EVALUATION PROTOCOL

A randomised controlled trial of mentalization-based therapy for conduct disorder for use with children referred to Forensic Child and Adolescent Mental Health Services

Anna Freud; University of Hertfordshire

Principal investigator: Julian Edbrooke-Childs

YOUTH ENDOWMENT FUND

The Mentalization Intervention for Children and Adolescents (MICA) study: A randomised controlled trial of support for aggressive and violent behaviour via Forensic Child and Adolescent Mental Health Services (FCAMHS)

Evaluation protocol

Evaluating institutions: Anna Freud and University of Hertfordshire

Principal investigator: Julian Edbrooke-Childs

Project title	**A randomised controlled trial of mentalization-based therapy for conduct disorder for use with children referred to Forensic Child and Adolescent Mental Health Services**
Developer (Institution)	University of Heidelberg
Evaluator (Institution)	Anna Freud and University of Hertfordshire
Principal investigator(s)	Julian Edbrooke-Childs
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Trial design	Two-armed randomised controlled trial with internal pilot and implementation process evaluation
Trial type	Efficacy with internal pilot
Evaluation setting	Forensic Child and Adolescent Mental Health Services (FCAMHS)
Target group	Children 10-17 years referred to FCAMHS for violent and disruptive behaviour
Number of participants	632 total, 316 in each arm.
Primary outcome and data source	Aggression and violent behaviour measured with the total score of the Reactive and Proactive Aggression Questionnaire (RPQ) completed by children at baseline and 6 months post-randomisation.
Secondary outcome and data source	**Child self-reported outcomes and measures:** 1. Conduct problems, hyperactivity/inattention, difficulties with peers, and emotional difficulties measured with the respective subscales, and impact score of the Strengths and Difficulties Questionnaire (SDQ), completed at baseline and follow up. 2. Mentalizing measured with the analyses of emotions and attending to others' emotions subscales of the Emotion Awareness Questionnaire (EAQ), completed at baseline and follow up.

	3. Family functioning measured with the total score of the Systemic Clinical Outcome and Routine Evaluation (SCORE-15), completed at baseline and follow up. **Parent/carer-reported outcomes and measures:** 1. Aggression and violent behaviour measured with the total score of the Reactive and Proactive Aggression Questionnaire (RPQ) completed at baseline and follow up. 2. Conduct problems, hyperactivity/inattention, difficulties with peers, and emotional difficulties measured with the respective subscales of the Strengths and Difficulties Questionnaire (SDQ), and impact score, completed at baseline and follow up. 3. Family functioning measured with the total score of the Systemic Clinical Outcome and Routine Evaluation (SCORE-15), completed at baseline and follow up. **Clinician-reported outcomes and measures:** Disruptive, antisocial or aggressive behaviour, non-accidental self-injury, substance misuse, peer relationships, family life and relationships, and school attendance measure with single items of the. Health of the Nation Outcome Scales for Children and Adolescents (HoNOSCA), completed at baseline and follow up.

Protocol version history

Version	Date	Reason for revision
1.2 [*latest*]		
1.1		
1.0 [*original*]		*[leave blank for the original version]*

Any changes to the design or methods need to be discussed with the YEF Evaluation Manager and the developer team prior to any change(s) being finalised. Describe in the table above any agreed changes made to the evaluation design. Please ensure that these changes are also reflected in the SAP (CONSORT 3b, 6b).

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1.0. Study overview

Community Forensic Child and Adolescent Mental Health Services (FCAMHS) comprise 14 services, at the time of writing, covering all of England, commissioned by NHS England & NHS Improvement in response to Future in Mind (Department of Health, 2015) and the Five Year Forward View (NHS England, 2014). These papers made calls to improve the quality and geographical consistency of service provision for children who are at high risk, high harm, and high vulnerability.

FCAMHS are targeted towards children with complex and high-risk presentations who are giving cause for professional concern, which usually refers to dangerous behaviour posing risk of harm to others, potentially involving the youth justice system. FCAMHS sit in the highest Tier of mental health support for children. Tier 1 promotes mental wellbeing while Tier 2 offers more targeted services, such as school and youth counselling. Tier 3 CAMHS are specialist services for children with severe mental health conditions. They offer assessments, diagnosis, psychological and systemic therapy, pharmacological treatment, and consultation and advice to other professionals. Tier 3 CAMHS are useful for children with severe depression, anxiety, self-harm, and suicidal behaviours. Tier 4 offers highly specialist services such as inpatient services and FCAMHS. Therefore, FCAMHS are useful for children who are beyond the traditional Tier 3 remit.

The FCAMHS service specification (NHS England, 2024) is being implemented in response to literature (Childs et al., 2021; NHS England, 2024) which suggests that children accessing these services experience multiple, complex needs. Further, they are more likely to present with high-risk behaviours (e.g., substance misuse), high levels of harm to self and others, and high vulnerability of victimisation (Hindley et al., 2017). The challenges of addressing these multiple needs mean that children often experience multiple transitions between services and geographical displacement. Previously, the provision of support for high-risk children across services was fragmented and lacking co-ordination, and the provision of forensic child and adolescent mental health services in the community has been described as geographically 'patchy' (Peto et al., 2015).

Community FCAMHS have been created to support the network around children who present with a) a high risk of harm to others, b) are in contact with the Youth Justice System, and c) about whom there are concerns regarding severe mental health difficulties or learning disability (see '6.1. Participant identification' for more information). The services also aim to provide advice about the interactions between a child's mental health and risk presentation and improve pathways and transfers between local services and secure inpatient services in cases where hospitalisation cannot be avoided (see '4.0. BAU description' for more information about FCAMHS service provision).

Over 80% of referrals to FCAMHS have aggression or violence as the primary reason for referral (based on South West FCAMHS data, 2022/23). Yet, there is currently no psychological therapy available specifically designed to work with the high levels of complexity and need with which these

children present, making this an underserved group, which is comprised of underserved groups (e.g., children with learning disabilities).

The aim of the present study is to address this gap by examining the impact and implementation of a mentalization-based therapy (MBT) for children displaying violent or aggressive behaviours who are referred to FCAMHS.

2.0. Study rationale and background

Mentalizing describes the ability to imagine mental states in oneself and in other people to explain behaviour (Fonagy et al., 2002). This refers to imagining mental processes, such as thoughts, feelings, desires, beliefs, or needs, which enable individuals to explain and predict behaviour (Allen et al., 2008; Fonagy et al., 2002). Mentalizing has been identified as a protective factor against externalising behaviours such as aggression and delinquency (Morosan et al., 2020; Taubner et al., 2016). Empirical studies have found evidence for reduced mentalizing abilities in children with disorders of conduct and emotions (Cropp et al., 2019) as well as in children and adults who have been detained due to violent crimes (Möller et al., 2014; Newbury-Helps et al., 2017; Taubner, 2008).

MBT was proposed to be a suitable treatment for individuals with conduct disorder (Taubner et al., 2021) when focussed on achieving a promotion of children's emotion regulation and increasing their scope of action through enhancing effective mentalizing (Hauschild et al., 2023). An aim is the development of an understanding of interpersonal situations and emotions, as well as an understanding of specific triggers and mentalization breakdowns associated with antisocial and aggressive behaviour (Taubner et al., 2021; Taubner & Hauschild 2021). Therefore, positively affecting a child's ability to mentalize is predicted to have an effect on children who present with disordered conduct, including reducing aggression and violence.

The criteria for a diagnosis of conduct disorder (CD) include repetitive and chronic patterns of aggressive behaviour toward people, animals, or other people's property, norm-violating behaviour, and cheating or stealing over a significant period of time resulting in significant impairment of personal, family, social, and educational areas of functioning (American Psychiatric Association, 2013; World Health Organization, 2022). For the purposes of this study, a formal diagnosis of CD is not required, nor will children referred to this study be assessed against the diagnostic criteria due to the effect of stigma; CD is found at the severe end of the 'stigma hierarchy' (Hazell et al., 2022). The weight of this stigma and discrimination has tangible consequences, far beyond just societal judgment. Negative perceptions of children with CD create significant barriers to receiving appropriate care, resulting in increased isolation, worsening symptoms, and delayed treatment (Hazell et al., 2022). Furthermore, it is often difficult for CD patients to find services to treat their condition or schools willing to accept them. Due to being labelled as *"dangerous",* organisations are hesitant to work with these children, fearing potential disruptions or harm to fellow students (Miller & Lee, 2021). The pervasive stigma may eventually enter a child's mind, leading them to internalize these negative labels and blame themselves, resulting in lower self-esteem and an escalation of their challenges (Drapalski et al., 2013). Furthermore, a diagnosis of CD does not confer any additional support for the child. Therefore, the study will focus on children who exhibit repeated aggression

and violence, recognizing these behaviours as significant concerns that may require intervention. Further discussion about diversity, equity, and inclusion is available in section 11.0 of this protocol.

A feasibility and pilot study of MBT-CD was recently conducted in Germany (Hauschild et al., 2023; Taubner et al., 2021). Despite a high attrition rate (47%) and wide variability in intervention duration, the findings suggest that MBT-CD may be a promising approach for treating children with CD. To illustrate, for whom follow up data was obtained, 59% no longer met criteria for a CD diagnosis while 9% made diagnostic improvements, mean level of self-reported aggression decreased, and a significant improvement in empathy was found (Hauschild et al., 2023). Further research with larger, more robust studies is needed to refine the treatment protocol and test its efficacy. That study was conducted as a single-arm pre-post-test feasibility study and included 45 children aged 11-18, with the primary diagnosis of CD or defiant oppositional disorder. Participants underwent MBT-CD, which was intended to involve weekly individual therapy sessions and monthly family sessions over six to 12 months. The treatment focused on improving the child's ability to mentalize, particularly in emotionally charged situations. The results indicated that among those who completed the treatment, 68% showed diagnostic improvement. There were also improvements in self-reported empathy and other psychological measures. However, recruitment difficulties and high attrition rates were significant challenges and consequently the analysis was underpowered. Therefore, particular efforts should be directed at developing and implementing effective recruitment and retention strategies in this current efficacy trial. The evaluators also recommended collaborating with several treatment centres with established recruitment networks in future research.

Given the learning from the feasibility and pilot study, FCAMHS are well-placed services for conducting an impact evaluation of MBT-CD. FCAMHS have been evaluated using a mixed-method realist evaluation (Childs et al., 2021). During the evaluation, there were 3,214 referrals to the service across 13 sites. Findings indicated improvements in the mental health and well-being of children who accessed the service. Children and parents/carers also reported high levels of satisfaction with the support provided by FCAMHS. The service was noted for providing individualised support, effective communication, and understanding the unique needs of each child.

3.0. Intervention description

MBT-CD is a psychological therapy designed to improve children's mentalizing abilities. The sessions will be delivered primarily to children though a small number of family/carer sessions are available. Children will receive up to 24 weekly 45-minute sessions delivered over six months, with the six 60-minute family/carer sessions spread throughout. MBT-CD will be delivered by trained clinicians at FCAMHS sites across England. Specific details of the MBT-CD intervention are provided below according to the template for intervention description and replication (TIDieR) guidelines (Hoffman et al., 2014). A child journey though the MBT-CD intervention can be found in Appendix 1.

3.1. What is delivered?

The manualised MBT-CD materials (Taubner and Gablonski, 2019; Taubner and Hauschild, 2021) will be adapted for use in Community FCAMHS following these broad procedures:

- Clinicians will use psychoeducation materials at the start and throughout the intervention.

- Clinicians will coproduce a mentalizing formulation with the child and their parents/carers. The formulation is a description of a child and their context, their current mentalizing stance (e.g., how much they focus on the self vs. others when understanding interactions), their strengths and challenges, and the areas of support to be focused on in treatment.
- Sessions will start with engagement, identifying problem priorities, and then setting a focus to synthesis problems.
- Clinicians will assess the child's mentalizing stance throughout interpersonal interactions (e.g., verbal and nonverbal communication) during the session. Clinicians will intervene accordingly when they spot pre-mentalizing, e.g.:
    - ↘ Psychic equivalent, or the certainty with which someone determines the mental states of others;
    - ↘ Teleological mode, or when an individual assumes a physical behaviour is needed to address a psychological problem and
    - ↘ Pretend mode, or when an individual's thoughts and emotions are disconnected, resulting in appearing non-genuine.
- Clinicians will utilise the not-knowing stance throughout the sessions; i.e., showing curiosity about the child's mental states.
- Clinicians will have a focus on mentalizing process, managing arousal by using contrary moves (to a different topic), parking (asking someone to revisit a topic later), and validation (acknowledging their emotional experiences).
- Clinicians will actively hold an affect focus, that demonstrates clarification, affect identification and mentalizing functional analysis of an event.
- Clinicians will also mentalize the therapist, client, and family relationships as well as mentalizing counter-relationship in family sessions.

3.2. Who will provide the sessions?

MBT-CD individual sessions will be delivered by mental health clinicians (such as Clinical or Forensic Psychologists, Child and Adolescent or Forensic Psychiatrists, Senior Mental Health Nurses, Occupational Therapists, Speech and Language Therapists) who work in Community FCAMHS. Family sessions will be co-facilitated by two clinicians who meet the criteria for individual sessions or one clinician and an assistant psychologist (AP). All clinicians will have clinical expertise in working with children up to 18 years of age and/or with concerns regarding aggression and violence. Each site will have the additional capacity equivalent to up to one full-time clinician (up to three therapists to be trained in any one site) and one assistant psychologist (0.8 Full Time Equivalent).

3.3. Training and supervision

Clinicians will receive four-day training in MBT for children using the model for conduct disorder developed by Prof. Svenja Taubner. Supervision will be used for clinicians to discuss the application of the model to work with families. This will be supplemented by four, half-day continuing professional development (CPD) sessions. CPD sessions will cover both organisational requirements (e.g., safeguarding), needs identified during the course of the study (e.g., how to support engagement), and areas already identified relevant to the study (e.g., race equity and equity, diversity, and inclusion). The plan is to deliver two training sessions in the first year, to allow for

training to align with variable start dates of staff recruited at each site. Three practitioners will be trained at each site, providing resilience against staff turnover. In year two there will be another training offered, so that new practitioners, recruited to replace staff who leave, can be trained. Clinical supervision will be led by Prof. Taubner, Principal Investigator in the German feasibility study (Hauschild et al., 2023; Taubner et al., 2021), and Dr Newman, the clinical lead for this project. Should there be a need for additional supervisors, those with experience in providing MBT supervision will be sought, with the aim to appoint those accredited by Anna Freud. Supervision will be monthly and include online groups of up to six clinicians.

Supervision using recordings of sessions is intended to be offered as part of the monthly supervision sessions. To facilitate this (and contribute to the implementation process evaluation (IPE)) sessions are intended to be recorded. . The aim of recording sessions for the IPE is to assess the clinician's adherence to the model, for example through a version of the Mentalization-Based Treatment Adherence and Competence Scale (MBT-ACS; Anna Freud Centre, 2020), developed for this specific intervention and target population. Thus, the need is to have sufficient recordings of a particular clinician to determine fidelity, rather than a focus on each child.
It is acknowledged that not all children will agree to be recorded and a decision not to be recorded will not exclude them from the study. For those who agree to be recorded, a choice of recording types will be available depending on child preference, as detailed below. The preferred order for session recording for evaluation purposes will be:

1. Video of both therapist and child;
2. Video of just the therapist with audio of the child (child off camera);
3. Audio only.

In providing initial training and supervision, Prof. Taubner and Dr Newman will be mindful of clinicians' previous length of experience and the modality of previous psychotherapy training. It is predicted that both may affect how quickly a therapist adapts to MBT.

3.4. Where?

The study will be run in 12 out of 14 FCAMHS sites across England. FCAMHS are based in the community, and support may be delivered in any of the following settings:

- Children's Services Setting;
- Clinic;
- Community Setting;
- Health Setting;
- Other Education Setting;
- Police or Criminal Justice Setting;
- Secondary School;
- Social Care Setting;
- Sports Club or Recreation/Leisure Facilities;
- Child's Home;
- Youth Centre or Other Community Setting;
- Online via Videoconferencing.

The sessions will be offered in a place where the child is most likely to engage, and confidentiality can be assured and will be agreed by the clinician and family on an individual basis. While FCAMHS is community based, it is possible that some children involved in the study will relocate, temporarily or otherwise, to secure settings such as in-patient hospitals or custody. In such scenarios, efforts will be made to maintain contact with the child and continue intervention delivery. As such, individual MBT-CD and family/carer sessions will be offered in person in the first instance but will also be offered virtually to aid engagement, if necessary.

