Emotion Regulation in Children (ERiC): Improving mental health outcomes for children aged 6-12

Information sheet for parents/carers: Key points

We would like to invite you and your child 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 aims to understand more about what kind of support is most helpful for children seeking help for emotional and behavioural difficulties.
- The study will be testing 'Mentalization based therapy' (MBT), which is a type of therapy already used with some adults and teenagers. It has been adapted for use with children aged 6-12 who have a mixture of emotional and behavioural difficulties.
- To test if MBT is more helpful than other types of support, 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 support, 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 the usual support. We do not choose who goes into which group as this is decided at random by a computer and this decision cannot be changed.
- 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 the usual support offered. If further support is needed after that, your therapist will discuss the next steps with you.
- All parents/carers and children who take part in the study will be asked to complete some surveys at four times– before support starts, halfway through, at the end, and 6 months later. We will also want to hear about your experience of receiving support and being a part of the research study.
- All families who take part will be given a £10 voucher each time they fill in the surveys, as a thank-you for your time (£40 in vouchers for taking part in the whole study). Additionally, for the third or fourth set of a follow-up survey completed, families will be entered into a quarterly prize draw for a chance to win a £100 voucher.
- If you decide not to participate, that is completely fine. You and your child will still be offered the usual support. If you take part and you change your mind later, you can stop taking part at any point.

A more detailed explanation of the study can be found here. This is not just the 'fine print', as it contains key information that will help you get a clearer understanding of the study and what will happen if you decide to take part.

What is the purpose of this research?
The purpose of the study is to find out more about the best support provided by both NHS and non-NHS mental health and/or wellbeing services for children, young people, and their families. Depending on your local service, this could be a mental health or early help service. For simplicity, we will be referring to this as your "local service" going forward.

There are many types of support available and we need to learn more about what works best and for which children. One of the kinds of support we would specifically like to learn more about is Mentalization based therapy (MBT). To explore this, we will look at how helpful MBT is compared with the usual support provided in your local service.

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

Who are the research team?
The team are experienced researchers working at **Anna Freud** – a mental health charity for children and families – and University College London, in London, England. Two parents with lived experiences of accessing such local services have helped design the study and are currently part of the core research team.

What is the difference between this research study and your local service?
While the research team at Anna Freud is responsible for conducting the research, your local service plays the role of providing the support. If you take part in this research study, the only difference will be which kind of support your child receives at your local service, as we do not know which one is more helpful. If offered MBT it will still be offered by practitioners from your local service that have been additionally trained in MBT.

On the other hand, the research team at **Anna Freud** will contact you to complete surveys at a few different times, along with an optional interview, to assess how helpful the support has been – this aspect is unique to our research study at **Anna Freud** and not part of standard service provision.

What is the usual support?
The usual support offered by your local service includes a range of different therapies and support types, and may e.g. involve you or your child working with a counsellor or going to support groups. 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. The usual support will be of similar length to MBT, usually around 6-8 sessions in total.

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

Why have I been invited to take part?
Your local service is in one of the several sites in England where the study is running. 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. Someone from your local service may have filled in a survey with you and used 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. You and your child would still get the support you would normally receive, whether you decide to take part or not, and taking part will not make a difference to how long it takes for your child to be seen by your local service. 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, your child can continue getting help from your local service, but we won't collect any more information about you. If you withdraw from the study and the support, then your local service will think with you about the options available for how to best proceed from there.

In the unlikely event that you lose capacity to consent during the study (e.g., due to a serious illness or accident that impairs your ability to make decisions), 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/my child if we take part?

ERiC study: summary of activities		
Before support begins (the steps shown here will happen over the course of a few weeks)		Phone call with someone from your local service to complete online survey to see if the study is suitable for you and your child 5-10 minutes
		Phone call with researchers to give you more information about the study and answer your questions Up to 30 minutes

		Sign consent form 5 minutes
		Complete online survey Up to 40 minutes
Halfway through support		Complete online survey Up to 30 minutes
At the end of support		Complete online survey Up to 40 minutes
		Interview about your family's experience of receiving support and taking part in research (optional) 30 minutes to 1 hour
6 months after support		Complete online survey Up to 40 minutes

Firstly, someone from your local service will have already completed a short survey with you on a call. The answers you provided allowed us to check that the study would be appropriate for you and your child.

