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Emotion Regulation in Children (ERiC): an evaluation of mentalization-based treatment for school-age children with emotional and behavioural difficulties

Submission date
14/06/2022

Recruitment status
No longer recruiting

Registration date
28/11/2022

Overall study status
Ongoing

Last Edited
07/09/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

There were twice as many children and young people referred to Children and Young People's Mental Health Services (CYPMHS) in 2020/21 compared with the previous 12 months. Many will present with mixed emotional and behavioural difficulties, but most mental health interventions are developed for single disorders. This means there is a lack of evidence-based interventions for this group that effectively target mechanisms underlying co-occurring mental health difficulties. There is a need for research on transdiagnostic interventions that target mechanisms underlying such mixed presentations, especially for school-age children (ages 6-12). Transdiagnostic interventions allow clinicians to address diverse diagnoses within a single treatment model, so limiting the training burden.

Difficulties with emotion regulation (the processes and strategies involved in regulating emotional states) present across a wide range of mental disorders and ER is the best-evidenced mechanism implicated in a range of common mental health disorders. One way in which to promote adaptive emotion regulation is by attending to the capacity to understand oneself and others in terms of underlying mental states (mentalizing). The ability to mentalize one's own experiences and those of others plays a key role in coping with stress, regulating emotions, and forming stable relationships. MBT is a well-evidenced therapy for a range of populations that aims to promote mentalization, which in turn increases ER capacities, leading to decreased emotional and behavioural difficulties. Until now, children aged under 12 years have not had the benefit of this transdiagnostic approach, as the evidence for its effectiveness in this population has not yet been examined. The aim of this study is to test the clinical- and cost-effectiveness of MBT for school-age children with emotional and behavioural difficulties. If effective, it is hoped that this scalable, transdiagnostic approach can become available to the growing number of children presenting to mental health services with a mix of emotional and behavioural difficulties. In addition, it may enable a more efficient allocation of health and social care resources by reducing the need for longer-term, more intensive specialist mental health interventions.

Who can participate?
Children referred to a range of CYPMHS aged 6-12 years with mixed mental health problems (emotional and behavioural) as the primary problem, and their parent/carers

What does the study involve?
Children will be randomly allocated to MBT (treatment group) or treatment as usual (control) and will receive treatment within the service they were referred to. MBT consists of 6-8 sessions, delivered fortnightly, which can flexibly involve different members of the family, with a primary focus on promoting mentalizing and emotion regulation in the parent-child relationship. Treatment as usual will be the usual care provided in the referring service, likely to include CBT, parenting groups, and/or children's social skills groups over 6-8 weeks. Parent/carers and children will be asked to complete outcome assessments (questionnaires and tasks) online at the start of treatment, mid-treatment, at the end of treatment and at follow-up.

What are the possible benefits and risks of participating?
Participants will have the chance of receiving MBT. For school-age children, there is preliminary evidence that promoting a child's mentalizing capacity can improve emotion regulation and children's behavioural and emotional difficulties. As with any therapy, there is potential for some distress for participants as part of exploring painful experiences.

where is the study run from?
The study is being run by the Anna Freud National Centre for Children and Families(AFNCCF), a registered mental health charity. The ERiC study brings together a team of researchers from AFNCCF, University College London (UCL) and Children and Young People's Mental Health Services (CYPMHS) (UK).

When is the study starting and how long is it expected to run for?
January 2022 to January 2027

Who is funding the study?
1. The Kavli Trust (Norway)
2. Anna Freud Centre (UK)

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
316392

Central Portfolio Management System (CPMS)
53863

Study information

Scientific Title
Emotion Regulation in Children (ERiC): a randomised clinical trial to evaluate the clinical and cost-effectiveness of mentalization-based treatment vs treatment as usual for school-age children with mixed emotional and behavioural difficulties

Acronym
ERIC

Study objectives
This study aims to evaluate the clinical- and cost-effectiveness of mentalization-based treatment (MBT) in improving mental health outcomes for children aged 6-12 with mixed (internalizing and externalizing) mental health problems.

Hypothesis 1: Children allocated to MBT will experience a significantly greater reduction in mental health problems – both internalizing and externalizing – when compared with the TAU group.
Hypothesis 2: Families allocated to MBT will also experience a greater improvement in a range of secondary outcomes, including quality of life, improved capacity for emotion regulation, and decreased parental stress, and a reduction in health and social service use and costs compared to the treatment as usual (TAU) group.
Hypothesis 3: The impact of treatment on child mental health will be mediated, in part, by changes in capacity for emotion regulation (in both parent and child).