3.5. When and how much?

Within this trial, the intervention or "treatment" will be offered in addition to business as usual (BAU). The treatment will last for six months with weekly, 45-minute individual sessions (24 sessions) and monthly 60-minute family/carer sessions (six family sessions offered). MBT is often offered for a full year, and this shorter design is partially based on the German feasibility study (Taubner, et al. 2021), that had envisaged treatment duration to be six to 12 months, with a minimum of six months. This trial is also designed to consider a comparison to BAU. Based on normal FCAMHS practice, it is more likely that children would be in BAU for six months rather than 12 months, so this is considered a fairer comparison.

Moreover, there is a pragmatic element to this decision. With a conservative effect size suggested (see section 5.6.), 316 children will be needed to complete treatment in the MBT arm, yet the trial delivery is limited to two years overall. Therefore, it is more likely to achieve the requisite case completion rate if intervention is aimed at being six, rather than 12, months. It would also be unethical to start a treatment that could not be completed so an extended delivery duration would necessitate a more limited recruitment phase.

It should also be acknowledged that this client group faces a number of needs and circumstances that create barriers to engaging in treatment. Therefore, aiming to provide treatment for six months is considered more appropriate for the target cohort than 12 months. This is also based on FCAMHS clinical experience with this cohort of children. Lastly from a logistical perspective, the services working with FCAMHS (e.g. CAMHS, Youth Justice Service, Social Services) look to close cases as soon as it is safe to do so, given the pressures on their services. This trial will ask those statutory/referring services to hold the child's case open for at least six months to enable the treatment. This is already a tall ask given the resources and responsibilities required of keeping a case open, but possible. However, asking a service to hold a child open for 12 months might be too big a request for buy-in to the study.

In relation to the evidence base, studies have been conducted to compare the effects of short-term and long-term MBT. Juul et al. (2019) compared 1:1 short MBT (five months of weekly sessions) and 1:1 long MBT (12 months of weekly sessions) for adults with borderline personality disorder (BPD) through a randomised controlled trial (RCT). The length of the MBT (i.e., short or long-term) did not have a statistically significant impact on BPD symptoms (mean difference [MD] = 0.99; 95% CI: –1.06 to 3.03; p = 0.341), level of functioning (MD 1.44; 95% CI: −1.43 to 4.32; p = 0.321), global functioning (MD −2.25; 95% CI: −6.70 to 2.20; p = 0.318), or quality of life (MD −0.91; 95% CI: −4.62 to 2.79; p = 0.626)(Juul et al. 2023). In short-term versus long-term MBT, there were fewer incidents of both self-

harm (risk ratio [RR] 1.37; 95% CI: 0.70–2.84; p = 0.335) and serious adverse events (RR 1.63; 95% CI 0.94–3.07; p = 0.088). Further, psychiatric hospital admissions were higher in the long-term group (RR 2.03; 95% CI: 0.99–5.09; p = 0.056). Overall, the authors suggest that briefer MBT may be more suitable when considering limited resources and safety concerns (Juul et al., 2023).

Hestbæk et al. (2022) carried out a qualitative study with participants from the Juul et al. (2019) study. Participants reported meaningful changes in emotional awareness, relationships, and communication skills. Some initially perceived being assigned to short-term MBT as a sign that their problems were less serious, though this concern often shifted as therapy progressed. In terms of duration, participants reflected that they thought five months of treatment was too short in the beginning, but upon completion, most felt it to have been an appropriate length and that short-term MBT had been helpful. However, a subgroup still felt the therapy was too short to address deeper, long-standing issues (Hestbæk et al., 2022).

Lastly, it should be noted that although six months of treatment has been posited, it may be more helpful to consider session numbers. We have outlined thresholds for full, partial, and non-compliance, which will be reviewed during the pilot (see '7.3. Compliance').

3.6. Tailoring

MBT-CD is designed to be personalised to each child's needs. The clinician will deliver sessions based on the child's presentation at each session, while maintaining the overarching aim and focus of MBT-CD.

The Community FCAMHS specification (NHS England, 2024) sets out that there should be an active collaboration with family and carers where possible. The development of children's mentalization is usually seen as being underpinned by their parents/carers. However, this has not always been the case for children seen by FCAMHS. Referred children have often not had an environment that supported mentalization, nor is it always safe for them to mentalize the self or others, when at home. It is therefore acknowledged that it may not always be safe for children's families to be involved in this trial, particularly if there are concerns in relation to violence or sexual abuse between the parents and/or towards the child.

Nonetheless, families are considered of fundamental importance to the formation of a child's sense of self. Therefore, when safe to do so, this trial will engage families or carers, continuing the model adopted in Germany, where individual mentalizing is prioritised but families are also invited into additional treatment sessions to engage them in supporting the development of mentalizing in the child. The focus of treatment in this trial will be centred on individual MBT sessions with the child. If a child's parents/carers do not want to engage in MBT sessions, if the child does not want their parents/carers to be offered sessions, or if it would be unsafe to do so, individual treatment will continue, and family non-engagement will not exclude the child from the trial. It will be possible to monitor parent/carer engagement in the pilot phase of the trial and adapt this strategy if appropriate.

3.7. Modifications

There are currently no planned modifications to the intervention itself. However, the model of supervision for therapists will be kept under review and may evolve as more areas join the trial/post-pilot and regional supervisory groups may become more viable. Additionally, as the trial grows, more supervisors will likely be needed beyond Dr Newman and Prof Taubner. CPD sessions may change in response to emerging needs identified during the study.

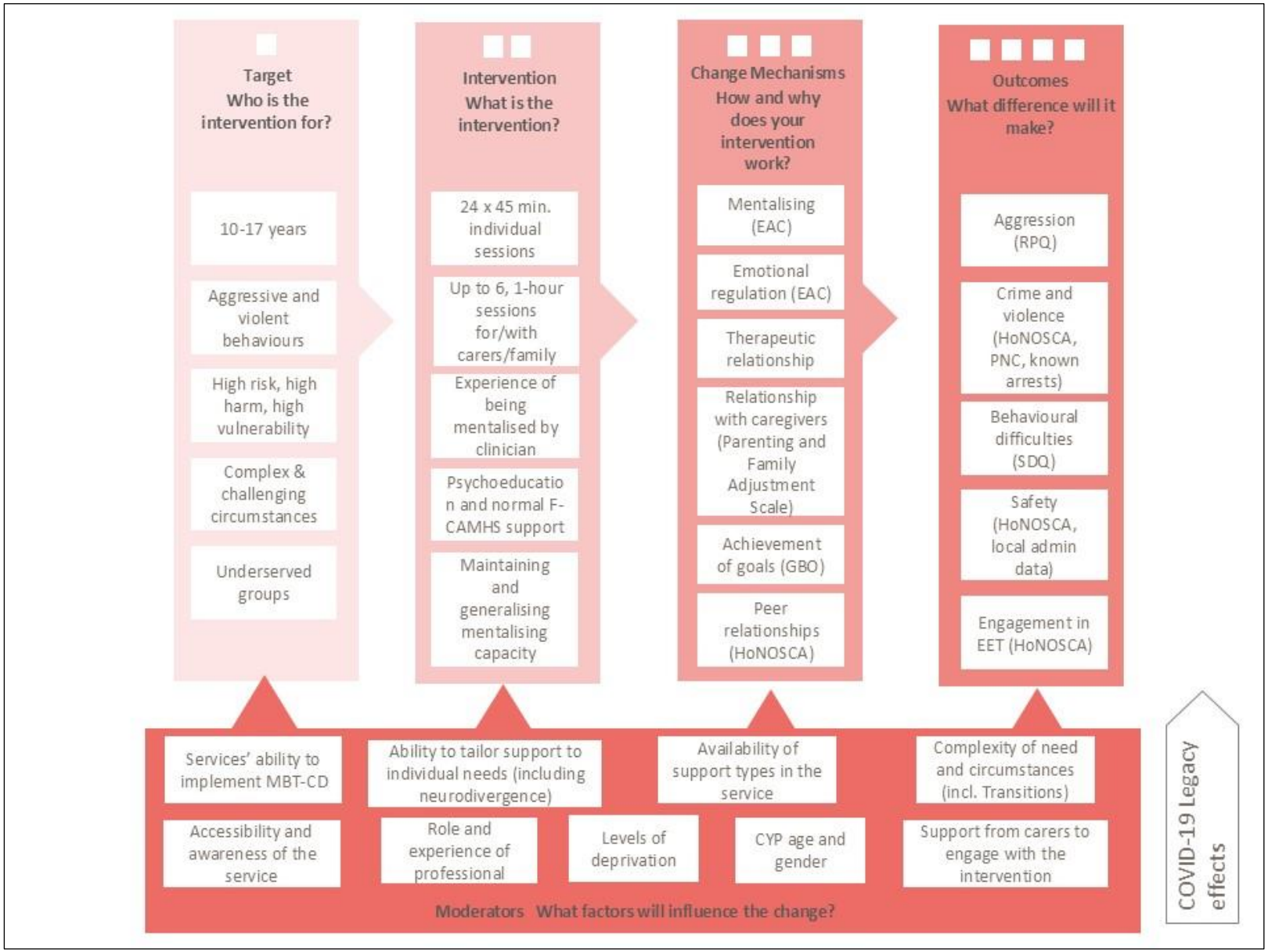
3.8. Compliance and fidelity

Compliance will be assessed through attendance and session duration data, which will be recorded at each session (see '7.3. Compliance'). All clinicians will receive the same MBT-CD training and will be offered supervision and regular (e.g., quarterly) CPD to ensure fidelity. Fidelity will be assessed through independent ratings of selected video or audio recorded sessions using, for example, a version of the MBT-ACS developed for this specific intervention and target population.

3.9. Logic model and Theory of Change

The logic model underpinning this intervention is summarised in Figure 1, below. The Theory of Change can be found in Appendix 2.

Figure 1: *MBT-CD Logic Model.*



4.0. BAU description

4.1. What is provided as BAU?

There are no mandated materials used in Community FCAMHS. It will however be common for services to use structured professional judgment tools (SPJs) with a focus on the child's main offending type, such as the Structure Assessment of Violence Risk in Youths (SAVRY) for children between 12 and 18 years old where violence in the primary reason for referral. In addition, structured assessments to aid mental health assessment are common, such as the Autism Observation Diagnostic Schedule (ADOS). Furthermore, psychometric assessment, such as the Conners (Conners, 2008) to support attention-deficit-and-hyperactivity-disorder (ADHD) assessment, are commonly used. This is in addition to unstructured and semi structured consultation and clinical interview. It should be noted that these assessments are generally conducted to facilitate intervention delivery within referring or other statutory services. Until now, the overwhelming majority of "casework" in FCAMHS has been psycho-educational, not clinical.

All FCAMHS teams deliver the following core service functions, summarised in Figure 2 (below):

- Consultation and advice, including:
  - ↘ Facilitation of smooth transitions for children between services and agencies and between children's and adult services and into and out of secure settings, including providing support, advice and follow-up of cases where children move out of area, or facilitating return from secure custodial, welfare or mental health placements.
  - ↘ Developing strategic links between local provision and regional and national specialist services, to identify and resolve gaps in service provision – ensuring children receive a high quality of individualised care irrespective of geography or system barriers.
  - ↘ Coordination of, and liaison with mental health, educational, social care services and the children and young people's secure estate, ensuring that care is provided in line with the welfare principles of the Children Act (1989 and 2004) and Code of Practice 2015 to the Mental Health Act (as amended 2007).
  - ↘ Liaison and specialist advice to youth justice partners, including local youth offending teams, courts, legal system, and secure settings. On occasion specialist advice and signposting may be required to support the justice process. This does not replace, or perform the role of, traditional medicolegal processes, but will include maintaining consistent links with professionals supporting children from their area, regardless of the setting in which they are placed.
  - ↘ Developing joint working arrangements with a wide range of interdependent children and young people's services to support the management of care.
  - ↘ Provision of training to clinicians from all agencies in relation to areas within the service's specialist remit.
  - ↘ Develop effective partnerships with agencies (children's social care, education, and the youth justice system) who are providing care for children presenting with complex, high-risk behaviours in the overall pathway for children involved in Youth Justice Services and mental health services (e.g., services for children with sexually harmful behaviours,

mental health in-reach to local secure welfare or custodial settings, and involvement in criminal justice liaison and diversion teams).

- ↘ Partner with local services to ensure the child has a timely assessment where there are indicators of undiagnosed needs that pertain to high risk, high vulnerability presentation. FCAMHS may be well placed to complete assessments in such instances, as part of their case formulation. FCAMHS teams should have clear policies in place to describe the circumstances in which they may be able to support assessment, where a delay is negatively impacting appropriate care and treatment pathways.
- ↘ Promotion of continuity of care wherever possible, ensuring a holistic approach to care and supporting the child to achieve their developmental potential, and to promote healthy family functioning.

- Direct assessment, including:
  - ↘ Case formulation in partnership with the referring agency and specialist mental health assessment (including forensic assessment) where appropriate. The referring agency remain the case holder of the child. Direct assessment will be offered only in high-risk cases, where there is a need for specialist opinion to ensure that children presenting high risk of harm to others are managed.

- Intervention within the child's professional network, including:
  - ↘ Clinical supervision to community clinicians, in line with the consultation model.
  - ↘ Specific training, reflection or guidance to professionals within the child's network to address specific issues identified during the formulation process.
  - ↘ Psychoeducation around diagnoses.
  - ↘ Time-limited support to support children to understand their formulation and next steps.

Interventions from FCAMHS are likely to be focussed on preventing admission to in-patient settings where appropriate alternatives exist or where in-patient admission is unlikely to prove successful, as well as preventing escalation of youth justice involvement. This should include close adherence to policies and procedures to help children with learning disability, autism, or both to remain in the community.

Figure 2: *Support provided by FCAMHS.*

4.2. Who provides BAU?

To effectively address the underlying causes of offending behaviour and risks inherent within individual experiences and circumstances, FCAMHS teams are overseen by a highly skilled professional, with extensive experience of working with children in forensic and mental health settings, and in the assessment and treatment of complex, high-risk cases. The multidisciplinary team should draw on expertise such as:

- Psychiatrists;
- Psychologist(s) with appropriate forensic and clinical experience;
- Clinical nurse specialist/senior mental health practitioner(s) (at least Band 7);
- Mental Health Nurses;
- Learning Disability Nurses;
- Occupational Therapists;
- Creative Therapists (art/music/drama);
- Family Therapists;
- Social Workers;
- Speech and Language Therapists;
- Dedicated team administration.

In particular, the service will have specialist understanding of statutory mental health, welfare, youth justice and educational processes and understanding of the interfaces between them. It must be experienced regarding the needs of children with neurodevelopmental presentations.

The emphasis should be on a small, highly experienced, and active team whose members are equipped to provide authoritative specialist support to local generic networks. It is recognised that recruitment and retention of suitable experienced specialist roles is a national challenge, and a flexible design and development of regional multi-disciplinary teams (MDTs) is encouraged to meet identified needs.

4.3. How and where is BAU provided?

Consultations and assessments can be offered virtually and or in person. They can be offered to a single professional or as a multiagency group. Equally, assessment may be just with a child or multiple family members/carers and or professionals.

Service provision should be flexible, using a mix of online, in-person, and hybrid delivery methods as appropriate, effectively managing risks the child and/or family are exposed to. Geographical co-location within existing children and young people's mental health service provision is highly advisable. This reinforces the fact that FCAMHS constitute part of an overall care pathway for children with mental health or neurodevelopmental needs.

There is no specified number or type, frequency, or time-period of sessions that should be provided, as the aim of the service is to meet the individual needs of a child, their family, and their professional network.

4.4. Tailoring and modifications

FCAMHS input is always tailored to the needs of the individual child, their family, and professional network. It can range from a one-off offering of advice to direct work with the child, their family, and the professional network over many years.

From initial implementation to now, there have been developments in the delivery of FCAMHS, most notably additional funding to ensure the needs of children with a diagnosis or suspected Autism and or Intellectual Disability are met where Community FCAMHS are involved.

