Emotion Regulation in Children (ERiC): A Clinical Trial
Information Sheet: Key Points

We would like to invite you to participate in this research study. This first page gives you a summary of what the study is about. The next pages give you more detailed information.

- This study will be testing a new type of therapy, called 'Mentalization Based Treatment' (MBT). It has been developed to help children aged 6-12 who have a mixture of emotional and behavioural difficulties.
- To test if MBT is more helpful than other therapies, we will be looking at how things go for some children who receive MBT and some children who receive the usual support offered by their mental health service. The usual support might include a range of different types of therapies or treatments, so what is offered depends on what will suit your child's needs, and what is available.
- Half the people taking part in the study will be offered MBT and the other half will receive usual support. We do not choose who goes into which group - this will be decided at random by a computer.
- Children who are offered MBT will be offered 6-8 sessions, with their parent/carer, over 16 weeks. This will be similar in length to is the usual support offered. If further support is needed after that, your therapist will think with you about next steps.
- All parents/carers and children who take part in the study will be asked to complete some questionnaires and tasks. There will be four times when we ask you to do this: before treatment starts; halfway through treatment; at the end of treatment; and then 4 months later. We will also want to hear about your experience of therapy.
- All families who take part will be given a £10 voucher each time they do the questionnaires and tasks, as a thank-you for your time (£40 in vouchers for taking part in the whole study).
- If you decide not to take part in this study, that is fine – and you will still be offered a treatment as usual. If you take part, and you change your mind later, you can stop taking part at any point.

Now here is the more detailed explanation – it isn't just 'the fine print' – it contains some important information and if you read it, you'll get a much clearer understanding of the study and what taking part would involve.

What is the purpose of this research?
The purpose of the study is to find out more about the best ways that NHS child mental health services can support children and their families. There are many types of treatment available and we need to learn more about what works best and for which children. One of the treatments we would like to learn more about is Mentalization Based Treatment (MBT). We will look at how helpful MBT is compared with the usual services provided in Child and Adolescent Mental Health Service (CAMHS).

This study is a randomised controlled trial. This means that children will receive EITHER treatment as usual OR MBT. Overall, half of the children will receive treatment as usual, and half will receive MBT. We do not choose who goes into which group- this is done by a computer and there is an equal chance of being in either group.

Who are the research team?
The team are experienced researchers working at The Anna Freud Centre and University College London, in London, England. Two parents with experience of using child mental health services helped design the study and are part of the core research team.

What is Treatment as Usual?
Treatment as usual includes a range of different therapies and treatment types, and what is on offer will vary in each area. What is offered to a specific family will depend on what is available and what the clinical team think will be most helpful for that family. Treatment as usual will be a similar length to MBT, around 6-8 sessions in total.

What is Mentalization Based Treatment (MBT)?
Children who receive MBT will be offered fortnightly sessions, with their parent/carer, over 16 weeks. MBT involves 6-8 sessions in total. MBT focusses on helping children and their parents to 'mentalize'. This involves a focus on stressful or challenging situations and learning to manage them by better understanding mental states like beliefs, emotions, feelings, and wishes. MBT is a talking therapy, but can also include games and play.

Why have I been invited to take part?
Your CAMHS service is in one of several services in England where the study will run. Up to 320 children and their parents/carers will take part in the study.

Children are invited to take part if they are aged 6-12 and experiencing a mix of emotional and behavioural difficulties. We ask parents to fill out a questionnaire and use this to check that being part of the study would be suitable for your child.

Do I have to take part?
No, it is up to you to decide whether or not to take part. This will not affect the support that you and your child would normally receive. If you decide to take part, you can withdraw at any time without giving a reason and without it affecting any benefits or support that you are entitled to. If you withdraw from the study, you can continue with the treatment you are receiving. If you withdraw from the study and the therapy, then your CAMHS will think

with you about possible other options. If you decide to withdraw you will be asked what you wish to happen to the information you have provided up that point.

In the unlikely event that you lose capacity to consent during the study, we would withdraw you and your child from the study and not collect any further data from you. The research team would retain personal data collected and continue to use it confidentially in connection with the purposes for which consent was given. This could include further research after the study has ended, but only in a format that does not identify you.

What will happen to me if I take part?
A researcher will contact you to discuss the study further, check that the study would be appropriate for you, and answer any of your questions. If you do decide to take part in the study, you will sign a consent form, a copy of which you can keep with this information sheet.

Your family will be randomly allocated to receive either MBT or treatment as usual, both of which will take place in your local CAMHS.

All parents/carers and children who take part in the research study will be asked to complete some questionnaires and an online 'discussion task' – a researcher will contact you to arrange to do this with you over a video or telephone call. Parts of this call will be recorded. There will be four times when we ask you to fill in questionnaires, and it should take approximately 40 to 75 minutes each time.

- At the beginning, before treatment starts
- Halfway through treatment
- At the end of treatment
- 4 months after the end of treatment

The 'discussion task' is only done twice: at the beginning and end of treatment. It takes about 10 minutes. The 'discussion task' involves you and your child talking together about times that your child has felt happy, sad, worried, or angry. This helps us to understand how your child copes and reacts when faced with emotional situations.