The Implementation and Process Evaluation (IPE) aims to investigate: a) model fidelity, b) the experience of MBT (including the change process) from the perspective of service users; and c) any barriers to implementation and scalability post-trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/09/2022, London – Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, 3rd Floor Barlow House, 4 Minshull Street, Manchester M1 3DZ, UK; +44 2071048272; Bloomsbury.rec@hra.nhs.uk), ref: 22/LO/0591

Primary study design
Interventional

Study design
Pragmatic multicentre individually randomized superiority trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mental health in school-age children with mixed emotional and behavioural problems

Interventions
Current interventions as of 11/09/2024:
Participants will be recruited in children's mental health services (including Child and Adolescent Mental Health Services (CAMHS), Mental Health Support Teams (MHSTs) and community services) and the interventions in both arms will be delivered by clinicians working in those services. Clinicians will be randomly selected to either deliver MBT or treatment as usual (TAU). Clinicians will be stratified by profession and level of experience. The MBT intervention will be a manualized, transdiagnostic model designed for children aged 6-12 and their carers. It aims to

promote adaptive ER by attending to the capacity to understand oneself and others in terms of underlying mental states. MBT consists of 6-8 sessions, delivered fortnightly, which can flexibly involve different members of the family, with a primary focus on promoting mentalizing and emotion regulation in the parent-child relationship. The control group will be offered treatment as usual (TAU). As there is no single evidence-based treatment for this group, and because practice is not standardised across children's mental health services in England, TAU is likely to include CBT, parenting groups, and/or children's social skills groups. Participants will be randomized to either MBT or TAU, stratified by service and age group (6-9 years and 10-12 years old), using permuted blocks of size 4 within each stratum. Parents/carers and children will not be blind to the intervention group, but the research team conducting data collection and analysis will be blind.

Previous interventions:
Participants will be recruited in Child and Adolescent Mental Health Services (CAMHS) and the interventions in both arms will be delivered by clinicians working in CAMHS. Therapists will be randomly selected to either deliver MBT or treatment as usual (TAU). Therapists will be stratified by profession and level of experience. The MBT intervention will be a manualized, transdiagnostic model designed for children aged 6-12 and their carers. It aims to promote adaptive ER by attending to the capacity to understand oneself and others in terms of underlying mental states. MBT consists of 6-8 sessions, delivered fortnightly, which can flexibly involve different members of the family, with a primary focus on promoting mentalizing and emotion regulation in the parent-child relationship. The control group will be offered treatment as usual (TAU). As there is no single evidence-based treatment for this group, and because practice is not standardised across child and adolescent mental health services (CAMHS) in England, TAU is likely to include CBT, parenting groups, and/or children's social skills groups. Participants will be randomized to either MBT or TAU, stratified by CAMH service and age group (6-9 years and 10-12 years old), using permuted blocks of size 4 within each stratum. Parents /carers and children will not be blind to the intervention group, but the research team conducting data collection and analysis will be blind.

Intervention Type
Behavioural

Primary outcome(s)
Emotional (anxiety and depression) and behavioural (ADHD and conduct) symptoms are measured using the parent-rated Strengths and Difficulties Questionnaire: Total Difficulties Score (SDQ) at baseline, 8 weeks (mid-treatment), 16 weeks (end of treatment) and 40 weeks (follow up)

Key secondary outcome(s)
1. Emotional and behavioural problems measured using Me and My Feelings self-report measure for children at baseline, 8 weeks, 16 weeks and 40 weeks
2. Personalized treatment goals measured using Goal Based Outcomes (parent/carer-defined) completed by carers at baseline, 8 weeks, 16 weeks and 40 weeks
3. Parenting stress measured using Parental Stress Index – Short Form parent-report at baseline, 8 weeks, 16 weeks and 40 weeks
4. Parental mentalizing capacity measured using the Parental Reflective Functioning Questionnaire parent-report at baseline, 8 weeks, 16 weeks and 40 weeks
5. Service use and costs, measured using the Child and Adolescent Service Use Schedule questionnaire at baseline, 16 weeks and 40 weeks
6. Emotion regulation in child and parent will be measured using:

6.1. The Emotional Awareness Questionnaire child self-report at baseline, 8 weeks, 16 weeks and 40 weeks
6.2. The Test of Emotional Comprehension online task at baseline and 16 weeks
6.3. The Emotion Regulation Checklist for Children parent-report at baseline, 8 weeks, 16 weeks and 40 weeks
6.4. The Difficulties in Emotion Regulation Scale parent report at baseline, 8 weeks, 16 weeks and 40 weeks
6.5. The Parent-Child Interaction Task – a parent-child discussion task at baseline and 16 weeks