4.5. Compliance and fidelity

Adherence to the national service specification is reviewed annually with commissioners. However, given the nature of FCAMHS, there is no consistent way of assessing compliance at an individual case level. To provide a measure of fidelity, FCAMHS practitioners providing support to children in the BAU arm will provide information on what they provided and/or recommended other services provide.

5.0. Randomised controlled trial

5.1. Research questions

The overarching objective is to examine the implementation and efficacy of MBT-CD for vulnerable children displaying violent and/or aggressive behaviours referred to FCAMHS in the context of existing or potential involvement in the Youth Justice System.

5.1.1. Primary research question

Is individual MBT-CD plus BAU an effective approach compared to BAU-only on reducing engagement in self-reported aggressive and/or violent behaviours among children aged 10-17 displaying violent and/or aggressive behaviours referred to FCAMHS?

5.1.2. Secondary research questions

Is individual MBT-CD plus BAU an effective approach compared to BAU-only on:

1. Reducing self-reported externalising difficulties and internalising difficulties?
2. Improving self-reported mentalizing?
3. Improving child-reported family relationships?
4. Reducing parent/carer-reported externalising difficulties and internalising difficulties?
5. Improving parent/carer-reported family relationships?
6. Reducing clinician-reported engagement in disruptive behaviour, non-accidental self-injury, and substance misuse?
7. Improving clinician-reported peer relationships, family relationships, and school attendance?
8. What are the potential mechanisms of change by which MBT-CD impacts aggressive and/or violent behaviour, externalizing and internalising difficulties, and family relationships?

5.1.3. Race equity, and equity, diversity, and inclusion

We do not yet know from existing research whether the effectiveness of MBT-CD varies for children with different demographic characteristics. Therefore, a secondary, exploratory analysis will focus on evaluating variations in effectiveness for children with different demographic characteristics, for example, children from different ethnic groups, with different ages and genders, with neurodivergence, or with school exclusions. Intersections between these factors will also be explored. Data for these variables are routinely collected by FCAMHS. Within the parameters of the current study, we will not be able to power the research to detect whether MBT-CD plus BAU compared to BAU-only has different levels of effectiveness for children with different demographic characteristics.

5.1.4. Tertiary aims and objectives

We will examine the extent to which the impact of MBT-CD plus BAU and BAU-only on the above outcomes varies across other variables (e.g., demographic characteristics including ethnicity, referral sources, amount and type of support received). We will also examine any unintended consequences of MBT-CD, BAU, and research processes by examining worsening of outcomes over time and reports of negative effects in the implementation and process evaluation and through monitoring (serious) adverse events (see section 6.6.).

5.2. Internal pilot

The first nine months of the RCT will serve as an internal pilot. The aim of the internal pilot is to test out the methods and make adjustments where necessary to refine the processes of recruitment, data collection, and delivery of the intervention. We will examine the completion of site set up, implementation of research and intervention processes, and recruitment of children and families. The decision to progress to the full trial will be based on the ratings of the progression criteria and the agreement of parties (evaluators, project team, Youth Endowment Fund (YEF)) on plans to increase ratings on any amber/red criteria. There are three objectives:

1. To assess readiness to progress to the full trial;
2. To determine the acceptability of the primary outcome measure;
3. To update parameters for the power calculations.

To assess readiness to progress to the full trial, we will assess progression at the end of the internal pilot against the criteria shown in Table 1 below.

Table 1: *Progression criteria.*

Criterion	Green	Amber	Red
Site set-up: This includes local governance and other approvals, completion of MBT-CD training, agreement of contracts, confirmation of capacity and capability, and approval on the Integrated Research Ethics System.	80-100% of sites set up (11-13 FCAMHS)	60-79% of sites set up (8-10 FCAMHS)	<60% sites set up (<8 FCAMHS)
Recruitment: This includes completion of consent, baseline measures, and randomization. The pilot sample recruitment target is 346 for the nine-month pilot (see Recruitment Targets, Appendix 3).	80-100% of target sample recruited: 277-346/346	60-79% of target sample recruited: 208-276/346	<60% of target sample recruited: <208/346
Evaluation retention: This is defined by completion of 6-month follow up survey. The target is 125, based on those recruited within the first 3 months.	80-100% of target sample retained: 100-125/125	60-79% of target sample retained: 75-99/125	<60% of target sample retained: <75/125
Intervention compliance: We will classify attendance of fewer than 12 sessions (<50%) as non-compliant, attendance of 12-17 sessions (50-74%) as partially compliant, and attendance of 18+ session (75%+) as fully compliant (see '7.3. Compliance'). Children will be at different stages of treatment by the end of the pilot and sessions are intended to be weekly. Therefore, "on track" will be determined based on proportion of number of sessions attended out of number of weeks in treatment.	80-100% of children on track to be compliant: 138-173/173	60-79% of children on track to be compliant: 104-137/173	<60% of children on track to be compliant: <104/173
Practitioner-reported data	80-100% data completion	60-79% data completion	<60% data completion
Acceptability: Children and parents'/carers' views of the evaluation materials and process.	Few reports from sites that children and parents/ carers (<20% of the sample) experience	Some reports from sites that children and parents/ carers (20-39% of the sample) experience	Many reports from sites that children and parents/ carers (40-100% of the sample) experience

	substantial challenges engaging in the evaluation materials and processes, even with support from a practitioner.	substantial challenges engaging in the evaluation materials and processes, even with support from a practitioner.	substantial challenges engaging in the evaluation materials and processes, even with support from a practitioner.

At this stage, the primary outcome is the total score on the child self-reported Reactive and Proactive aggression Questionnaire (see '7.0. Outcome measures'). It is comprised of two subscales: reactive and proactive aggression. The proactive aggression subscale contains items on high-risk behaviours that would require the evaluators to break confidentiality and notify the site (e.g., question stem: "How often have you...", items: "Had fights with others to show who was on top", "Had a gang fight to be cool", "Used physical force to get others to do what you want", "Used force to obtain money or things from others", "Carried a weapon in a fight"). To determine the acceptability of this measure, we will examine levels of data completion at baseline in the pilot. We will review the measure with our Young People's Advisory Group (YPAG) for their views on acceptability and how we could maximise the ability for participants to respond openly. We will gather feedback from sites about any concerns with acceptability, including their ability to manage safeguarding issues identified from the measure. If we determine that the proactive subscale is not acceptable, we would consider changing the primary outcome to only include the reactive subscale, which would still permit us to include the internal pilot data in the final analysis.

We will compare data completion across child- and parent/carer-reported measures to inform planning for the full trial, especially in light of risks of collecting follow-up measures due to the complex and challenging circumstances in which the target group of families live.

We will update our power calculations based on learning from the pilot, especially pertaining to recruitment and retention rates.

5.3. Design

The design of the trial is a pragmatic two-arm (MBT+BAU vs. BAU-only) randomised controlled trial, with randomisation at the individual child-level, focusing on children 10-17 years referred to FCAMHS with problems related to aggression and/or violence. Like many other psychotherapy trials, blinding of children, parents/carers, and clinicians will not be possible though quantitative analysis will be blinded.

Table 2: *Trial design.*

Trial design, including number of arms	Two arm randomised controlled trial.
Unit of randomisation	Individual participant child.

Stratification variables **(if applicable)**	1) Forensic Child and Adolescent Mental Health Service sites. 2) Participant gender.
Primary outcome and data source	Aggression and violent behaviour measured with the total score of the Reactive and Proactive Aggression Questionnaire (RPQ) completed by children at baseline and 6 months post-randomisation.
Secondary outcome and data source	**Child self-reported outcomes and measures:** 1. Conduct problems, hyperactivity/inattention, difficulties with peers, and emotional difficulties measured with the respective subscales of the Strengths and Difficulties Questionnaire (SDQ), and impact score, completed at baseline and follow up. 2. Mentalizing measured with the analyses of emotions and attending to others' emotions subscales of the Emotion Awareness Questionnaire (EAQ), completed at baseline and follow up. 3. Family functioning measured with the total score of the Systemic Clinical Outcome and Routine Evaluation (SCORE-15), completed at baseline and follow up. **Parent/carer-reported outcomes and measures:** 4. Aggression and violent behaviour measured with the total score of the Reactive and Proactive Aggression Questionnaire (RPQ) completed at baseline and follow up. 5. Conduct problems, hyperactivity/inattention, difficulties with peers, and emotional difficulties measured with the respective subscales of the Strengths and Difficulties Questionnaire (SDQ), and impact score, completed at baseline and follow up. 6. Family functioning measured with the total score of the Systemic Clinical Outcome and Routine Evaluation (SCORE-15), completed at baseline and follow up. **Clinician-reported outcomes and measures:** Disruptive, antisocial or aggressive behaviour, non-accidental self-injury, substance misuse, peer relationships, family life and relationships, and school attendance measure with single items of the Health of the Nation Outcome Scales for Children and Adolescents (HoNOSCA), completed at baseline and follow up.

5.4. Setting

The project will take place in FCAMHS in England.

5.5. Participants

This project is focused on children who are referred to FCAMHS. These children typically experience high-risk behaviours and may already be or become involved in the Youth Justice System.

5.5.1. Inclusion and exclusion criteria

The inclusion criteria for the present evaluation are:

- Age 10-17 years at the time of referral;
- Aggression and/or violence are indicated at referral or assessment;
- Participation in the evaluation would not interfere with statutory orders;
- Child and parent/carer (for children 10-15 years) are able to consent and engage with the study materials;
- Living in the community at time of referral and no imminent plans to move to hospital, residential, or secure settings.

Children being referred to and supported by FCAMHS are likely to experience a range of risks, harms, vulnerabilities, and instability in e.g. home life. The presence of these factors underline the importance of providing support and using research to determine the potential usefulness of different therapies. Therefore, the aforementioned factors will not be viewed as a reason to exclude children from taking part in this study. FCAMHS clinicians are experienced and skilled in managing these cases, as per the remit of Tier 4 services, so will be able to manage the risks and vulnerabilities present. However, regardless of risks and vulnerabilities, eligible children will not be able to participate when: a) it is unsafe for the child to participate (e.g., immediate serious safeguarding concerns need to be addressed before any other intervention can take place), b) participation would present an imminent risk of harm to self or others, or c) participation would increase levels of existing risk of harm to self or others. This clinical decision will be made by a MDT using information gathered during referral and/or assessment.

Other exclusion criteria are:

- Age under 10 or age 18 or older at the time of referral;
- No evidence of aggression and/or violence indicated at referral or assessment;
- FCAMHS are only offering a one-off consultation or assessment (e.g., the network around the child requires support to manage risk but additional input is not required);
- Child's level of English is not sufficient to engage in the intervention;
- Child and/or parents/carers refuse to engage with FCAMHS;
- No statutory service is involved in supporting the child;
- No statutory service will agree to hold the child's case open for a minimum of six months.
- Currently involved in another psychological intervention research study.

5.6. Sample size calculations

The target population will reside across England and could be receiving treatment at any of the 13 FCAMHS sites. There will be stratification by gender, and other demographics of children (age, ethnicity) will be monitored to ascertain whether participants reflect the wider service population, which is important to monitor inclusivity of recruitment to the evaluation. Recruitment will also be stratified by FCAMHS site.

A pilot study in Germany assessing the role of MBT-CD for children included the RPQ in their analyses (Hauschild et al., 2023). It reported a mean baseline RPQ score of 13.6 (SD 6.8) and a post-treatment mean score of 11.5 (SD 7.3), a reduction of 2.1 in n=17 children. The pilot study indicates a pooled standard deviation (SD) of 7.05, giving an effect size of 0.3 (2.1/7.05), a conservative interpretation given the small sample. Baseline SD could be considered a better indication of the population SD, giving an upper limit effect size of 0.31 (2.1/6.8).

Studies that report related interventions and outcomes for related client groups have reported effect sizes in the range d=0.34 to 1.46. Halfon and Bulut (2017) reported an improvement in externalising behaviour (d=0.41 to 1.15). Studies by Rossouw and Fonagy (2012) (d=0.34) and Bo et al. (2017) (d=0.58 up to 1.46) worked with children with borderline personality disorder. Griffiths et al. (2019) reported reduced risk taking (d=0.6). The Herts and Minds study (Midgley et al., 2019) reported an effect size d=0.7. Assuming that these studies provide an indication of the likely expected effect size, taking a conservative approach we adopt an MDES=0.25 for the current study.

Allowing for an effect size of 0.25, with power 1-β=0.8, the required sample size is 253 participants per arm, 316 per arm allowing for 20% attrition, giving 632 in total. Additionally, the MDES of the intervention may be greater than 0.25. Table 3 demonstrates the study power given recruitment of n=632 participants, assuming effect sizes ranging from 0.25 to 0.36 and attrition rates from 10% to 30%. Even at 30% attrition the study would be powered at 75% to detect an effect of 0.25. The sample size, therefore, provides good power across a range of potential scenarios.

If, after the pilot, it is decided to use only the reactive aggression subscale of the RPQ, the sample size will remain as calculated since it is determined by the standardised effect size.

Table 3: *Study power (1-β) given α=0.05 assuming recruitment of n=632 at various effect sizes and attrition rates.*

Effect size	Attrition rate		
	10% (n=568)	20% (n=506)	30% (n=442)
0.25	0.84	0.80	0.75
0.30	0.95	0.92	0.88
0.36	0.99	0.98	0.97

To recruit 632 to the study, it is necessary to screen between 902 and 1,264 referred individuals, equivalent to a 70% to 50% conversion rate, respectively. Assuming an even split, each site will be required to recruit 49 participants to meet the target of n=632. For a 24-month fieldwork period and a six-month intervention period, there are 18 months for recruitment. Assuming a two-month period for onboarding and sites going live, our active recruitment period is 16 months. This is equivalent to a recruitment target of 3-4 children per site per month, as shown in Table 4. To achieve this target, sites will need to screen 5-7 children monthly. Should a site withdraw from the study, the remaining

FCAMHS would be required to recruit a total of 73 participants, still within the 4-5 range, with similar screening numbers required (5-7).

Table 4: *Screening numbers required per site assuming 16-month recruitment period.*

	Recruitment per site		Screening per site					
			50% conversion rate		60% conversion rate		70% conversion rate	
	Total	Per month	Total	Per month	Total	Per month	Total	Per month
13 sites	49	4	98	7	82	6	70	7
12 sites	53	4	106	7	89	6	76	7

The sample size calculations required for primary outcome analyses are summarised in Table 5.

Table 5: *Sample size calculations.*

		PARAMETER
Minimum Detectable Effect Size (MDES)		0.25
Pre-test/post-test correlations	Level (participant)*	$0.51 = \sqrt{\frac{6.8^2+7.3^2-8.6^2}{2\times6.8\times7.3}}$
	Level 2 (cluster)	NA
Intracluster correlations (ICCs)	Level (participant)	NA
	Level 2 (cluster)	NA
Alpha		0.05
Power		0.8
One-sided or two-sided?		Two
Average cluster size (if clustered)		NA
Number of clusters	Intervention	NA
	Control	NA
	Total	NA
Number of participants	Intervention	316 participants
	Control	316 participants
	Total	632 participants

* Hauschild et al., 2023; Machin et al., 2009; Taubner et al., 2021

We have considered stratifying by children's NHS Trust based on their home address. We do not see it as viable to stratify by Trust as this would 1) increase the required sample size, and 2) BAU provided by LAs will not necessarily map to NHS Trusts (e.g., Youth Offending Teams, social care), so stratifying by Trust would likely not account for type of BAU provided.

The German pilot study found high levels of attrition (47%) (Hauschild et al., 2023; Taubner et al., 2021). Learning from that and other studies has informed our mitigation strategies:

1. Delivering the trial in FCAMHS as these services have the expertise of working with the target group of families and are well place to enable families to remain engaged;
2. Flexibility of how MBT-CD can be delivered to meet individual family needs (e.g., face-to-face or online, with or without parent/carer sessions);
3. An AP based at each FCAMHS to support the delivery of the intervention and evaluation, including engaging with families;
4. Dedicated support at each site (AP) for supporting families with completing evaluation activities;
5. Regular keeping in touch communications with families not being regularly seen at the FCAMHS (e.g., those in the BAU-only arm, those not engaging in MBT-CD).

6.0. Trial procedures

6.1. Participant identification

Children will be referred to FCAMHS in the usual way e.g., from CAMHS, education, and social care professionals. On making the referral, referrers will inform the child and/or parents/carers about the study and that they may be invited by FCAMHS to take part. Once a referral has been received by FCAMHS it will be triaged to determine whether it meets their acceptance criteria, as below.

- Under 18 years old at the time of referral.
- Presenting with serious conduct and emotional issues, neuropsychological difficulties, or serious mental health problems and/or neurodevelopmental conditions (including learning disability or autism) with/without learning difficulties, where there are legitimate concerns about the existence of such conditions.
- Usually involved in dangerous, high-risk behaviours whether they are in contact with the youth justice system or not. This will include children who present a high risk to others through such behaviours as fire setting, physical assault, and sexual offending.

Participants will also be identified from clinician's existing caseload. Clinicians will review their existing caseload for children who may be eligible for the study, i.e. under 18 years old and present with aggressive/violent behaviour. There is no restriction on how long a child has already been on a clinician's caseload, but to reduce any factors that might influence outcomes (e.g. existing therapeutic relationship), potential participants on existing caseloads will only be eligible for the study when:

- There has been no direct contact between child and FCAMHS clinicians, including assessments.
- There has been no indirect therapeutic support provided by FCAMHS e.g. advising non-FCAMHS professionals on therapeutic support.

It is permissible for the clinician to have previously engaged in consultation activities where these did not involve contact with the child.

6.2. Screening

Children identified through caseloads and referrals that meet the FCAMHS acceptance criteria will be passed to the local site lead or delegated individual to be considered against the study inclusion and exclusion criteria. Where further information is required, this will be obtained either through contact with the referrer or through an assessment session with the child and/or family themselves. Once full information regarding inclusion and exclusion criteria is available, a suitability determination will be made by the local site lead or delegated individual. This decision will be recorded in the study database. Those who are deemed eligible for the study will receive information to enable them to decide whether to take part and will be provided with the opportunity to ask questions so they can provide informed consent. Training about screening and all study processes will be provided by the evaluation team to each site, accompanied by written materials. Screening logs will ask sites to record reasons for non-referral.

6.3. Informed consent/assent

If a child is eligible to take part in the study, the allocated clinician will start the process of obtaining informed consent. The process used will differ based on the age of the child and who has parental responsibility. There is no legal statute in England governing the age of consent for children to a clinical trial of psychological therapy (NHS Health Research Authority, 2024). As such, it is considered that those aged 16 years have the capacity to consent to research (NHS Health Research Authority, 2024; NIHR, n.d.), which aligns with the capacity to consent to medical treatment (General Medical Council, 2024). Therefore, written consent will be obtained from children aged 16 years and older. For children aged less than 16 years, written consent will be obtained from a person with parental responsibility and written assent will be obtained from the child. It will be important that both parents/carers and children understand what will be required and fully agree to take part.

Before obtaining consent, the allocated clinician will discuss the study with the child and, for those under 16, also with their parent/carer. To facilitate fully informed consent, clinicians will also provide the child, or child and parent/carer, with written information about the aims, methods, anticipated benefits, financial compensation (participants (child and parent/carer) will each receive a £5 voucher for completing baseline questionnaires and a £10 voucher for completing follow-up questionnaires), and potential risks of the study in participant information sheets (PISs) in addition to a privacy notice. There will be two PISs for the children (one for children 10-15 years and one for children 16-17 years) and one for their parents/carers. These will be supplemented with a video that includes core information about taking part. The allocated clinician will ensure participants have seen and understood information about the study, reading to them the PIS where necessary.

Parents/carers will also be asked to provide consent for their own participation in the study (e.g., completing parent/carer-reported questionnaires). For children under 16, this will occur concurrently with parental consent for the child's participation. For children 16 and over, during the consent discussions, we will ask for their permission to contact their parent/carer (and their contact

details) so we can approach them about taking part. Should the child decline permission to contact their parent/carer, or should contact with the parent/carer be determined by the clinician to confer additional risks to the child, we will not attempt to include the parent/carer.

If parental responsibility is held (fully or partly) by the local authority (LA), then the process for obtaining an agreement will depend on the legal status of the child. The child's social worker will confirm whether the parent holds parental responsibility, and if so, the process above will be used. If parental responsibility is held solely by the LA the local site lead, or delegate, will obtain the name of the child's social worker and identify the name of the person at the LA who would be responsible for giving informed consent for the child to participate in the study. This person should be an officer of the LA who has knowledge of the child's background along with sufficient authority to provide consent to take part. They will be provided with the PIS for LAs and asked to provide consent on behalf of the child. Some LAs may also require parents/carers to provide consent, even where the LA holds full parental responsibility. In such instances, consent will be obtained from both the LA and a parent/carer. If parental responsibility is shared, both the parents/carers and the LA will need to provide consent, using the processes outlined above.

After receiving the PISs, families will be given sufficient time (e.g., at least 24 hours) to decide whether to take part and will have the opportunity to ask questions. Those who decide to participate will be asked to provide consent directly on the study database.

Informed consent will be obtained prior to the participants' involvement in any aspect of the study. It will be made clear to the children and those providing consent on behalf of the children that they have the right to refuse participation and are able to withdraw at any time from the study without giving reasons and without prejudicing the care they will receive. All data collected up to the point of withdrawal of consent will be retained unless participants ask for their data to be deleted.

If any matters arise during the study that result in significant changes in the risk/benefit analysis such that the PISs and informed consent forms are updated, active participants will be provided with the new PIS and asked to confirm their wish to continue in the study by signing the new consent form. Participants will be given sufficient time (e.g., at least 24 hours) to decide whether they want to continue to take part. If participants do not reconsent to take part before a) they are due to take part in the next evaluation activities or b) their next MBT-CD session, then they will be withdrawn from the study and notified of this.

The local lead at each FCAMHS site will ensure that any person delegated responsibility to participate in the informed consent process in the site delegation log is duly authorised, trained, and competent to participate according to the ethically approved protocol, principles of Good Clinical Practice, and Declaration of Helsinki (World Medical Association, 2024).
Families not in regular contact with FCAMHS for MBT-CD appointments (e.g., those in the control group, those disengaged from MBT-CD) will receive up to four (excluding the baseline and endline data collection months) monthly check in texts/calls/emails from the site AP. This will be to provide updates on the study, retain engagement with families, and ensure contact information is up to date.

6.4. Randomisation

Children will be randomised at the individual level and randomisation will be stratified by gender and by study site. Individuals who are assessed as suitable for the study, consent to take part in the trial, and complete the baseline assessments will be randomised with a 1:1 allocation ratio to either the MBT-CD intervention (the intervention arm) or business as usual (the BAU arm). Allocation will be stratified by the study site and child's gender (male, female, non-binary) with a block size of 10. The randomisation process will be managed online via the evaluation database (REDCap). Once a child and parent or carer has consented to take part in the trial and completed baseline assessments, REDCap will trigger an alert to the evaluation team members with necessary access permissions who will trigger randomisation. An allocation for that child will then be generated within REDCap. The allocation code, along with the child's study ID, will be emailed to the agreed specified point of contact (within the FCAHMS service) and the trial manager. The specified point of contact will inform the child and/or parent or carer of trial arm allocation by telephone.

6.5. End of trial

The end of trial will be when all participants have completed all scheduled assessments; i.e., all questionnaires/data items have been completed and interviews taken place. A declaration of end of study form will be completed and sent to the research ethics committee within 90 days of the end of the study.

6.6. Safety

The interventions under examination are considered low-risk. BAU is standard practice and MBT is a widely used and evidenced intervention. The previous study evaluating MBT-CD did not report any specific risks or untoward incidents. Families in the intervention arm will be required to engage with therapy sessions that might raise feelings of distress, however FCAMHS clinicians are experienced in managing this in their service (e.g., through their training, clinical supervision, reflective practice) and in many ways this is the same as would be the case for trials of many psychotherapeutic interventions. The research materials and processes are also widely used.

The nature of the study, including the setting and the needs and contexts of the participating families, means that there will likely be high levels of pre-existing and ongoing risks and harms, including aggression and violence. Therefore, for the purposes of this study, an adverse event would be classified as an escalation in pre-existing and ongoing risks and harms present at time of study start, or the occurrence of new risks and harms that first appear during the study. These events could operate at any of three levels: child-to-child (i.e., self), others-to-child, and/or child-to-others. The adverse events are listed below, with serious adverse events indicated in bold with an asterisk:

- New or escalation of involvement in violent behaviour that results in physical harm.
- **New or escalation of hospitalisations due to violence, drugs, alcohol, self-harm, or psychiatric reasons*** (including in-patient hospitalisation or significant disability/incapacity).
- New or escalation of self-harm.
- New or escalation of suicidal ideation: a preoccupation with suicide/thoughts about suicide, with no clear plans to take own life.

- **New or escalation of suicidal intent***: concrete and deliberate plans to end own life, with a conscious desire to escape from the world and a resolve to act purposively in this regard (e.g., a suicide attempt). This may be a deliberate action or disclosing of a deliberate action.
- **New or escalation of exploitation (e.g., criminal, sexual), extremism, and criminal activity (e.g., identified through a multi-disciplinary strategy discussion to manage a child's safety)*.**
- **Death*.**
- **Involvement in serious criminal activity (e.g., sexual assault, murder) *.**

An adverse event form will be used alongside site's usual safeguarding procedures. The principal investigator will be informed of an SAE within 24 hours, either through completing the adverse event form (which will trigger an alert) or through direct contact. Where the latter is used, the adverse event form will be completed within two days. Serious adverse events will be immediately reviewed by the Principal Investigator and Safeguarding Lead. They will consult with senior members of the research team to determine whether or not the event was related to the study and expected. Serious adverse events deemed related to the study and unexpected will be reported to the research ethics committee within 15 days of the Principal Investigator being notified, with a copy sent to Anna Freud, as the sponsor, along with a copy of the research ethics committee receipt.

Adverse events will be reported using the adverse event form within five days. This will trigger an alert to the evaluators. All adverse events and safeguarding concerns will be recorded by the study team on the database, along with a log of action taken.

All adverse events will be monitored on a regular basis in team meetings and at least quarterly in meetings of the Trial Management Group. Serious adverse events will be reported to the Data Monitoring and Ethics Committee (DMEC) and, if there are significant concerns, the DMEC will be asked to convene immediately.

Adverse events will be reported in the annual progress report to the research ethics committee and copied to Anna Freud as the sponsor. The Youth Endowment Fund risk register will be updated accordingly and submitted with each quarterly monitoring report.

7.0. Outcome measures

Children, parents/carers, and clinicians will complete outcome measures directly onto REDCap. At baseline and follow-up, REDCap will send an email to children and parents/carers containing a link to complete measures online. The AP will be able to monitor completion of outcome measures within REDCap and will contact children and parents/carers to offer support with completion.

7.1. Primary outcome

The primary outcome is aggression and violent behaviour measured by the child-reported 23-item total score, which is the combination of the reactive and proactive aggression subscale scores, of the Reactive and Proactive Aggression Questionnaire (RPQ; Raine et al., 2006) completed at baseline and six months post-baseline (primary endpoint). The total score can range from 0-46. It is a measure in the YEF database and has demonstrated evidence of reliability in previous studies for the total

score and subscale scores; e.g., Cronbach's alpha = .84-.9 (Raine et al., 2006). Validity was also fully assessed by Raine et al. (2006). Specifically, construct validity was shown by relationships between raw and residualised proactive and reactive scales to 16 measures measuring similar concepts; convergent validity was assessed by comparing RPQ with age 16 self-report and parent rated Child Behaviour Checklist (CBCL) aggression scores; criterion validity was shown by relating age 7 aggression measures and age 16 delinquency/violence classification; discriminant validity was shown by demonstrating that age 16 CBCL scales were unrelated to aggression scores. Additionally, confirmatory factor analysis shows consistency for a two-factor model across multiple populations (e.g., Chen et al., 2022; Heynen et al., 2021; Raine et al., 2006). It was selected as it has been used in a previous study of MBT-CD with children (Hauschild et al., 2023; Taubner et al., 2021). In the internal pilot, we will examine whether to retain the total score as the primary outcome or instead use the reactive aggression subscale score only.

7.2. Secondary outcomes

All secondary outcomes will be completed at baseline and six months post-baseline. The maximum number of items a child will be completing in one survey is 78. We consulted the Peer Researcher and other young people about the proposed measures, who are of a similar age to the target sample but do not have the same levels of needs. They completed the measures in 11-25 minutes. Estimating four items are completed in a minute in the target sample, the survey will take 20 minutes. We will review burden during the pilot and consider prioritizing secondary outcomes for the full trial.

7.2.1. Child-reported outcomes

Five outcomes will be measured using the 30-item Strengths and Difficulties Questionnaire (SDQ; Goodman, 1999), including impact supplement.

1. Conduct problems using the conduct problem subscale (5 items, score 0-10);
2. Inattention difficulties using the hyperactivity/inattention subscale (5 items, score 0-10);
3. Emotional difficulties using the emotional symptoms subscale (5 items, score 0-10);
4. Difficulties with peers using the peer relationship problems scale (5 items, score 0-10);
5. Impact of difficulties (5 items, score 0-10).

The SDQ is a widely used measure of mental health difficulties for children and has demonstrated reliability and validity in previous studies (e.g., Cronbach's alpha: 0.65-0.78) (Goodman et al., 2010). Reduced externalising difficulties (as measured through outcomes 1 and 2, above) and internalising difficulties (as measured through outcomes 3 and 4, above), arising from increased mentalizing capacity, are outcomes in the logic model and/or theory of change. Therefore, we have chosen to measure as the individual subscales rather than a total difficulties sum score.

Mentalizing is a short-term outcome of MBT-CD and will be used as a secondary outcome. Two outcomes will be measured to assess mentalizing using two subscales (10 items) of the Emotion Awareness Questionnaire (Rieffe et al., 2008):

1. Analyses of emotions (5 items, score 5-15) (sample item: "When I am angry or upset, I try to understand why"). This subscale was chosen as it pertains to an individual's capacity to understand and reflect on their own emotions and how these impact their behaviour, a central component of mentalizing.

2. Attending to others' emotions (5 items, score 5-15) (sample item: "It is important to know how my friends are feeling"). This subscale was chosen as it pertains to an individual's capacity to understand and reflect on other people's emotions and how these impact their behaviour, a central component of mentalizing.

The EAQ has been used with children 10 – 14 years (Rieffe et al., 2008) and with children receiving support from specialist mental health services (e.g., Midgley et al., 2023). It has demonstrated evidence of reliability and validity in previous studies (e.g., Cronbach's alpha = 0.64-0.77; Rieffe et al., 2008). We considered other measures such as the Reflective Functioning Questionnaire-Youth (Sharp et al., 2022), which was not chosen due feedback from the evaluation and delivery teams about item complexity.

Family relationships is an outcome in the logic model, and one family outcome will be measured using the total score of the SCORE-15 (Stratton et al., 2010) (score 15-75) (sample item: "In my family we talk to each other about things which matter to us"), which has demonstrated evidence of reliability and validity in previous studies (e.g., Cronbach's alpha = 0.89-0.90; Hamilton et al., 2015; Stratton et al., 2010). It has been found to be able to differentiate clinical and non-clinical samples and to show change over the course of receiving support. Other measures were considered (e.g., Parenting and Family Adjustment Scale; Sanders et al., 2014) but were not chosen as they did not have child and parent/carer versions and/or they had a greater focus on constructs not represented in the logic model, such as parenting practices, parental wellbeing, and satisfaction with parenting.

7.2.2. Parent/carer-reported outcomes

One outcome, aggression and violent behaviour, will be measured using the RPQ (Raine et al., 2006) (see '7.1. Primary outcome' section, above). The RPQ has been used with caregivers in previous studies and has been determined to be psychometrically appropriate for this respondent group (Fite et al., 2024). It has been shown to have good test-retest reliability over a six-month period (total score, r=0.84, proactive subscale, r=0.79, reactive subscale, r=0.81; Baker et al., 2008). Additionally, internal reliability has been found to be good/very good as demonstrated with Cronbach's alpha (0.86, 0.77, and 0.83 for total score, proactive subscale, and reactive subscale, respectively; Baker et al., 2008) and McDonald's Omega (0.80 and 0.88 for proactive and reactive subscales, respectively; Fite et al., 2024). In the internal pilot, we will examine whether to use the total score or instead use only the reactive aggression subscale score.