Once we have checked that the study is appropriate for you and your child, a researcher will try to arrange a suitable time to call you and answer any questions you may have about the study. The call can take about 30 minutes. If you do decide to take part in the study, you will be asked to sign a consent form online. If you wish, you can download a copy of your consent form to keep with this information sheet.

Your family will be randomly allocated to receive either MBT or the usual support, both of which will take place in your local service.

All parents/carers and children who take part in the research study will be asked to complete some surveys. There will be four times when we ask you to fill in surveys, and it should take up to 40 minutes each time in total. **The surveys don't have to be completed in one go: you can save what you've done and continue later on.**

- At the beginning, before support starts
- Half way through support
- At the end of support
- 6 months after the end of support

We will send you links to complete the surveys online in your own time. If you need assistance, please contact us (email eric@annafreud.org) and we will arrange for a researcher to call you. You can also call us on 07778 360272 or 07442 401988.

You will also be asked if you would like to take part in an online interview with a researcher after support, to help us understand more about your experiences of receiving support and taking part in the research. This interview will be video recorded. This is optional, and you can still take part in the study if you don't want to give feedback on your experience.

The research team will also ask your local service 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 types of support.

It is possible that in future, more research will be done to look at how families on the ERiC study get on in the years after the support they received. You will be asked to say on the consent form whether you are happy to be contacted in future. This is optional, and you can still take part in the study if you don't want to be contacted in the future.

Will I be recorded and how will the recorded media be used?
The support 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 meeting that take place on a video call, in particular, the post-support interview. This is so the researcher can listen and watch carefully, without needing to write notes during the discussion. You will be asked for your permission before anything is recorded, and you can still take part in the study if you don't want to be recorded.

The recording, 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. While the research team will be the primary group handling the recordings, another organisation will view the audio part of the recording to transcribe it for us and we will make sure that they also keep your information safe.

When the recording has been written up, we will replace your and your child's name with random numbers and the recording will be deleted.

What are the possible disadvantages and risks of taking part?
Some people can find it upsetting talking about their thoughts and feelings, or completing surveys 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 the usual support, 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 the usual support or MBT will be most helpful for your child – that is why we are doing this research project.

When a child is getting help at your local service, it can be hard for all members of the family, and sometimes difficult emotions can be brought up for anyone involved. Anxiety and depression may feel worse before they start to feel better, and relationships can come under strain. If anyone in your family is struggling with the study therapy, please let your local service practitioner know, so that they can support you. They may also share some information with us to help us monitor whether the study therapy is safe.

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

You might enjoy meeting with the research team, filling in surveys, 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 kinds of support when provided by NHS and non-NHS mental health and wellbeing 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 surveys (£10 voucher for each time point, up to a value of £40 altogether). Additionally, for each set of surveys completed at the three follow-up time points, you will be entered into a quarterly prize draw for a chance to win a £100 voucher.

Has an Ethics Committee 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 local service. Compensation for any injury caused by the management or conduct of therapy within this study will be in accordance with policy of the service from where you have been referred. You can ask for further information from a member of your local service team.

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.

Will you tell anyone I am taking part?
If you agree to take part in the study, your local service may write to your child's GP to let them know that they are taking part, and tell them which support your family will be having.

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 phone number
- Your age
- Your gender
- Your email address
- Information about your health
- Your child's age
- Your child's gender
- Your child's ethnicity
- Information about your child's health
- Information about your family circumstances.
- Video recordings 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 please note that withdrawing from the study does not automatically mean any data collected up until that point will be deleted.
- 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 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 your local service to help get you the support you need. 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

Anna Freud is the data Controller for the data processing in this research study. The Anna Freud Data Protection Officer provides oversight of Anna Freud 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/research/current-research-projects/emotional-regulation-in-children-a-clinical-trial-of-mentalization-based/.

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 Anna Freud 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. Please keep this information sheet so you can look at it again if you need to. If you decide to take part, you will need to give consent. You'll then be able to complete the first survey.

Contact for further information
For further information about this study, please contact the research team at eric@annafreud.org , or you can directly contact the lead researcher (also known as the chief investigator), Professor 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.