

Research funded by:



Participant Information Sheet

“A case series study of Compassion Focused Therapy for distressing experiences”

Invitation to take part in this study

We'd like to invite you to take part in our research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

This study aims to develop and test the feasibility of a new therapy called Compassion Focused Therapy (CFT). This therapy helps people manage distressing experiences by helping people to feel safe in relation to their experiences and to develop compassion towards themselves and others. In order to keep improving the help we can provide for people with distressing experiences, we need to keep improving our therapies by testing out new approaches. A good place to start in improving current therapies is to look at some of the approaches that people are finding helpful for other mental health difficulties, such as anxiety and depression. CFT is a promising new approach that has been successfully provided for people with a range of difficulties. It is also based in the most up-to-date knowledge and science about how the mind works (both normally and under stress).

If you participate, you will have some individual sessions of CFT with Dr Charlie Heriot-Maitland, who is one of the psychologists in the service. This therapy will last up to 26 sessions (about 6 months), which is the same as standard therapy (ie Cognitive Behaviour Therapy; CBT). Not only will you be receiving this new therapy, but you will also be helping us develop and improve it as we go along; i.e. helping us learn how to help others with similar difficulties in the future.

Why have I been invited to take part?

You have been invited because you have recently been referred to see a therapist in South London and Maudsley NHS Foundation Trust, and you meet the study criteria because you have distressing experiences.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. Your decision whether or not to take part will have no effect on the current services and treatments you are receiving, your legal rights, nor will it affect your access to the routine therapy offered by the service (CBT). If you did wish to have CBT, as well as the Compassion Focused Therapy (CFT) in this study, then this would have to start after the CFT has finished because the two therapies cannot run at the same time. You would stay on the waiting list for CBT while in the CFT study, and your place on the list would continue to move up over time as normal.

If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. You are still free to withdraw at any time in the process of the study without giving a reason.

What will happen to me if I take part?

Taking part will involve up to 26 therapy sessions (1 hour weekly, over 6 months), along with 5 questionnaire sessions. The 5 questionnaire sessions will be spread out over the therapy: 1. as soon as possible; 2. just before starting therapy (2-6 weeks later); 3. in the middle of therapy; 4. at the end of therapy; and 5. 6-8 weeks after therapy. These sessions will last about 30 minutes, including a short interview about your

experiences, and a few questionnaires about, e.g., how you see yourself in relation to others. We will also ask your permission to monitor your heart rate briefly for 6 minutes at the end of the questionnaire sessions, but this is optional, so if you don't give permission, you can still take part in the study. You will be reimbursed £10 + travel expenses for each questionnaire session (so total £50 + travel). In the period before starting therapy (2-6 weeks), you will have brief contact with the therapist each week to complete a short 2-minute questionnaire (either over the phone or in person, with any travel expenses reimbursed). This short questionnaire will also be completed in the first 2 minutes of each therapy session.

As this is research, your therapist will ask your permission to audio or video record the therapy sessions. This is simply so that we can analyse and think about what's been said, and how we responded to that. This will help us learn. The only people who will hear or watch the tapes are the therapist, the supervisor, and one external expert in CFT who can check that the therapy is adhered to. All recordings will be anonymised and confidential, so the supervisor and expert will not know your name or any other personal information. You can ask for the recordings any time you want, and you can also ask for them to be deleted at any time. All recordings will be deleted anyway at the end of the study in 2017. If you would like to have your own copies of the recordings, you are most welcome, and indeed we would be very interested in your thoughts. After all, this is really about helping to understand you and how to be more helpful for you and others.

What will happen if I start but then don't want to carry on with the study?

You can withdraw from the study at any time without having to justify your decision. If you decide to withdraw from the study you can tell us whether you are happy for us to use the information obtained up to that point. If you are not, any information that you have given will be destroyed and you will not be contacted by us again.

What are the possible risks of taking part?

As with most therapies, you may be talking about issues that are sensitive and/or distressing for you, such as difficult experiences and relationships. However, you don't have to talk about anything you don't want to, and actually a major component of CFT is helping people feel safe in relation to their experiences. If difficult feelings do arise, your therapist is highly trained and experienced in guiding people through emotional conversations. Your therapist will also be able to contact other professionals and services if necessary.