Five child outcomes will be measured using the 30-item SDQ including impact supplement:

1. Conduct problems using the conduct problem subscale (5 items, score 0-10);
2. Inattention difficulties using the hyperactivity/inattention subscale (5 items, score 0-10);
3. Emotional difficulties using the emotional symptoms subscale (5 items, score 0-10);
4. Difficulties with peers using the peer relationship problems scale (5 items, score 0-10);
5. Impact of difficulties (5 items, score 0-10).

One family outcome will be measured using the total score of the SCORE-15 (Stratton et al., 2010) (score 15-75) (see above).

7.2.3. Clinician-reported outcomes

Six child outcomes will be measured using six items of the Health of the Nation Outcomes Scales for Children and Adolescents (HoNOSCA; Gowers et al., 1999), each scored 0-4:

1. Disruptive, antisocial or aggressive behaviour;
2. Non accidental self-injury;
3. Substance misuse;
4. Peer relationships;
5. Family life and relationships;
6. School attendance.

The HoNOSCA is a widely used measure of health and social functioning, and it has shown evidence of reliability and validity in previous studies (Pirkis et al., 2005).

7.2.4. Demographic and activity data

Staff (e.g., assistant psychologists) at each site will be asked to record demographic and activity data for each participant in the study database through an open interface to which they will have access, including:

- Demographics (e.g., date-of-birth, age, sex and gender (both of which are likely to be stored by the site), ethnicity, social care status, special educational needs, caring responsibilities, living arrangement), postcode, NHS Trust;
- Reasons for referral and referral source;
- Needs (including diagnoses) identified at referral and/or initial assessment;
- Medications prescribed;
- Engagement in education, employment, and training (at referral/assessment and six-months post baseline);
- Other agencies providing support to the child and family;
- Information on sessions delivered for both MBT-CD and BAU (e.g., number and type of child/family sessions attended, number of multi-agency meetings, number of referrals to or contact with the multi-agency safeguarding hub);
- Reasons for case closure;
- Time between referral, screening, and treatment, and duration of treatment.

Each site will maintain a screening log used to record numbers of children screened, eligible, and recruited (with reasons for exclusion at each point). This will be provided to the research team periodically throughout the trial for monitoring and reporting purposes.

7.2.5. Implementation and process measures

Two mediators or mechanisms of change will be assessed in the intervention arm at three timepoints: session 1-3, session 10-13, and session 20-24. The measures will be administered by clinicians as part of their routine data collection. Thus, the measures will be used both as an evaluation tool and a clinical tool.

1. Therapeutic alliance, measured by the Session Rating Scale (SRS; Miller et al., 2000). The SRS assesses the client's perceptions of: respect and understanding, relevance of goals and topic,

client-clinician fit, and overall alliance. It is widely used and has demonstrated good reliability and validity (e.g., Campbell & Hemsley, 2009; Duncan et al., 2003). The therapist's focus on developing the therapeutic alliance to improve the client's mentalizing capacity and behaviour is central to MBT-CD (Taubner et al., 2021).

2. Progress towards goals, measured by the Goal Based Outcomes Tool (GBO; Law & Jacob, 2015) at three timepoints. The GBO enables clients to rate the extent to which they feel that they have achieved their goals set at the outset of treatment, on a scale of 1-10. The GBO is widely used in CAMHS.

7.3. Compliance

The intended flexibility with which MBT-CD will be delivered to meet the needs of individual children makes identifying a meaningful metric of intervention compliance challenging. For example, the number of sessions completed by those deemed to have completed treatment in the German study varied from 8 to 69 (Hauschild et al. 2023). We considered attendance of key milestone sessions, but the model is not prescriptive enough to warrant this. We will examine compliance based on number of child sessions attended. Based on a maximum of 24 sessions (weekly sessions over six months), we will classify attendance of fewer than 12 sessions (<50%) as non-compliant, attendance of 12-17 sessions (50-74%) as partially compliant, and attendance of 18+ session (75%+) as fully compliant.

8.0. Analysis

8.1. Internal pilot

Descriptive statistics will be used to summarise information in accordance with the progression criteria. Tracking of the progression criteria will be cumulative, providing early warning of non-performance against the progression criteria and swift assessment of the readiness to progress at the end of 6 months, reducing any delays. Green, amber, and red targets for each criterion have been outlined earlier.

Reporting will include the following:

- Site set up: completion of contracting and local approvals, MBT-CD training, and initiation visits.
- Participant recruitment: Proportions consenting and randomised, and numbers completing baseline assessments stratified by study site.
- Retention and attrition: Proportion of randomised children and families withdrawing from treatment and withdrawing from the study.
- Practitioner-reported data: Submission of practitioner-reported data, and data completeness (with data recovery) stratified by site.
- Outcome data: proportion of study outcomes completed by scale, with a focus on the RPQ reactive and proactive subscale completion.
- Support received: by children stratified by study arm and study site.

8.2. Full trial

8.2.1. Primary outcome analysis

Evaluation of intervention efficacy will be conducted on an intention-to-treat (ITT) basis using complete cases. The primary outcome (aggression and violent behaviour) will be measured by the total score of the child-reported Reactive and Proactive Aggression Questionnaire, RPQ (see '7.0. Outcome measures').

Group differences (MBT-CD vs. BAU) at the primary outcome timepoint (six months) will be evaluated (group difference; 95% confidence intervals) using a linear mixed effect model adjusted for group allocation, baseline participant characteristics (age, gender, ethnicity), baseline RPQ, and with FCAMHS site as a random effect.

8.2.2. Secondary outcome analyses

Similar analyses will be performed for the secondary outcomes. Multivariable linear mixed effect models will be evaluated, adjusting for group allocation, baseline participant characteristics (age, gender, ethnicity, Trust) and any baseline values collected for secondary outcomes, to explore the explanatory mechanisms of change for the MBT-CD intervention (again including FCAMHS site as a random effect).

8.2.3. Subgroup analyses

This study will not be powered for subgroup analyses. However, where possible, exploratory analyses will be used to assess differences between subgroups for which we do not yet know whether differences may be present in terms of intervention effectiveness; gender (female, male, non-binary/other), age at referral (10-15 years, 16-17 years), ethnicity (Asian, Black, Mixed, White, Other). and neuro-non-typicality. The influence of any diagnosed mental health conditions recorded (grouped according to classification) and the use of prescribed medications will also be considered.

Where possible, linear mixed effect models will be used to account for the data structure in exploratory analyses. Adjustments will be made for baseline status and participant demographic characteristics, as appropriate, with FCAMHS site a random effect. Group means and 95% confidence intervals (or medians and interquartile ranges) will be reported, and comparison between study arms evaluated using models or more simple group comparisons (e.g., t-test). As these analyses are exploratory and underpowered, no adjustment will be made for multiple comparisons. Additionally, it is noted that while the sample size may be suitable for observing patterns, it will be important not to overinterpret potentially very small subgroup analyses.

8.2.4. Further analyses

Similar secondary analyses will also be performed for the secondary outcomes, using multivariable linear mixed effect models to explore explanatory mechanisms of change for the MBT-CD intervention. Inclusion of mentalizing (analyses of emotions, attending to others' emotions), therapeutic alliance, and progress towards goals will be assessed, with interactions included where indicated, again fitting FCAMHS centre as a random effect.

For the primary outcome (aggression and violent behaviour measured with the RPQ model specification will be checked for robustness by fitting models which include all baseline imbalanced variables, a simple model which includes only group allocation, and a saturated model with all variables (to be specified in the statistical analysis plan once randomisation has commenced).

8.2.5. Interim analyses and stopping rules

No interim analyses are planned in this study, so no formal stopping rules will be in place. However, the TSC and DMEC will have oversight of the study throughout, as described in section 15.2., and will give advice regarding whether the trial should continue, be modified, or be stopped if ethical or safety issues arise (see section 6.6. for reporting of adverse events).

8.2.6. Longitudinal follow-up analyses

Outcome measures will be assessed at baseline and six months post-baseline, adjusted for baseline values. Aside from the implementation and process measures, data will not be collected or analysed for other timepoints. A variable for time will not be included in analyses since measures should be captured at six months post baseline for all participants.

8.2.7. Imbalances at baseline

Summary statistics (number and percentage for categorical/binary variables, means and standard deviations or medians and interquartile ranges as appropriate for continuous variables) will be estimated and reported, alongside visual representations (e.g., histograms). The flow of participants through the study will be presented in the CONSORT flow chart to evaluate the flow of participants from referral, through screening and consent, to randomisation and implementation of the intervention or BAU, as appropriate, and follow up. The number of individuals referred to the programme, recruited, and the number who attritted will be reported by age, sex, gender, and ethnicity, in line with YEF guidance.

Participant characteristics and measures collected at baseline (participant: RPQ, SDQ, EAQ, SCORE-15; parent/carer: SDQ, SCORE-15 clinician: HoNOSCA) will be summarised by intervention group. Comparisons will explore the extent of diversity: ethnicity, gender, special educational needs/disability, diagnosed mental health conditions and prescribed medications, and social care status, and the degree to which groups are under or overrepresented based on local and/or national data. Baseline differences in participant characteristics between FCAMHS sites will be assessed using appropriate statistical methods (e.g. t-tests).

8.2.8. Missing data

It is possible that there may data missing from the trial, in which case YEF guidance for handling missing data will be followed. Missing data patterns will be explored for outcome measures across both trial arms and to assess whether any systematic differences exist. The extent of missingness will be established, and the number of complete cases reported. Missing data will be considered with potential mechanisms (missing completely at random [MCAR], missing at random [MAR)], missing not at random [MNAR]), which will be explored using logistic regression. Where appropriate, the variables predictive of nonresponse will be identified. If missing data is less than half but more than a trivial amount (5%) and the data are not MNAR, then multiple imputation using the

Multivariate Imputation by Chained Equations (MICE) procedure will be performed, with the imputation model containing at least those variables in the analytic model. Further details will be included in the statistical analysis plan. Sensitivity analyses will compare results to those from complete case analyses.

8.2.9. Compliance

Subgroup analyses will assess differences in efficacy by intervention compliance (non-compliant [<50% sessions attended] vs. partially compliant [50-74%] vs. fully compliant [75+]). Linear mixed effects models will be used as described above, adjusted for baseline values and characteristics and FCAMHS sites as random effects.

8.2.10. Presentation of outcomes

All results will be reported alongside 95% confidence intervals where appropriate. Effect sizes will be estimated with Cohen's d (Lakens, 2013) (which will provide a similar estimate to Hedges' g given the expected sample size) alongside 95% confidence intervals.

9.0. Implementation and process evaluation

9.1. Research questions

9.1.1. Intervention fidelity and quality

- Is the programme being delivered with enough consistency across the sites?
- How well are the different components of the intervention being delivered?

9.1.2. Dosage, reach, and responsiveness

- How much of the intended intervention has been delivered?
- What is the rate of participation by intended recipients?
- To what extent do the participants engage with the intervention?
- How does treatment engagement differ by demographic characteristics (e.g., for compliant vs. non-compliant MBT-CD cases)?

9.2.3. Perceptions, experiences, and opinions

- What are participants' experiences of, and opinions on, receiving or delivering the intervention? What is the experience of different groups of children, including those from minoritised ethnic groups?
- What are participants' perceptions of impact and the mechanisms behind this?
- What are participants' perceptions of barriers and facilitators to implementation and impact?
- How do structural factors affect children from minoritised ethnic backgrounds in accessing/receiving the intervention?
- What are participants' suggestions for improving the intervention (including access to the intervention)?
- Are changes needed to accommodate context and population needs?
- Potential for intervention scalability – what is the level of need and readiness for change within sites and the wider context?

9.2.4. Evaluation quality and suitability

- What is the quality and suitability of any Implementation and Process Evaluation (IPE) instruments, collection methods, sampling procedures, etc.?
- How is the evaluation engaged with and perceived by participants?

9.2. Research methods

9.2.1. Intervention fidelity and quality

To assess intervention fidelity and quality in the intervention arm, we will conduct researcher ratings of video- or audio-recorded sessions using, for example, a version of the MBT-ACS developed for this specific intervention and target population. The MBT-ACS consists of 18 items assessed across six domains: not-knowing stance, mentalizing sessional structure, mentalizing process, identification of non-mentalizing modes, mentalizing affective narrative, and relational mentalizing.

At the outset of the intervention, all children will be asked for written consent/assent by their clinician for their sessions to be video- or audio-recorded. This consent will be checked at the beginning of each session. Session recordings will be assessed across all sites from MBT-CD clinicians with clients who are at least partially compliant (see '7.3. Compliance'). Two sessions will be selected randomly to assess for each clinician. Interrater reliability checks on ratings will be conducted initially on 10% of sessions to explore whether further training for researchers on using the scale is needed. If necessary, reliability checks on ratings will be conducted on an additional 10% of sessions.

Fidelity and quality ratings will primarily take place during the efficacy phase, but testing of the scale will begin during the pilot phase. We will also examine the of feasibility of obtaining recorded sessions in the pilot.

If video or audio recordings of sessions are not available, such as if sessions take place in a community space, then we will explore whether, for example, an adapted, self-report version of the scale could be completed by clinicians at specific intervals; e.g., at three timepoints: session 6, session 12, and session 18.

At the outset of the study, all MBT-CD clinicians will be asked to complete a brief questionnaire about their training and experience history. Items will include asking clinicians how long they have been practicing as a therapist, which client groups they have typically worked with, and in which therapeutic modality they tend to work most. This training and experience history data will provide contextual data for the treatment adherence ratings.

9.2.2. Dosage, reach, and responsiveness

In both the pilot and efficacy phases, we will measure programme dosage and reach and participant responsiveness in the intervention and control arms, through therapists' routinely collected site data; e.g., records of child and parent/carer (where applicable) session attendance. Reach will also be assessed by examining differences in treatment engagement by demographic characteristics. A dose-response analysis, such as CACE, will be conducted and this will be detailed in the statistical analysis plan.

9.2.3. Perceptions, experiences, and opinions

Participants' perceptions, experiences, and opinions will be explored through qualitative data collection with multiple participant groups. Semi-structured interview schedules or topic guides will draw on the Experiences of Therapy and Research Interview – child, parent/carer, and therapist versions (Midgley et al., 2011). In these semi-structured interviews, the interviewer is guided by pre-defined topics to cover, but the conversation is led by the participant in terms of the issues that are most relevant to them to discuss in relation to these topics. All interviews will be audio recorded and then transcribed verbatim.

When children consent/assent to take part in the trial, they will acknowledge that they may be invited to take part in an interview. Children who are invited to take part in an interview will be asked to provide consent/assent at that point. For children under 16, a parent/carer with parental responsibility will be asked to consent to the child taking part in an interview when they provide consent to the trial. When a child is invited for interview, parental consent will be rechecked via opt out. Demographic information collected as part of the wider trial will be used to ensure that we are reaching children from different groups. Children will also be asked to give their (or their parent/carer's) contact information at this point (e.g., email address, phone number) to enable the research team to contact them to schedule their interview. Semi-structured interviews will be conducted with up to three children from each site (*N* = max. 39). Overall, 75% of interviewees will be recruited from the intervention arm and 25% of interviewees will be recruited from the control arm. Interviews will be conducted at mid-to-end of intervention (e.g., from session 12 onwards). We will record for each child when their expected mid-intervention timepoint is and contact them from that point (i.e., three months post-randomisation). This will ensure that we capture children's experiences across different patterns of intervention attendance. If preferred, children will be offered an alternative option of completing an open-ended questionnaire. All children will receive a £15 voucher as a thank you for taking part. Interviews with children will primarily take place during the efficacy phase.

Parents/carers will be asked to give consent to take part in an interview when signing their consent form to take part in the wider trial. Parents/carers will also be asked to give their contact information at this point (e.g., email address, phone number) to enable the research team to contact them to schedule their interview. Semi-structured interviews will be conducted at mid-to-end of intervention with parents/carers of children in the intervention arm - up to two from each site (*N* = max. 26). All parents/carers will receive a £15 voucher as a thank you for taking part. Interviews with parents/carers will primarily take place during the efficacy phase.

All clinicians across sites in the intervention arm will be invited to express interest in taking part in an interview. Semi-structured interviews will be conducted with up to two clinicians from each site (*N* = max. 26). Interviews with clinicians will take place across both the pilot and efficacy phases.

Other staff members (e.g., clinical supervisors, single points of contact (SPoC) for the trial, trainers) involved in the implementation of the trial across sites will also be invited to express interest in

taking part in an interview. Semi-structured interviews will be conducted with one staff member at each site (*N* = max. 13). These interviews will primarily take place during the pilot phase.