Completion date
17/01/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/09/2024:
1. Child aged 6-12 years at the time of randomisation
2. Carer-reported Strengths and Difficulties Questionnaire (SDQ):
2.1. Total difficulties score for child ≥14
2.2. Emotional problems ≥5 AND/OR conduct score ≥3
2.3. Functional impairment score ≥1
3. Valid informed consent
4. Parent(s)/carer(s) have the capacity to engage with the trial, including providing informed consent and completing baseline and follow-up measures

Previous inclusion criteria:
1. Child aged 6-12 years at the time of randomisation
2. Carer-reported Strengths and Difficulties Questionnaire (SDQ):
2.1. Total difficulties score for child ≥14
2.2. Emotional problems ≥5
2.3. Conduct score ≥3
2.4. Functional impairment score ≥1
3. Valid informed consent

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex

All

Total final enrolment
316

Key exclusion criteria
Current exclusion criteria as of 11/09/2024:
1. Indications of, or pre-existing clinical diagnosis in child of psychotic disorder
2. Indications of, or pre-existing clinical diagnosis in child of eating disorder
3. Indications of, or pre-existing clinical diagnosis in child of severe learning difficulty
4.Children will be excluded where the referring clinician identifies an immediate risk of harm to self or others
5. Current participation in another mental health intervention trial. This includes where the family has previously participated in the ERiC study.
6. Children with a sibling, or another child who lives in their home, who has taken part in the ERiC study

Previous exclusion criteria:
1. Indications of, or pre-existing clinical diagnosis (in child or parent) of psychotic disorder
2. Indications of, or pre-existing clinical diagnosis (in child or parent) of autism spectrum disorder (ASD)
3. Indications of, or pre-existing clinical diagnosis (in child or parent) of psychotic disorder
4. Indications of, or pre-existing clinical diagnosis (in child or parent) of pervasive developmental disorder
5. Indications of, or pre-existing clinical diagnosis (in child or parent) of eating disorder
6. Indications of, or pre-existing clinical diagnosis (in child or parent) of severe learning difficulty
7. Indications of, or pre-existing clinical diagnosis (in parent) of severe substance abuse disorder
8.Children will be excluded where the referring clinician identifies an immediate risk of harm to self or others

Date of first enrolment
04/04/2023

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lincolnshire Partnership NHS Foundation Trust Hq
NHS Foundation Trust
Carholme Court
Long Leys Road
Lincoln

England
LN1 1FS

Study participating centre
Barnet Integrated Clinical Services
London Borough of Barnet Family Services
2nd Floor
2 Bristol Avenue
Colindale
London
England
NW9 4EW

Study participating centre
Riverside Family Hub
Minton Lane
North Shields
England
NE27 6DQ

Study participating centre
Anna Freud Centre
4-8 Rodney Street
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N1 9JH

Study participating centre
Cheshire and Wirral Partnership NHS Foundation Trust
Sycamore House, Cheshire Oaks Business Park, Lloyd Drive
Ellesmere Port
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CH65 9HX

Study participating centre
East of England Community Health and Care NHS Trust
Norwich Community Hospital
Bowthorpe Road
Norwich
England
NR2 3TU

Study participating centre
North London NHS Foundation Trust
4th Floor, East Wing
St. Pancras Hospital
4 St. Pancras Way
London
England
NW1 0PE

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Hospital
Warneford Lane
Headington
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OX3 7JX

Sponsor information

Organisation
Anna Freud Centre

ROR
https://ror.org/0497xq319

Funder(s)

Funder type
Charity

Funder Name
Kavlifondet

Alternative Name(s)
The Kavli Trust, Kavli Trust, O. Kavli og Knut Kavlis Almennyttige Fond

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Norway

Funder Name
Anna Freud Centre

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository, the UCL Research Data Depository (https://www.ucl.ac.uk/library/open-science-research-support/research-data-management/ucl-research-data-repository). Only fully anonymised questionnaire data and task scores will be shared. The data will become available after the core research team has completed all planned analyses and they are published. It will be retained for a minimum of 10 years (the funder has made no requirements for data sharing) and this will be specified in the PIS. Access will be provided to registered researchers via request to UCL.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/08/2023	18/08/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other files	Health economic analysis plan version 1.0	04/06/2026	07/09/2026	No	No
Participant information sheet	version 1.2	13/10/2022	25/11/2022	No	Yes
Participant information sheet	version 5.0	13/02/2025	11/08/2026	No	Yes
Statistical Analysis Plan	version 2	12/08/2026	13/08/2026	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes