

Emotion Regulation in Children (ERiC):

Health economic analysis plan

Version history log

Version	Date	Details of Change
0.1	4 Jun 2026	
1		Changes in response to TSC comments: - Add a version history log - Specify the sample size (recruitment target) in study design - Provide details of the information to be collected from the Service Use Data and CA-SUS, and specify the corresponding data collection timepoint. - Include cost-effectiveness acceptability curves as part of the methodology

1. Introduction

Mental disorders in school-aged children represent a significant and growing public health concern in England. Approximately one in five children and young people had a probable mental disorder [1]. Mental disorders in childhood have profound implications across numerous domains, including impaired functioning, poor health outcomes [2], and reduced health-related quality of life (HRQoL) [3]. Without appropriate intervention, affected children are at risk of experiencing escalating difficulties, with long-term consequences for both individual and society.

It was estimated that poor mental health cost the UK economy £300 billion a year in 2022, driven by productivity losses, reduced quality-of-life and increased health and social care costs [4]. As impacts of childhood mental disorders may persist or even escalate throughout life, the long-term consequences are estimated to cost the UK over £1 trillion in lost lifetime earnings across a single generation [5].

Poor emotion regulation (ER) is a core transdiagnostic mechanism underlying the wide range of emotional and behavioural difficulties. It is therefore considered a key target for therapeutic intervention [6, 7]. Mentalization, defined as the capacity to understand one's own and others' mental states underlying the over behaviours of oneself or others, is considered an important component of ER [8]. Mentalization Based Treatment (MBT) was originally developed to improve ER for adults with borderline personality disorder [9]. The MBT has been adapted for therapeutic work with children and families [10]. Preliminary evidence indicates that improving a child's capacity for mentalizing can enhance ER and thus lead to improvements in functioning, including decreasing behavioural and emotional difficulties [10, 11].

The Emotion Regulation in Children (ERiC) trial is a pragmatic, individually randomised, superiority trial comparing MBT with treatment as usual (TAU) [12]. This health economic analysis plan describes the methods for conducting the within-trial economic evaluation alongside the ERiC trial. The results of the economic evaluation will provide evidence on the costs and outcomes associated with MBT compared with TAU, thereby informing healthcare decision-making.

2. Methodology

2.1. Study design

In brief, the ERiC trial is a two-arm randomised controlled trial (RCT) designed to assess the clinical- and cost-effectiveness of MBT versus TAU for school-age children with comorbid internalising and externalising difficulties. The recruitment target is 320 children. Further details on sample size are available in the statistical analysis plan

(version 1.0). Participants were randomised to the intervention (MBT) or control (TAU) arms with a 1:1 ratio.

Data were collected at baseline (pre-randomisation), 8 weeks after the start of treatment (mid-treatment), 16 weeks after the start of treatment (end of treatment), and 40 weeks follow-up. The primary outcome of the trial is the parent-rated Strengths and Difficulties Questionnaire (SDQ) Total Difficulties Score [13, 14], measured at the end of treatment.

The economic evaluation will evaluate and compare the costs and outcomes of MBT to TAU from the perspective of the NHS and personal social services. The primary analysis will be a cost-consequence analysis (CCA), where we will report a disaggregated summary of all the costs and outcomes across the two arms. A secondary analysis will involve a cost-utility analysis (CUA), which will estimate an incremental cost per quality-adjusted life year (QALY) gained for MBT compared to TAU, expressed as the incremental cost-effectiveness ratio (ICER).

2.2. Study population

All trial participants will be included in the economic evaluation. Children aged 6-12 with mixed (internalising and externalising) mental health problems, and their parents/carers, will be recruited from referrals to participating services. Eligible children must have valid informed consent and a carer-reported SDQ total difficulties score of at least 14, an emotional problems score of at least 5 and/or a conduct score of at least 3, and functional impairment score of at least 1. Parents/carers must have the capacity to engage with the trial, including providing informed consent and completing baseline and follow-up measures. Further details regarding the eligibility criteria and recruitment procedure can be found in the trial protocol [12].

2.3. Comparison groups

2.3.1. Intervention

The intervention is an adaptation of MBT using a manualised, transdiagnostic model designed for children and their carers. The primary focus of the intervention is to promote mentalisation and emotion regulation (ER) in the parent-child relationship.

The MBT requires 6-8 sessions promoting mentalisation, delivered fortnightly, mostly in-person, and possibly involving carers. These sessions are run by therapists who have completed a 3-day MBT training. Therapist costs will be estimated based on their job titles, using standard salary and unit cost references [17].

2.4. Treatment as usual

Treatment for mental health problems is usually highly personalised and contains high levels of heterogeneity. Hence, it is not possible to define a standard TAU for participants. TAU is likely to include CBT, parenting groups, and/or children's social skills groups. In this

analysis, TAU will be captured using the Child and Adolescent Service Use Schedule (CA-SUS).

2.5. Outcomes

For the CUA, the primary outcome of the trial, the SDQ scores, will be mapped onto the Child Health Utility 9D (CHU9D), a preference-based quality of life measure for children, using a published algorithm [15]. We will compute CHU9D at baseline, mid-treatment, end-of-treatment, and 40 weeks follow-up by using the SDQ scores at the corresponding timepoints. Participant-specific utility values will be generated by linear interpolation between utility values at each measurement point. QALYs will then be computed as the area under each participant's utility profile from baseline to 40-week follow-up.