9.2.4. Evaluation quality and suitability

Rates of participation in surveys and interviews will be monitored during the pilot and efficacy phases. During the pilot phase, a small number of questions relating to participants' opinions on the evaluation will also be included in child surveys. Clinicians in the intervention and control arms and SPoCs across sites will also be asked to complete brief feedback surveys about their opinions on the evaluation during the pilot phase.

9.3. Analysis

To assess intervention fidelity and quality, we will conduct researcher ratings of video or audio recorded sessions using, for example, the MBT-ACS. The mean treatment adherence level across sessions will be calculated within and across anonymised sites during the efficacy phase. Percentages of MBT-CD sessions by adherence level (meeting, partially meeting, and not meeting adherence thresholds) will also be calculated. Adherence level data will also be explored in the context of the data collected on clinicians' training and experience history (e.g., adherence levels according to core modality or length of experience).

We will measure programme dosage and reach and participant responsiveness (including demographics) in the intervention and control arms through therapists' routinely collected site data; e.g., records of session attendance. Mean attendance levels will be calculated within trial arms and within and across anonymised sites. A dose-response analysis, such as CACE, will be conducted to explore the optimum number of sessions for response. Reach will be assessed by examining differences in treatment engagement by demographic characteristics (e.g., compliant vs. non-compliant MBT-CD cases).

Child completion of the SRS as a measure of therapeutic alliance will further assess participant responsiveness in the intervention arm across three timepoints. Mean SRS scores at each timepoint and change over time in SRS scores will be calculated within and across anonymised sites. Children in the intervention arm will also complete the GBO at the same three timepoints. Mean GBO scores at each timepoint and change over time in GBO scores will be calculated within and across anonymised sites.

Descriptive statistics will be used to report findings on rates of participation in surveys and interviews. Participants' opinions on the evaluation will also be analysed using content analysis (e.g., Elo & Kyngäs, 2008) and descriptive statistics.

Qualitative data will be analysed by participant group across sites. Analysis will draw on the stages of reflexive thematic analysis (Braun & Clarke, 2006, 2020). This involves coding interview transcripts and collating extracts with similar codes into themes and subthemes across transcripts. Themes represent *"patterns of shared meaning"* in terms of participants' perceptions, experiences, and opinions (Braun & Clarke, 2020, p.4). Use of the NVivo qualitative data analysis software package will provide clear audit trails for and facilitate a team approach to the analysis process.

We will adhere to the American Psychological Association (APA) standards for reporting on qualitative research, ensuring credibility and trustworthiness of our qualitative research processes (Levitt et al., 2018).

Table 6: *IPE methods overview.*

Research methods	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed	Implementation/ logic model relevance
Researcher ratings of treatment adherence	E.g., a version of the MBT-ACS developed for this specific intervention and target population.	Session recordings will be assessed across all sites from MBT-CD clinicians with clients who are at least partially compliant. Two sessions will be selected randomly to assess for each clinician.	Mean treatment adherence levels; percentages of sessions meeting, partially meeting, and not meeting adherence thresholds.	Is the programme being delivered with enough consistency across the sites? How well are the different components of the intervention being delivered?	Intervention fidelity and quality
Self-report questionnaire	Brief questionnaire about clinicians' training and experience history.	All MBT-CD clinicians	E.g., examination of treatment adherence levels in the context of clinician core modality or length of experience.	Is the programme being delivered with enough consistency across the sites? How well are the different components of the intervention being delivered?	Intervention fidelity and quality
Routinely collected data	E.g., child and parent/carer demographic data, session attendance records.	All children and parents/carers in the intervention and control arms.	Mean attendance levels; examining differences in treatment engagement by demographic characteristics.	How much of the intended intervention has been delivered? What is the rate of participation by intended recipients? To what extent do the participants engage with the intervention?	Dosage, reach, and responsiveness
Qualitative	Semi-structured interviews	Up to 3 children from each site (*N* = max. 39). 75% of interviewees will be recruited	Reflexive thematic analysis.	What are participants' experiences of, and opinions on, receiving or delivering	Perceptions, experiences, and opinions

		from the intervention arm and 25% of interviewees will be recruited from the control arm; parents/carers of children in the intervention arm - up to 2 from each site (*N* = max. 26); up to 2 clinicians from each site (*N* = max. 26); 1 staff member involved in trial implementation at each site (*N* = max. 13).		the intervention? What is the experience of different groups of children? What are participants' perceptions of impact and the mechanisms behind this? What are participants' perceptions of barriers and facilitators to implementation and impact? How do structural factors affect children from Black, Asian, and ethnic minority backgrounds in accessing/receiving the intervention? Suggestions for improving the intervention? Are changes needed to accommodate context and population need?	
Routinely collected data; self-report questionnaires	Rates of participation in surveys and interviews; brief feedback surveys about the evaluation.	All children and clinicians in the intervention and control arms; all SPoCs.	Descriptive statistics; content analysis	What is the quality and suitability of any IPE instruments, collection methods, sampling procedures, etc.? How is the evaluation engaged with and perceived by participants?	Evaluation quality and suitability

10.0. Cost data reporting and collecting

We will follow YEF Cost Reporting Guidance. We will work with the 13 FCAMHS sites to determine their costs for delivering MBT-CD, using a 'bottom-up' approach. These costs will be presented for the whole programme and an average cost per site and an average cost per child.

We will obtain data on costs through a brief survey completed by the SPoC or finance contact at each site and through practitioner-reported FCAMHS and trial data. This will be obtained and collated during the internal pilot and at the end of the full trial data collection period.

For staff costs, the survey will ask about MBT-CD clinician roles and grades, salary bands, and non-wage labour costs. Where salary information is disclosive, sector-wide assumptions will be applied (e.g., Personal Social Services Research Unit database). Data from the survey will be compared against practitioner-reported FCAMHS and trial data on number and length of MBT-CD training sessions for clinicians and trainees (or staff cover time if appropriate), number and length of MBT-CD sessions delivered to children and families, and time for any additional preparation, ongoing training/supervision, and administration. Data on clinician's travel and subsistence costs to deliver the intervention will also be included.

The survey will ask about other inputs (i.e., renting additional buildings and facilities, and material and equipment such as printing). There are no anticipated programme procurement costs.

Our Quantitative Lead will be responsible for data collection, with support from the PI and wider team.

11.0. Diversity, equity, and inclusion

Ensuring the research is ethnically equitable and removing barriers for minoritised ethnic groups will be considered throughout the evaluation lifecycle, as discussed in detail below. Overall, this will be considered from the start of the study, including the development of study and promotional materials so that they are accessible and represent the diverse range of children to be recruited. Once the study is running recruitment data will be monitored and the YPAG, Trial Management Group, and Trial Steering Committee will be consulted. These groups will meet regularly (see '15.2. Study Oversight' for timings) throughout the study allowing regular review of equity within the study and to take action on any identified barriers.

The Lammy Review (Lammy, 2017), which calls for wide reforms of the criminal justice system, records the treatment and experience of people from minoritised ethnic groups and makes several recommendations. Recommendation 4 of the Lammy Review calls for a principle of *'explain or reform'* and we plan to look at our referral demographic data on a six-monthly basis and apply this principle.

The service will continuously monitor ethnicity of referrals and lead targeted service promotion, particularly to areas where there is an over- or under-representation of children from different ethnicities compared to population and criminal justice data for the area.

Consideration will be given to exploring how accessible and relatable FCAMHS promotional and information resources are across all ethnic groups. If language in this material is not relatable or representative, it may present a barrier into the service before contact is made or considered. This will be explored with the YPAG (see below).

Risks to be mitigated during study design include: service users might be viewed/treated without cultural humility, clinicians/evaluators may hold biases, and suitably validated measures may not be culturally appropriate.

FCAMH services and staff need to be explicit in the responsibility they are taking to ensure they are not the drivers of service barriers for those from racially minoritised backgrounds in line with the NHS England Patient and Carer Race Equality Framework. This is especially relevant given evidence on racial disparities in mental health care. For example, training events around the conscious or unconscious bias which is embedded within this area of work may be a useful starting point. Going forwards from this it must remain on the radar of services, as to not simply be a token gesture but so services are able to support longstanding and meaningful change. Thus, we plan to have a specific CPD half day early on in the project to reflect upon and question mitigating bias and to consider ethnicity and culture in our referral pathway. This training will be extended to the evaluation team. We plan to use the social GGRAAACCEEESSS model to support clinicians to reflect on their own experience and that of the children in the project. We also plan to implement social GGRRAAACCEEESSS into supervision sessions to support ongoing consideration of unconscious bias, ethnicity, and culture. We will also include the Privileged Identity Exploration (PIE) model (Watt, 2007; Watt, 2015) to help to facilitate positive and productive discussion in supervision.

Study design must begin with an awareness of the potential disparity in outcomes for the MBT-CD intervention, as with any intervention, and how these may impact recruitment into the evaluation. We will work with FCAMHS to identify known inequities and how they are currently addressed. The MBT-CD intervention targets mental processes unique to each child and as such can account for individual identity considerations. One issue is the requirement to be able to speak English. MBT requires development of an attachment-based relationship between the therapist and the client. Having a translator in the sessions would impact that relationship. However, the FCAMHS team have very few children in their service who do not speak English, so we do not envisage this being a large problem for recruitment, although it does represent inequity to access. It is also important to highlight that as an intervention designed for children, we do not rely on talking alone. It will be common to use drawing and toys to support the intervention. This will be particularly helpful if English is not a child's first language or if they are closer to 10 years old. It is also not necessary to have a traditional therapy seating arrangement. MBT-CD can be delivered whilst walking or playing on the floor, as long as confidentiality can be assured.

It is important to highlight that in a study across 45 cultures, the data generally supports the link between mentalizing and mental health across cultures (Aival-Naveh et al., 2019). It was also found that self over other mentalizing in individualistic cultures, other over self mentalizing in collectivistic cultures, were more dominant. This is an important factor to consider within the supervision of the clinical practice. Indeed, cultural humility will be a focus in supervision to ensure equability of service

access. We will draw on the work of Dr Afsana Faheem and her work on cross-cultural validity of evidence-based psychological interventions offered by Improving Access to Psychological Therapies (IAPT) services (2023).

A Young People's Advisory Group (YPAG) of up to 10 Experts by Experience (EbEs) will be convened. We intend to recruit the group through existing EbE groups affiliated to FCAMHS teams and/or Trusts, and Youth Justice Services groups, prioritising local experience, but can use Anna Freud's (AF) and YEF's EbE network if needed. The group will be made up of a diverse group of young people with representation from different genders, ethnicities, sexual orientation etc. as far as we are able. They will meet quarterly to provide broad views and perspectives on the research, to refine processes and documentation, and help interpret and disseminate findings. AF and University of Hertfordshire's (UH) earlier work (e.g., Reflective Fostering Study) has highlighted the importance of representation for minoritised groups in research advisory groups (Izzidien et al., 2025).

In the YPAG, we will work with children from minoritised ethnic backgrounds to inform our approach to recruitment and design of study materials. We will seek to involve them in as many aspects to the study as possible, so, for example, we will ask them: to help write the participant information sheets and consent forms ensuring they are appealing to children, for ideas about how to keep the children in the BAU arm engaged with the study (to maximise completion of follow-up measures), to write blogs/newsletters to keep in touch with children in the study, to contribute to meetings and reports, and to aid dissemination. To increase accessibility and representation, we plan to use videos, , to support the supply of participant information sheets, featuring diverse representation from children talking about the research, coproduced with the YPAG.

We have recruited a peer researcher to the core research team from AF's EbE network of young people with relevant lived experience and additional research training. Relevant lived experience in this context includes experience of mental health difficulties. The peer researcher will contribute to all stages of study development and delivery. As with other members of the research team, they will contribute to discussions and decisions about recruitment, retention, engagement, data collection, analysis, troubleshooting, and management of risks and issues. They will be involved in conducting elements of the research (e.g., collecting and analysing interview data) where appropriate.

The plan is for data collection to be done online, using the study database. This will reduce concerns that individuals will be judged on the responses provided. However, for some participants, digital exclusion where poverty may be an issue, others may have difficulties with reading particularly with doing so on screen, and there may be some children who can speak and understand English but are less confident reading English text. We will be flexible about how questionnaires are collected, including providing the opportunity to have the measures read to them (in an interview).

Most of the study outcome measures being used are validated and translations are not available, so it is not possible to collect these data in language other than English. This does create a barrier to involvement for some families. However, FCAMHS report that they have a very low percentage of children who are unable to speak and understand English. It is more common that their

parents/carers do not speak English well and in these cases it may not be possible to collect parent/carer-reported data.
Having incorporated feedback to the design and conduct of the study, we will continuously monitor representation and engagement throughout the study. Building on generic demographic data from FCAMHS teams, we will closely monitor our recruitment data to see whether the ethnic backgrounds of children in the study are representative of those referred to the service locally and nationally. If any group appears underrepresented (at the national or local level), we will work with the YPAG and seek advice from YEF's race equity advisers and Youth Advisory Board to maximise recruitment to the trial.

We will continually assess whether engagement with treatment differs according to ethnicity, gender, neurodiversity, and their intersections. We will apply the same lens to attrition rates and reasons for withdrawing. If we find inequities, measures to increase representation will be discussed with the advisory group and referrers.

The peer researcher and YPAG will be supported by AF's participation team, which uses the Lundy model of participation (see https://www.annafreud.org/participation/) and its four principles of space, voice, audience, and influence. As with all our EbE work, we will work to understand support needs, communication preferences, and goals for involvement. They will receive training in research methods and study protocol, ongoing supervision and support.

12.0. Ethics and registration

This study will be conducted in accordance with data protection legislation (e.g., UK General Data Protection Regulation (GDPR; Assimilated Regulation (EU) 2016/679) and the Data Protection Act (2018)) and the guidelines of the Declaration of Helsinki (World Medical Association, 2024). The trial will be undertaken according to the principles of ICH GCP, and all relevant ethics and governance processes, including the HRA approvals.

Health Research Authority (HRA) approvals (including approval from the Research Ethics Committee) will be sought as soon as possible, and the study will start once these have been obtained. Research and Development (R&D) department approval will be sought from each site before recruitment begins at that FCAMHS team. This process is expected to take up to six months, given the involvement of the NHS Research Ethics Committee (REC), HRA, and participating Trusts.

It is the PI's responsibility to produce an annual progress report to be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. The PI will notify the REC of the end of the trial and if the trial is ended prematurely, the PI will notify the REC, including the reasons for the premature termination. Within one year after the end of the trial, the PI will submit a final report with the results, including any publications/abstracts, to the REC.

The trial will be registered with the ISRCTN Registry and at www.controlled-trials.com. The team will ensure that trial registry is updated with outcomes at the end of the trial.

12.1. Ethical considerations

Informed consent/assent: Voluntary and fully informed written consent/assent will be obtained from all participants before they take part in any study activities. Clear and accessible information sheets and consent forms will explain to participants why we need the data, what we will hold, how it will be used, and give them the opportunity to ask questions or raise objections. Participants will be made aware of their right to withdraw from the trial at any point.

Obtaining consent on behalf of children and on their behalf may be lengthy, especially if they are looked after by someone other than their parents.

Confidentiality: Collection and processing of participants' personal information will be limited to what is necessary to ensure the study's scientific practicability, and in line with relevant legislation e.g., UK GDPR (Assimilated Regulation (EU) 2016/679). Each participant will be allocated a study code on entry which will be used to identify data relating to that participant. Identifiable data will be restricted to those who require it. There will be limits to confidentiality, in terms of safeguarding, and these will be explained to participants in information sheets, in the consent forms and at the outset of interviews. Our PI and Safeguarding Lead will ensure staff understand best practice guidance for identification and management of safeguarding risks.

Interviews will be securely recorded (e.g., Encrypted Dictaphone, AF MS Teams) and will be stored securely on AF servers. The reporting of results (including quotations) will be fully anonymised.

Sessions will be video/audio recorded by sites using their standard procedures. These will be accessed by the evaluators either with AF being granted access to local secure folders directly or through someone at the site securely uploading recordings to the secure AF server. Access to the session recordings will be limited to those in the study who need access to complete fidelity ratings.

Issues arising from the intervention: For those taking part in the MBT-CD intervention, taking part may involve discussing sensitive, potentially shaming, matters but this will be done in a supportive context. The nature of the intervention, reinforced through supervision, will help to support the focus on mentalizing rather than a sense that remorse is a target of therapy.