You may also be asked to take part in an online interview with a researcher after treatment, to help us understand more about your experiences of therapy and the research.

The research team will also ask your local CAMHS to provide information about the dates and types of services you have been offered and attended during your time in the study. This will help us to work out the total cost and compare it between the two treatments.

Will I be recorded and how will the recorded media be used?
The therapy that your child is offered will not be recorded as part of the research; it will happen as it normally would.

With your permission, we will record part of the research meetings, in particular the 'discussion task' and the post-treatment interview, which take place on a video or telephone call. This is so the researcher can listen carefully, without needing to write notes during the discussion. You will be asked for your permission before anything is recorded. The

recordings, as well as all other data collected from you, will be stored in secure files and will not be associated with your name or any other information that could identify you.

The recordings made during this research will be used only for addressing the study aims. No other use will be made of them, and no one outside the research team will be allowed access to the recordings.

What are the possible disadvantages and risks of taking part?
Some people can find it upsetting talking about their thoughts and feelings, or completing questionnaires which ask about their child's difficulties. All information gathered by the researcher during your meetings is strictly confidential, but if there is anything that you do not wish to discuss, or if you want to interrupt the call for any reason, your researcher will talk to you about this and pause or stop if you decide to do so.

It is important to know that if you take part in the study, you will not be able to choose whether your child receives Treatment as Usual, or MBT. This is because a computer will automatically allocate you at random. In either condition, the care that you will be receiving will be in accordance with current best practice and routine procedures and will be carried out by professionals working on-site at your local service.

We do not know whether Treatment as Usual or MBT will be most helpful for your child – that is why we are doing this research project.

What are the possible benefits of taking part?
Whichever care you receive (MBT or Treatment as Usual), your child will be monitored closely throughout their time in the study.

You might enjoy meeting with the research team, filling in questionnaires, and having the opportunity to talk about the issues that are important for you and your family and the type of support that is and is not helpful.

This study will help us to learn more about the usefulness of different therapies when provided by NHS mental health services, which we hope in the future will lead to better service provision for other children who are struggling with similar difficulties. You might feel good to know that you have been part of an important study and contributed to this.

You will also be offered vouchers for your time given to complete the questionnaires and the discussion task (£10 voucher for each time point, up to a value of £40 altogether).

Has an Ethics Committee has checked the research project?
All research projects are looked at by an independent group of people, called a Research Ethics Committee, to protect your rights. This research has been reviewed and agreed by the London – Bloomsbury NHS Ethics Committee: (Project ID Number: 316392).

What if something goes wrong?
If you have any complaints about your care provided within the project, these can be addressed to your CAMHS. Compensation for any injury caused by the management or conduct of treatment within this study will be in accordance with policy of the CAMHS from where you have been referred. You can ask for further information from a member of your CAMHS team, or contact your CAMHS servce's patient advice and liaison service (PALS).

If you have any complaints about the research part of the study, then please contact the lead researcher whose details are at the bottom of this letter.

How will we use information about you?

We will need to use information from you, your child and your child's medical records for this research project.

This information will include the following for you and your child:

- Your name
- Your address
- Your phone number
- Your age
- Your gender
- Your email address
- Your child's age
- Your child's gender
- Your child's ethnicity
- Information about your child's health
- Information about your family circumstances.
- Recordings (sound and video) of parts of our researchers' calls with you and your child (see 'will I be recorded and how will recorded media be used?' above)

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. Your data will have a code number instead. 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.

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.
- 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 agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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 detailed privacy notice, which is available at https://www.annafreud.org/eric/
- by asking one of the research team
- by sending an email to dpo@annafreud.org

Limits to confidentiality
Please note that confidentiality will be maintained as far as is possible, unless the researcher feels worried that you or another person is in danger of harm. In this case, they may need to inform relevant agencies of this. Wherever possible, this would be discussed with you beforehand.

What will happen to the results of the research project?
At the end of the study, reports will be written about the findings. The results within these reports will be presented in such a way that no one can identify you or know that you took part. Findings will be presented in terms of what we observe among the whole group rather than individuals. For example, the report might note that 60% of people in the study held a certain opinion.

It is expected that the results of the research will be available approximately 12 to 24 months after the end of the study. We will share the findings of the study with all families who take part.

Local Data Protection Privacy Notice
The Anna Freud Centre, also known as the Anna Freud National Centre for Children and Families, is the data Controller for the data processing in this research study. The Anna Freud Centre Data Protection Officer provides oversight of AFC activities involving the processing of personal data and can be contacted at DPO@annafreud.org. Further information is provided on the privacy notice , available online at https://www.annafreud.org/eric/.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact AFC in the first instance at DPO@annafreud.org.

Who is organising and funding the research?
This study is funded by the Kavli Trust, a Norwegian organisation that funds health research, with a special interest in improving child mental health services.

What happens next?
Please feel free to discuss the information above with others, if that would help you to decide whether to take part. You can keep this information sheet to look at whenever you need to. If you decide to take part, you will need to give consent and a member from the research team will contact you to arrange a time to go through the questionnaires.

Contact for further information
For further information about this study, please contact the researcher or the principal investigator, Nick Midgley
Email: nick.midgley@annafreud.org
Phone: 020 7794 2313

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