2.6. Costs

This economic evaluation will be taken from the perspective of the NHS and personal social services sectors, including those provided within the education sector.

2.6.1. Resource use

Resource use data will be captured across two components: (1) intervention resource use and (2) health service use.

Intervention resource use will include training costs and staff time associated with the delivery of MBT or TAU sessions. Detailed information regarding the delivery of MBT or TAU sessions, including the number of sessions, mode of delivery (in-person or online), the length of session, types of professionals seen by the family, will be derived from the Service Use Record collected at 40 weeks. Types of services provided for those in the TAU arm could be cognitive behavioural therapy, dialectical behavioural therapy, child psychotherapy, child psychoeducation, parent coaching/parent psychoeducation, drama therapy, art therapy, psychiatric assessment or intervention, or neurodevelopmental intervention.

Health service use data will be collected through CA-SUS [24], collected at baseline, 16 weeks (end of treatment) and 40 weeks (follow-up). This questionnaire covers A&E attendances, hospital inpatient and outpatient appointments, intensive care unit admissions, community care services and medication use.

2.6.2. Unit costs

Unit costs will be applied to resource use data to calculate total costs. They will be derived from standard national reference sources, including the NHS Payment Scheme for services within the hospital setting [25], NICE British National Formulary for medication costs [26] and Personal Social Services Research Unit (PSSRU) for staff costs and services within primary and community settings [17].

Total costs and each cost components will be reported across two arms at baseline, mid-treatment, end-of-treatment, and 40 weeks follow-up.

2.7. Cost-consequence and cost-utility analysis

The primary analysis (CCA) will report costs and outcomes separately without attempting to combine them into a single measure.

The secondary analysis (CUA) will report an incremental cost-effectiveness ratio (ICER) based on incremental cost per QALY gained from the intervention.

$$ICER = \frac{Cost_{MBT} - Cost_{TAU}}{QALY_{MBT} - QALY_{TAU}}.$$

This ICER will allow us to examine if the intervention falls within the current willingness-to-pay (WTP) threshold suggested by NICE (lower threshold: £25,000/QALY gained; upper threshold: £35,000/QALY gained) [27]. In addition, we will calculate the incremental net monetary benefit (INMB) by using the current NICE thresholds.

$$INMB = (QALY_{MBT} - QALY_{TAU}) \times \lambda - (Cost_{MBT} - Cost_{TAU}),$$

where λ indicates the cost-effectiveness threshold.

2.8. Statistical analysis

For the CCA, means and standard deviations will be reported for all outcomes and costs across two arms. Following the statistical analysis plan (version 1), mean differences will be estimated using multi-level models with random intercept terms for participants, CAMH service and therapists. If the model fails to converge, a 3-level model with random intercept terms for participants and CAMH service only will be fitted instead. All models will adjust for age and the relevant outcome at baseline.

Uncertainty around mean differences will be assessed using non-parametric bootstrapping with 1,000 replicates. The 95% confidence intervals around mean differences will be based on the biased-corrected and accelerated bootstrap confidence intervals.

For the CUA, the ICER and INMBs will be calculated. A cost-effectiveness plane will be generated by plotting the 1,000 bootstrapped incremental costs and incremental QALY pairs, providing a visual representation of the joint distribution of uncertainty around the ICER [28]. Each replicate will be plotted across the four quadrants of the plane, with the horizontal axis being incremental QALY and vertical axis being incremental cost. Hence, the north-east quadrant indicating that MBT is more effective and more costly than TUA; the south-east quadrant indicating greater effectiveness at lower cost (dominant); the south-west quadrant indicating lower effectiveness at lower cost; and the north-west quadrant indicating lower effectiveness at higher cost.

We will further generate cost-effectiveness acceptability curves (CEACs) using the bootstrap replicates to illustrate the probability of MBT being cost-effectiveness compared with TAU across a range of WTP thresholds.

All analyses will be performed in R (version 4.5).

2.9. Missing data

Resource use and outcome data are prone to missing data. We will discuss the missing data with the study investigators to understand the underlying missing data mechanism. As typical in trial-based economic evaluations, data are unlikely to be missing completely at random (MCAR). Hence, we will use multi-level multiple imputation (MI) with chained equations, assuming that the data are missing at random (MAR). In other words, we will assume that any differences between individuals with complete data and missing data can be explained by the observed patient characteristics. For example, potential variables that may help explain those differences and considered for the imputation model include SDQ total difficulties, EAQ subscales, CAMH service, demographic participant characteristics for both child (gender, age, ethnicity, type of school, presence of special educational needs, social care involvement, and eligibility for free school meals) and the carer (age, gender, household size, partnership status, tenancy, long-term illness, highest qualification, employment status, income, and relationship to child). The imputation for costs and utilities will be conducted jointly within each treatment arm.

2.10. Sensitivity analysis

Similarly to the statistical analysis, the CUA will consider the following sensitivity analyses:

- Adjustment for baseline characteristics, particularly CHU9D as this tends to be imbalanced.
- Information-anchored sensitivity analyses to potential departures from the MAR assumption.
- Complier average causal effect (CACE) analysis

References

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