What are the possible benefits of taking part?

CFT is intended to have beneficial effects for people, e.g., in reducing emotional distress and improving psychological well-being, and there is growing evidence for these benefits in a range of people using mental health services. There is a chance that participants in this study will experience these therapeutic benefits. In addition, it may also be a positive experience for participants to have an opportunity to contribute to other people's well-being by being involved with developing and researching a new therapy.

Will my taking part be kept confidential?

All the information collected during the course of the research will be kept strictly confidential, and will be stored in accordance with the Data Protection Act 1998, secured against unauthorised access. Your personal details will not be seen by anyone other than the primary researcher. Your questionnaire data and audio/video recordings will be assigned an anonymous code before they are used for supervision purposes with the research and therapy supervisors.

Your therapist will adhere to the normal NHS Trust guidelines and procedures on service-user confidentiality. With your permission, the therapist will liaise with other people involved with your care, such as GP or Care-Coordinator, and will keep brief notes about sessions for the clinical records, e.g. saying when you met etc., which are only accessible to those involved with your care. The therapist won't write things that you don't want them to, and you can look at these notes if you like. The only limits to confidentiality would be if, for whatever reason, things get very difficult for you, and there are issues of harm (e.g. you say something that suggests there may be a risk of harm to yourself or others), then the therapist may have to share information with others. Please note that this is likely to be a very rare occurrence.

How is the project being funded?

The project is funded through a Medical Research Council (MRC) Clinical Research Training Fellowship awarded to Dr Charlie Heriot-Maitland (ref: MR/L01677X/1).

What will happen to the results of the study?

The research should be completed by mid-2017. The results will be written-up as part of a PhD, and submitted for a peer-reviewed journal. This will be openly accessible through King's College London's publications repository. No individual will be identifiable from the published results. A summary will be published in the service newsletter, and a copy of this summary will be sent to participants if they wish.

What if something goes wrong?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you can speak with the Primary Researcher (contact details below) in the first instance or the Research Supervisor (contact details below), who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure (below) or through the Director of Research Quality (below).

Compensation for harm arising from an accidental injury and occurring as a consequence of your participation in the study will be covered by King's College London. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against King's College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Who has reviewed the study?

This research has been reviewed and funded by the Medical Research Council. People with experience of using NHS psychosis services have also been involved with advising on how to conduct this study in these services. All research in the NHS is also looked at by an independent group of people called a Research Ethics Committee, in order to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the NRES Committee London – Dulwich (REC ref: 15/LO/0198)

Contact details

If you have any questions relating to this research, or concerns about participation, please contact:

Primary Researcher

Dr Charlie Heriot-Maitland, MRC Clinical Research Training Fellow
King's College London, IoPPN (PO78), De Crespigny Park, London SE5 8AF
Email: charles.heriot-maitland@kcl.ac.uk / Tel: 07710 386138

Research Supervisor

Dr Emmanuelle Peters, Reader in Clinical Psychology
King's College London, IoPPN (PO77), De Crespigny Park, London SE5 8AF
Email: emmanuelle.peters@kcl.ac.uk / Tel: 020 7848 0347

If you would like to speak to someone to get some independent advice about your rights as a research participant, you can contact the local PALS (Patient Advice and Liaison Service):

PALS Office SLaM

Maudsley Hospital
Denmark Hill, London SE5 8AZ
Email: pals@slam.nhs.uk / Tel: 0800 731 2864

If you wish to make a complaint about the conduct of this study, you may speak to someone in your NHS clinical team initially, or if you would like to make a formal complaint, you can write to either of the following:

Complaints Department

Maudsley Hospital
Denmark Hill, London SE5 8AZ
Email: complaints@slam.nhs.uk / Tel: 020 3228 2444/2499

Director of Research Quality

Dr Gill Dale
Joint R&D Office of SLAM NHS Foundation Trust and Institute of Psychiatry, Psychology & Neuroscience
King's College London, IoPPN (PO05), De Crespigny Park, London SE5 8AF
Email: gill.dale@kcl.ac.uk / Tel: 020 7848 0675

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