Inclusion: Our team have established ethically approved procedures for working with disadvantaged and vulnerable groups, and AF have developed best practice guidance around appropriate language and terminology to use in relation to EDI. Research materials will be inclusive in how we discuss and ask about protected characteristics and sensitive topics.

Safeguarding issues: Study participants will be advised in advance, that there may be situations where there is an obligation to share information that reveals a safeguarding risk. Any disclosures that occur during MBT-CD and/or BAU sessions will be managed through the site's local safeguarding procedures. As this is a standard part of clinical interactions, the evaluation team will likely not be notified, unless the issue impacts the ability to participate in the study.

Risk disclosures may occur during interviews in the IPE. When arranging interviews, the interviewer

will identify a senior member of the team available during and after the interview to address safeguarding concerns. Safeguarding concerns will be immediately raised with a senior member of the research team and the PI and Safeguarding Lead will be notified. Interviews with children or parents/carers will be followed by a debrief between the interviewer and a senior member of the research team within one business day to ensure timely identification of safeguarding issues.

We will notify the agreed safeguarding contact at the local FCAMHS sites of any identified safeguarding issues, who will follow local procedures for dealing with safeguarding issues. If the research team requires further advice on how to manage the safeguarding concern, the Safeguarding Lead will consult with Clinical Safeguarding Group at Anna Freud, comprised of senior clinicians with experience of managing complex safeguarding issues. The local site leads will follow local procedures for dealing with safeguarding issues. The FCAMHS site holds ultimate safeguarding responsibility for both MBT-CD and BAU participants.

Participants allocated to “Business as Usual” may not receive any intervention directly from FCAMHS, beyond what is set out in the specification as limited intervention, although they will be monitored for the evaluation.

Limited intervention within the child's professional network may involve:

- Clinical supervision to community clinicians, in line with the consultation model.
- Specific training, reflection, or guidance to professionals within the child's network to address specific issues identified during the formulation process.
- Psychoeducation around diagnoses.
- Time-limited support to support children to understand their formulation and next steps.

The comparatively limited support in BAU may be viewed as problematic, as referrers and families may have a belief that there is benefit to receive the intervention. We will clearly set out that families are being invited to take part in the trial (rather than the intervention) and that it is not yet known that the intervention is of benefit. Indeed, more will be expected of those in the intervention arm.

Some of the responses to survey items used in the study will indicate risks (either to the child or to others) that would not have been identified had they not been in the study. These may have to be notified as safeguarding matters. Through the FCAMHS, relevant authorities and/or services may need to then become involved.

13.0. Data protection

AF and UH operate with strict information governance policies, complying with relevant legislation, and all staff receive annual data protection training.

Ahead of ethical approval, we will create privacy notices, a data protection impact assessment (DPIA), and record of data processing activities. We anticipate the legal bases being legitimate interest (Article 6(1)(f)) and archiving for research purposes (Article 9(2)(j)) for special category data.

Where processing criminal data, this will be assessed during completion of the DPIA, and an Appropriate Policy Document and safeguards will be put in place.

Data management will be undertaken by UH's CTSN following standard operating procedures. The trial database will be provided on a REDCap platform supported on an independent server behind the UH firewall. Data protection on the server meets the highest standards (UK Cyber Essentials Certified, meeting ISO 27001). Access to the database will be restricted to relevant staff and necessary areas, with full access audit.

Data sharing agreements will be signed between evaluators and Trusts, as necessary. Data collection and transfer across all strands of the evaluation will only take place via approved secure mechanisms; e.g., use of encrypted Dictaphones for qualitative data. All data will be stored securely and kept strictly confidential. An external company - with an existing non-disclosure agreement - will be used for interview transcription.

Information on the YEF Data Archive will be included in these agreements, privacy notices, participant information sheets and consent forms, in line with YEF guidance. Data obtained from the study, including names, will be securely transferred to the Department of Education who will match data with that held by the Ministry of Justice. Anonymised data will be securely transferred to the Office of National Statistics who will deposit data in the YEF archive indefinitely. Further, anonymised data will be retained by UH and Anna Freud for a period up to 10 years for the purposes of secondary analysis, publications, and queries that may arise through these processes. This retention period is reduced to 5 years for MBT session recordings. Audio recordings of IPE interviews will deleted at the end of the study.

14.0. Stakeholders and interests

Evaluation team

- Julian Edbrooke-Childs – Principal Investigator (AF)
- Hannah Allcott-Watson – Trial Manager (UH)
- Emily Stapley – Qualitative/IPE Lead (AF)
- Karen Irvine – EDI, Mentoring and Governance Support (UH)
- Jess Stepanous – Quantitative Lead (AF)
- Erin Nicholson – Peer Researcher (AF)
- Innamana Pettyll – Research Officer (AF)

With support from:

- Joanna Adler – Forensic Psychology Lead (UH)
- Charli Atkinson-Ryan – Head of EDI (AF)
- Amanda Busby – Statistician (UH)
- Jessica Deighton – Quality Assurance Lead (AF)
- Rachel Hart – Information Governance Manager (AF)
- Jenna Jacob – Research Lead (AF)
- Yifei Jiang – Database Assistant (UH)

- Andrew Laughland – Database Manager (UH)
- Laura Talbot – Safeguarding Lead (AF)
- David Wellsted – Clinical Trials Oversight (UH)

14.1. Developer and delivery team

14.1.1. Developer

The theory underpinning the MBT being used in this trial was developed by Peter Fonagy and Anthony Bateman of Anna Freud. The specific version used in this trial, for conduct disorder, was developed by Svenja Taubner of the University Heidelberg, Germany.

14.1.2. Delivery team lead

Andrew Newman – South West (North) Community FCAMHS (NHS).

14.2. Conflicts of interest

AF has a long tradition of pioneering MBT therapies for children. Peter Fonagy and Anthony Bateman developed the core theory of mentalization through empirical research (Fonagy et al., 2002), that has been developed for children by colleagues such as Nick Midgley. This includes compelling evidence of its role in help-seeking (Fonagy et al., 2015). Employees of AF were instrumental in the development of MBT, but do not have any involvement in this proposed evaluation. We have managed similar potential conflicts of interest like this before in previous projects (e.g., More Good Days at School).

15.0. Risks

A risk register has been completed and a digital copy will be kept in the Trial Master File. The risk register will be reviewed and updated quarterly.

15.1. Study monitoring

CTSN staff will review data for errors and missing key data points. The trial database will be programmed to generate reports on errors and error rates. The TM will monitor the investigator site files and outputs from the data review.

The frequency, type, and intensity of routine and triggered site monitoring will be detailed in the Quality Management and Monitoring Plan, which will detail the procedures for review and sign-off of monitoring reports. The monitoring will be conducted by a member of the CTSN who is independent of the study team.

15.2. Study oversight

15.2.1. Trial Steering Committee (TSC)

The TSC is an independent group that will meet twice a year (approximately every six months) and will provide overall supervision for the study on behalf of the project sponsor (Anna Freud) and the Funder (YEF). It will ensure the trial is conducted to the rigorous standards set out in the DHSC's Research Governance Framework. Overall, 75% of the members will be independent of the

evaluation team. Membership will include independent: PPI member(s), a statistician, and a clinician.

15.2.2. Data Management and Ethics Committee (DMEC)

The DMEC will monitor the safety and progress of the trial. They will meet twice a year (approximately every six months). They ensure the safety rights and well-being of the study participants. They will advise on whether the trial should continue, be modified, or be stopped if safety or ethical issues arise. The DMEC will consist of 3-4 members who will all be independent and will include a statistician. The DMEC will report to the Chair of the TSC.

15.2.3. Trial Management Group (TMG)

This will comprise all co-applicants, members of the CTSN, and the local leads at each site. It will be responsible for monitoring the progress of the study, addressing any key issues that arise, and reporting to the funder, including via the TSC. Meetings will take place at least every three months, but may be more frequent if the phase of the study requires.

15.2.4. Trial Team (TT)

There will be a core team, comprising the PI and the Trial Manager to monitor day-to-day progress. The team will be expanded to include other members of the research team where relevant to the phase of the study. This team will ensure all practical aspects of the study are progressing well and will identify any issues early.

15.2.5. Clinical Trials Support Network (CTSN)

The CTSN is the University of Hertfordshire's Clinical Trials Unit. The CTSN will lead on statistical input, oversee the design, development and delivery of data management, data collection, and data monitoring processes. They will also provide operational oversight and quality assurance of the trial, including input to drafting study documents and access to the quality management system providing Standard Operating Procedures and templates for key documents.

15.2.6. Young Person's Advisory Group (YPAG)

A YPAG of up to 10 EbEs will meet quarterly to provide broad views and perspectives on the research, as described in 'Diversity, equity, and inclusion'.

16.0. Timeline

Table 7 provides an overview of the different phases of the study. Within each phase, key activities are listed along with the team member(s) leading that activity. A detailed breakdown of the timeline is available as a Gannt chart in Appendix 4.

During the internal pilot phase, 13 NHS sites will be set up between April to September 2025 so they are ready to go live in September 2025. This will allow for timescale variations between sites for obtaining local Trust approval. It will also allow for the recruitment of trial staff at each NHS site, specifically the assistant psychologist and where needed, a clinician. Once appointed, clinicians will be trained in MBT-CD, while assistant psychologists will receive training relevant to their role. Two

MBT training windows are available for clinicians, to account for variations in staff recruitment, in August/September 2025, and November/December 2025.

The timeline will be monitored by the TT, who will have oversight for day to day running of the trial, under supervision of the PI. They will provide updates to the TMG who will regularly review the timeline through a standing agenda item for meetings. The TMG will meet every three months, starting in April 2025. Alongside TMG meetings, the TSC will meet every 4-6 months, depending on the study phase, starting in April 2025. See 15.2. Study oversight' for details on members of each oversight group and their respective responsibilities.

To ensure approaches can be applied consistently across sites and study arms, it will be important to have regular communications with trial sites throughout; e.g., fortnightly meetings with site leads moving to monthly at the end of the pilot.

Table 7: *Overview of study phases.*

Dates	Activity	Staff responsible/leading
March 2025 – September 2025	Inception and mobilisation including: - Preparing study documents - Finalising protocol - Ethics approval - Development of the study database - Setting up sites - Setting up oversight groups	Julian/Hannah/Karen
September 2025 – May 2026	Internal pilot including: - Staff recruitment and training - Sites go-live - Participant recruitment - Baseline data collection - Intervention delivery - Interviews to assess acceptability	Hannah/Julian NHS sites (oversight from UH)
May 2025 - June 2025	Review of the pilot including: - Completion of Transition Decision document - YEF review and transition decision - Changes to study documents, database, protocol - Ethics amendment	Julian/Hannah/Karen YEF
June 2026 – June 2027	Full trial including: - Participant recruitment - Baseline data collection - Intervention delivery - Follow-up data collection	NHS sites (oversight from UH)
September 2025 – June 2027	IPE including: - Fidelity ratings of session - Qualitative interviews	Emily

	- Data analysis	
April 2025 – September 2027	Analysis and reporting including: - Quantitative data analysis - Qualitative data analysis - Producing final report - Data archiving	Jess S/Amanda Julian/Hannah

17.0. Publication and dissemination

A Dissemination Policy will be written and submitted for approval to the TSC. The TSC have responsibility for ensuring effective dissemination of the study results. On completion of the study, the data will be analysed and tabulated and a Final Trial Report prepared for presentation to the funder.

The study findings will be disseminated to various stakeholders, including the Grantee, academics, commissioners, Policy makers, and clinicians as well as to an academic audience.
There are several intended outputs of the research:

- Study protocol;
- Statistical analysis plan;
- Interim report based on the internal pilot;
- Final report;
- Summaries of findings for sites and participants available through email or study webpages;
- Peer reviewed journal articles with public summaries (three are estimated: pilot findings, RCT findings, and IPE findings). Articles will be submitted to YEF for approval ahead of publication;
- Presentation at academic conferences – both orally and poster.

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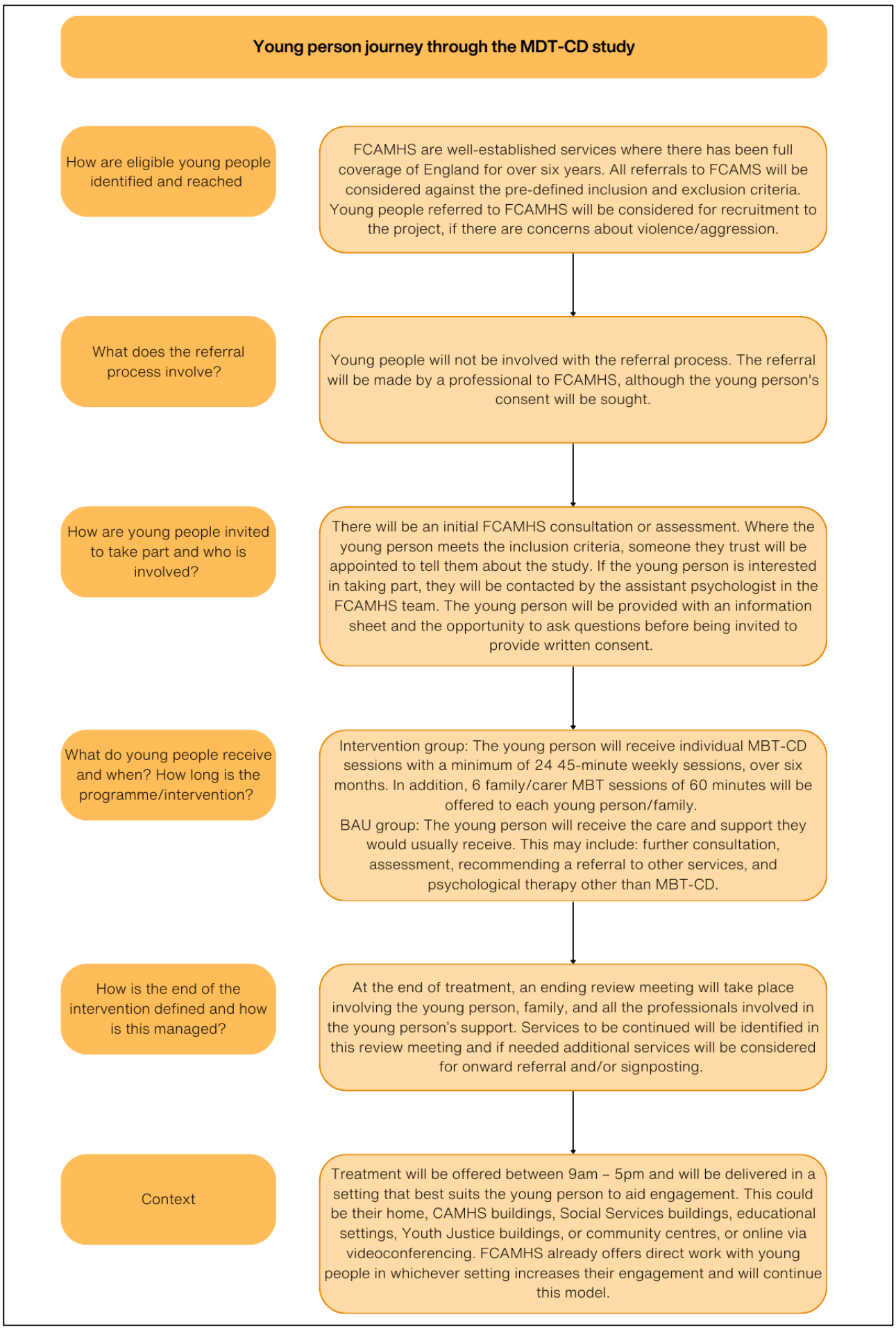
Appendix 1: Child journey



