questions that you do not want to. You are free to ask the researcher to move on to another subject, skip the given task, or stop the session altogether if you find any of the procedures upsetting. No major adverse effects are anticipated for participants in the study, but we will monitor your well-being throughout the trial by regular assessments after each session. It is unlikely that anything in the study would cause any distress; however, if it does you can report it during these calls or contact a member of our research team at kaan.karamanli@kcl.ac.uk or 07445094708.

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

Any of the procedures may have some benefit for symptoms of depression and anxiety. The information we collect during the study will help us know whether this is the case and if so, develop the procedure further so that it will be helpful for people in the future.

**Will my responses be confidential?**

Yes. Everything you tell us will remain completely confidential, within the limits of the law (namely the Data Protection Act). If you tell us anything that puts yourself or someone else at risk of serious harm, or reveals criminal activity, then we must break confidentiality and inform your care team or the relevant authorities. We will discuss this with you first. All information collected from you will be kept confidential and identified only by a unique code that will not personally identify you. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will inform your clinical team/GP of your involvement in the research. If you are in distress while taking part, we may inform your GP/clinical care team. If there are significant concerns about your or someone else's safety, the research team may deem it necessary to share information with your care team or the relevant authorities.

An online survey platform (i.e., Qualtrics) will be used to gather some data. Their privacy statement can be viewed here: https://www.qualtrics.com/privacy-statement/.

If you have further questions, please refer to the following website for more information on KCL's statement of the Use of Personal Data in Research: https://www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research and the King's privacy notice can be viewed here https://www.kcl.ac.uk/terms/privacy.

**How will we use information about you?**

We will need to use information (i.e., data) from you for this research project. This information will include your name, age, gender, ethnicity, clinical diagnostic information and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. The principal investigator of the study (Prof Yiend) and the PhD student of the project (Mr Karamanli) will handle and analyse the data. Your data will have a PIN number instead. We will keep all information about you safe and secure.

All information provided by you will be labelled using this PIN number, thus ensuring sensitive data cannot be directly linked to a specific individual. A master list linking participants' names with their PIN number will be password protected at the individual file level and stored on a secure network drive in a different location than the data and contact details. At that stage, only the research team will be able to access the data. After the analyses are completed, the master list will be destroyed, meaning that the data will be fully anonymised and any information cannot be traced back to you. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**How will the data be collected and stored?**

Your data will be collected online surveys and pen and paper questionnaires. An online survey platform (i.e., Qualtrics) will be used to gather some data. Their privacy statement can be viewed here: https://www.qualtrics.com/privacy-statement/.

The collected data will be stored in accordance with the General Data Protection Regulation (GDPR UK) and King's College London's Records and Data Retention Schedule. The data will be password protected at the individual file level and stored on a secure network drive provided by King's. The data will be kept for 5 years after project completion since it is set out as a good practice by the King's College London's Records and Data Retention Schedule.

**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, if you have agreed to our doing so on the consent form. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you complete the study, you can choose to withdraw your data by contacting us at any time up until we delete all the information that can identify you, otherwise known as anonymisation (this occurs at the end of the final analysis which is estimated to take place by the 1st of August 2026). At that point and beyond you can no longer withdraw your data because we can no longer track any information back to 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/
- our leaflet available from www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research (KCL) or https://www.slam.nhs.uk/about-us/privacy-and-gdpr (SLaM)
- by asking one of the research team
- by sending an email to info-compliance@kcl.ac.uk (KCL) or dataprotectionoffice@slam.nhs.uk (SLaM)

**What will happen to the results of the study?**

The results are planned to be published in a peer-reviewed journal and presented in an international conference to increase its dissemination and benefit to the wider public. At the point of publication and presentation, the data will be fully anonymised, meaning that none of the analyses and results will include any personally identifiable information.

You are welcome to learn about the results of the study once it is completed, if you wish. The progress and results of the study will be accessible via the study website: www.curedtrial.co.uk.

The information (data) collected during this study will also be saved in a publicly available repository called the UK Data Archive after it is fully anonymised, so that it may be used by other researchers. There is a specific field regarding this on the consent form where you can state whether you agree for your data to be shared in this way.

**Who is organising and funding the research?**

This research is being done as part of the PhD project of Mr Kaan Alp Karamanli under the supervision of Professor Jenny Yiend. Prof Sukhi Shergill, and Dr Jonas Everaert. King's College London is the lead sponsor of the research and South London and Maudsley NHS Foundation Trust (SLaM) is the co-sponsor for the research. The study is being funded by the Ministry of Education of Turkey through the PhD research expenses awarded to Kaan Alp Karamanli.

**Who has reviewed the study?**

People with experience of using mental health services have provided advice on study approaches and documents so that the study will be carried out in the best possible way. All research in the NHS is also looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion (approved) by the London-Fulham Research Ethics Committee on 19/03/2025.

**What should I do if I have questions or concerns about the research?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions Professor Jenny Yiend (jenny.yiend@kcl.ac.uk), at King's College London on 07977978655. If you remain unhappy and wish to complain formally, you can do this through the SLaM Patient Advice and Liaison Service (PALS) on 0800 731 2864, pals@slam.nhs.uk. In the event that something does go

wrong, and you are harmed during the research, you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

For any questions relating to data protection, please contact the Data Protection Officer(s): info-compliance@kcl.ac.uk (KCL).

**Thank you for reading this information sheet and for considering taking part in this research.**