Appendix 2: Theory of Change

WHY		WHO	HOW	WHAT will the intervention achieve?		
Evidence-based assumption	**Evidence-based assumption**	**Evidence-based assumption**	**Intervention**	**Evidence-based short-term outcomes**	**Evidence-based medium-term outcomes**	**Evidence-based long-term outcomes**
Evidence-based observations	**Evidence-based need**	**Target population**	**Intervention activities that will address the need and how it will work**	**Intermediate outcomes**	**Intermediate outcomes**	**Primary outcomes**
There is a cohort of children, often known to multiple agencies who are involved in, or at risk of becoming involved in crime and violence. Children supported by Community Forensic Child and Adolescent Mental Health Services (F-CAMHS) are some of the most vulnerable in the	There is a need for evidence-based interventions to support children with conduct difficulties experiencing high levels of risk, harm, and vulnerability. The children referred to F-CAMHS are often supported by a number of services, but this often focusses on managing risk	Children 10-17 years old referred to F-CAMHS through statutory routes (e.g., social care, CAMHS, Youth Justice System (YJS)) due to the possible association between their offending behaviours and histories of mental-ill health, neglect or abuse and display disordered conduct.	MBT-CD aims to challenge disordered conduct (e.g. repeated aggression towards others) by addressing the assumed pathological mechanisms underlying the disordered behaviours to improve the ability to understand and predict the effect of one's behaviour on the self and others. The intention is that young people will develop an understanding of interpersonal situations and emotions, specific	Child is enabled to experience a trusting relationship with the clinician. Child is enabled to experience being mentalized by the clinician. Therapeutic goals are achieved. Child is better able to mentalize themselves. Child is better able to mentalize others. Potential for increased distress due to better	Child and their carer/family are better able to maintain mentalizing and get it back on track quicker when lost. Child and their carer/family are better able to maintain mentalizing more consistently across different contexts. Initial reduction in behavioural difficulties.	Sustained reduction in aggression and violence (type, severity and/or frequency). The primary outcome measure will be the Reactive Proactive Aggression Questionnaire (Raine et al. 2006). This will be supplemented by use of administrative data and assessments routinely made

country, at risk of exploitation by and of others and frequently displaying significant, repeated levels of violence and aggression. These children are currently under-served and experience deleterious long-term outcomes: - involvement in crime and violence; being housed in the children and young people's secure estate; - experiencing poor mental health; and - having low levels of access to education,	through behaviour modification, without considering drivers or motivations underlying young people's behaviours. The levels of vulnerability for this cohort mean there is • a lack of specialist input to help tackle the underlying causes of the difficulties and risk and • a lack of services with	Specifically, those who meet one or more of the following criteria: Experience conduct difficulties, particularly those associated with chronic violence and/or aggression;_ Are at high levels of risk of harm, vulnerability, exploitation, and trauma as assessed by the referring agencies using tools such as AssetPlus (see also statutory guidance on case assessment of young people who have offended);	triggers and mentalization breakdowns associated with antisocial and aggressive behaviour (Taubner et al., 2021). Also, that children's emotion regulation will improve and their scope of action will increase through enhancing effective mentalizing (Hauschild et al., 2023). MBT-CD has been developed out of MBT for borderline personality disorder. A guide for intervention has been created (Taubner and Hauschild, 2021) and will be adapted further in the pilot phase, for use in Community F-CAMHS. It has three broad components: psychoeducation, mentalizing the self, and mentalizing others.	understanding of harmful relationships (although this would be managed in sessions).	Some reduction in aggression and violence. Improved conflict management/resolution skills. Improved emotional regulation. Reduced emotional difficulties. Improved engagement with statutory agencies. Improved family/carer relationships. Improved peer relationships. Potential for increased harm due to disengagement with exploitative others (although this would be managed as part	within F CAMHS, including use of the HoNOSCA (Gowers et al. 1999). Reduced involvement in crime. Reduced interaction with the YJS. Children are supported to have stable engagement with education, employment, and training. Increased stability in living situations and placements (e.g., family, care). Reduced numbers, severity, and frequency of victims of crime. Reduction in risk of harm to self

employment, and training. Mentalizing has been identified as a protective factor against externalizing behaviours such as aggression and delinquency (Taubner et al., 2016; Morosan et al., 2020) and therefore, MBT-CD is posited to be beneficial for those young people typically referred to F-CAMHS.	sufficient specialism to do so. The cohort of children have often been under-served and not had formal or consistent mental health support.	Are looked after children and/or care-experienced; Have previous experiences of intervention characterised by a lack of trust; Are in contact with the (YJS). Have neuro-developmental conditions, are neuro-non typical, and/or have learning difficulties; Live in complex, challenging, and transient contexts.	Each young person will have a tailored intervention but there are standard ways of working, comprising: Initial formulation of current challenges in mentalizing and desired endpoints for treatment, co-produced between clinician and referred young person, potentially including their parents and/or carers; Sessions will start with engagement, identifying problem priorities and then setting a focus that synthesises problems; Clinicians will assess the types and levels of mentalizing being used by young people within sessions, and adjust each session, responding actively; Clinicians will draw on a 'not knowing stance'		of standard F-CAMHS support).	and others (e.g., hospitalisations).

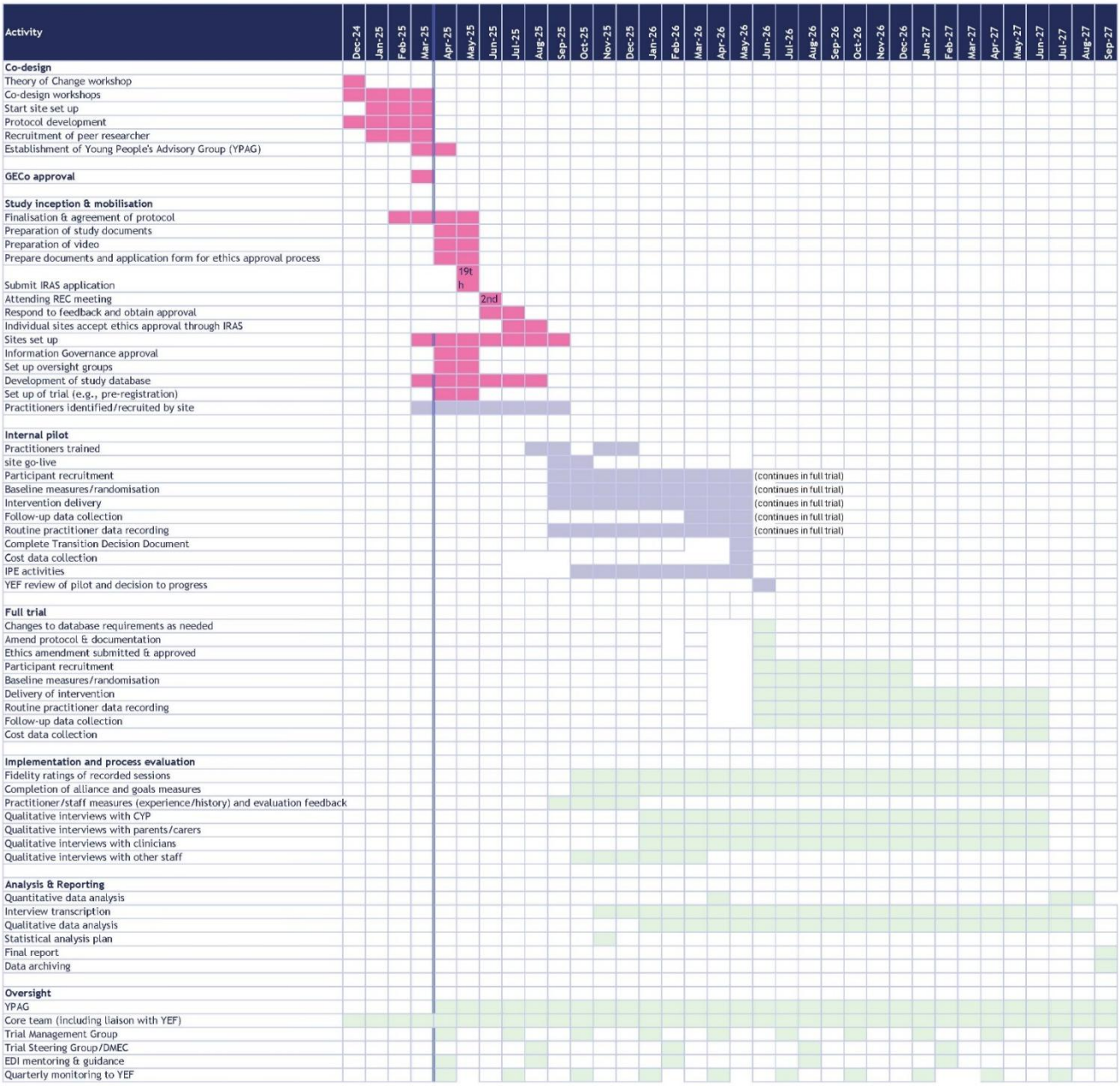
			throughout sessions--asking children to explain, not assuming mutual understanding; Clinicians will have a focus on mentalizing processes, managing young people's arousal using specifically developed techniques including: contrary moves away from the stimulus; parking the idea/action that was associated with the arousal and validating the young person's responses; Clinicians will actively hold an affect focus, that demonstrates clarification, affect identification and mentalizing functional analysis of an event; Clinicians will also mentalize the therapist, client and family relationships as well as mentalizing counter-			

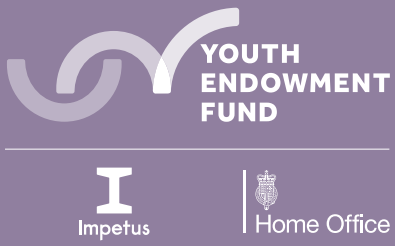
			relationships in family sessions.			

Appendix 3: Recruitment targets.

	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	Jul-26	Aug-26	Sep-26	Oct-26	Nov-26	Dec-26	Jan-27	Feb-27	Mar-27	Apr-27	May-27	Jun-27	Jul-27	Aug-27	
Month by month																									
Site 1	3	3	4	2	3	3	3	4	4	4	3	2	4	4	4	3									53
Site 2	3	3	4	2	3	3	3	4	4	4	3	2	4	4	4	3									53
Site 3	3	3	4	2	3	3	3	4	4	4	3	2	4	4	4	3									53
Site 4	3	3	4	2	3	3	3	4	4	4	3	2	4	4	4	3									53
Site 5	3	3	4	2	3	3	3	4	4	4	3	2	4	4	4	3									53
Site 6	3	3	4	2	3	3	3	4	4	4	3	2	4	4	4	3									53
Site 7	3	3	4	2	3	3	3	4	4	4	3	2	4	4	4	3									53
Site 8	3	3	4	2	3	3	3	4	4	4	3	2	4	4	4	3									53
Site 9	2	3	4	2	3	3	3	4	4	4	3	2	4	4	4	3									52
Site 10	2	3	4	2	3	3	3	4	4	4	3	2	4	4	4	3									52
Site 11	2	3	4	2	3	3	3	4	4	4	3	2	4	4	4	3									52
Site 12	2	3	4	2	3	3	3	4	4	4	3	2	4	4	4	3									52
	32	36	48	24	36	36	36	48	48	48	36	24	48	48	48	36									632
Cumulative																									
Site 1	3	6	10	12	15	18	21	25	29	33	36	38	42	46	50	53	53	53	53						
Site 2	3	6	10	12	15	18	21	25	29	33	36	38	42	46	50	53	53	53	53						
Site 3	3	6	10	12	15	18	21	25	29	33	36	38	42	46	50	53	53	53	53						
Site 4	3	6	10	12	15	18	21	25	29	33	36	38	42	46	50	53	53	53	53						
Site 5	3	6	10	12	15	18	21	25	29	33	36	38	42	46	50	53	53	53	53						
Site 6	3	6	10	12	15	18	21	25	29	33	36	38	42	46	50	53	53	53	53						
Site 7	3	6	10	12	15	18	21	25	29	33	36	38	42	46	50	53	53	53	53						
Site 8	3	6	10	12	15	18	21	25	29	33	36	38	42	46	50	53	53	53	53						
Site 9	2	5	9	11	14	17	20	24	28	32	35	37	41	45	49	52	52	52	52						
Site 10	2	5	9	11	14	17	20	24	28	32	35	37	41	45	49	52	52	52	52						
Site 11	2	5	9	11	14	17	20	24	28	32	35	37	41	45	49	52	52	52	52						
Site 12	2	5	9	11	14	17	20	24	28	32	35	37	41	45	49	52	52	52	52						
	32	68	116	140	176	212	248	296	344	392	428	452	500	548	596	632	632	632	632						
Number randomised to MBT-CD																									
Site 1	1.5	3	5	6	7.5	9	10.5	12.5	14.5	16.5	18	19	21	23	25	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	
Site 2	1.5	3	5	6	7.5	9	10.5	12.5	14.5	16.5	18	19	21	23	25	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	
Site 3	1.5	3	5	6	7.5	9	10.5	12.5	14.5	16.5	18	19	21	23	25	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	
Site 4	1.5	3	5	6	7.5	9	10.5	12.5	14.5	16.5	18	19	21	23	25	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	
Site 5	1.5	3	5	6	7.5	9	10.5	12.5	14.5	16.5	18	19	21	23	25	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	
Site 6	1.5	3	5	6	7.5	9	10.5	12.5	14.5	16.5	18	19	21	23	25	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	
Site 7	1.5	3	5	6	7.5	9	10.5	12.5	14.5	16.5	18	19	21	23	25	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	
Site 8	1.5	3	5	6	7.5	9	10.5	12.5	14.5	16.5	18	19	21	23	25	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	26.5	
Site 9	1	2.5	4.5	5.5	7	8.5	10	12	14	16	17.5	18.5	20.5	22.5	24.5	26	26	26	26	26	26	26	26	26	
Site 10	1	2.5	4.5	5.5	7	8.5	10	12	14	16	17.5	18.5	20.5	22.5	24.5	26	26	26	26	26	26	26	26	26	
Site 11	1	2.5	4.5	5.5	7	8.5	10	12	14	16	17.5	18.5	20.5	22.5	24.5	26	26	26	26	26	26	26	26	26	
Site 12	1	2.5	4.5	5.5	7	8.5	10	12	14	16	17.5	18.5	20.5	22.5	24.5	26	26	26	26	26	26	26	26	26	
In treatment, assuming no dropout and 6 month duration																									
Site 1	1.5	3	5	6	7.5	9	9	9.5	9.5	10.5	10.5	10	10.5	10.5	10.5	10	8.5	7.5	5.5	3.5	1.5	0	0	0	
Site 2	1.5	3	5	6	7.5	9	9	9.5	9.5	10.5	10.5	10	10.5	10.5	10.5	10	8.5	7.5	5.5	3.5	1.5	0	0	0	
Site 3	1.5	3	5	6	7.5	9	9	9.5	9.5	10.5	10.5	10	10.5	10.5	10.5	10	8.5	7.5	5.5	3.5	1.5	0	0	0	
Site 4	1.5	3	5	6	7.5	9	9	9.5	9.5	10.5	10.5	10	10.5	10.5	10.5	10	8.5	7.5	5.5	3.5	1.5	0	0	0	
Site 5	1.5	3	5	6	7.5	9	9	9.5	9.5	10.5	10.5	10	10.5	10.5	10.5	10	8.5	7.5	5.5	3.5	1.5	0	0	0	
Site 6	1.5	3	5	6	7.5	9	9	9.5	9.5	10.5	10.5	10	10.5	10.5	10.5	10	8.5	7.5	5.5	3.5	1.5	0	0	0	
Site 7	1.5	3	5	6	7.5	9	9	9.5	9.5	10.5	10.5	10	10.5	10.5	10.5	10	8.5	7.5	5.5	3.5	1.5	0	0	0	
Site 8	1.5	3	5	6	7.5	9	9	9.5	9.5	10.5	10.5	10	10.5	10.5	10.5	10	8.5	7.5	5.5	3.5	1.5	0	0	0	
Site 9	1	2.5	4.5	5.5	7	8.5	9	9.5	9.5	10.5	10.5	10	10.5	10.5	10.5	10	8.5	7.5	5.5	3.5	1.5	0	0	0	
Site 10	1	2.5	4.5	5.5	7	8.5	9	9.5	9.5	10.5	10.5	10	10.5	10.5	10.5	10	8.5	7.5	5.5	3.5	1.5	0	0	0	
Site 11	1	2.5	4.5	5.5	7	8.5	9	9.5	9.5	10.5	10.5	10	10.5	10.5	10.5	10	8.5	7.5	5.5	3.5	1.5	0	0	0	
Site 12	1	2.5	4.5	5.5	7	8.5	9	9.5	9.5	10.5	10.5	10	10.5	10.5	10.5	10	8.5	7.5	5.5	3.5	1.5	0	0	0	

Appendix 4: Project Gantt chart.





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The Youth Endowment Fund Charitable Trust

Registered Charity Number: 1185413