EVALUATION PROTOCOL

Evaluation of Tavistock Relationships MBT-PP to improve child outcomes by reducing inter-parental conflict: a pragmatic efficacy randomised controlled trial with internal pilot

Sheffield Hallam University

Principal investigator: Professor Abigail Millings

YOUTH ENDOWMENT FUND

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Evaluation protocol

Evaluating institution: Sheffield Hallam University
Principal investigator(s): Dr Abigail Millings

Project title[1]	Evaluation of Tavistock Relationships MBT-PP to improve child outcomes by reducing inter-parental conflict: a pragmatic efficacy randomised controlled trial with internal pilot
Developer (Institution)	Tavistock Relationships
Evaluator (Institution)	Sheffield Hallam University
Principal investigator(s)	Prof Abigail Millings
Protocol author(s)	Prof Abigail Millings, Dr Elaine Clarke, Sean Demack, Prof. John Reidy, Prof. Maddy Arden, Dr Charlotte Coleman, Anna Stevens, Dr Kate Whitfield
Trial design	Two armed balanced 2-level clustered RCT with children clustered into (referred) families and randomisation at the family level.

Trial type	Efficacy with internal pilot
Evaluation setting	3 x local authorities (Bristol, Bournemouth, Christchurch & Poole (BCP) and Dorset). Intervention will be embedded into Early Help, creating a 'reducing parental conflict' referral pathway
Target group	Families with children/young people aged 8-14 experiencing inter-parental conflict
Number of participants	We will recruit 350 families with approx. 700 children and young people (CYP), to retain 630 CYP to trial completion
Primary outcome and data source	Child externalising and internalising problems (as measured by the parent report SDQ 'difficulties' scale)
Secondary outcome and data source	Inter-parental conflict (parent report and child report) Child psychological well-being (child report) Parenting style (parent report) Parent mentalising capacity (parent report) Parent anger expression (parent report) Parent emotional adaptation (parent report)

Protocol version history

Version	Date	Reason for revision
3.1 [latest]	10-05-24	Amended inclusion criteria to allow families with CYP turning 8 during intervention phase to participate. Amended progression criteria to include % of 2 vs 1 parent engaging families. Rephrased progression criteria for attrition to eliminate duplication and assess for systematic differences

		between arms. Changed time window for progression criterion on eligibility of referrals to account for project delay and subsequent extension to pilot phase.
3 [latest]	24-11-23	Amended recruitment strategy to allow families to be accepted into the trial with one willing parent. Timescales updated with four-month extension to pilot delivery period.
2.3	06-09-23	Amended descriptions of inclusion/exclusion criteria and piloting of qualitative evaluation materials to reflect trial processes. Updated diversity training info. Other minor inconsistencies corrected.
2.2	12-05-23	Minor amendments to correct inconsistencies
2.1	02-02-23	Minor amendments to correct inconsistencies
2	16-01-23	Revised according to feedback following award of funding
1.1	21-10-22	Revised according to feedback
1.0 [*original*]	30th September 2022	

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Study rationale and background

Interparental conflict (IPC), whether in separated or intact families, is consistently related to poorer child adjustment (van Eldik et al., 2020), and this link is often mediated by parenting style (van Dijk et al., 2020). Research suggests that children fare better following parental separation or divorce when their parents engage in supportive and cooperative co-parenting, and that the absence of this can be a risk factor for poor child outcomes, such as emotional and behavioural problems and poor academic outcomes (Adamsons & Pasley, 2006). IPC in both intact and separated families is problematic for children, with hostility being related to externalising behaviours and emotional responses (van Eldik et al., 2020). However, it is important to note that low relationship quality, conflict frequency, and specifically child-related conflict are also damaging (van Eldik et al., 2020).

While the short, medium and long-term damaging effects of IPC on children are well-established, there is paucity of evidence-based interventions to reduce IPC. An additional barrier is the lack of an established referral pathway for families to access support with IPC. Because IPC is a problem that crosses multiple domains, such as health, education, social care, family law, and economic security, there is no obvious single referral point, and a high degree of coordination between sectors would be required to create one. That said, significant inroads have been made in recent years to tackling the issue. Two notable examples come from the Department for Work and Pensions (DWP) and the Ministry of Justice (MoJ). The DWP's Reducing Parental Conflict (RPC) programme funded the delivery of IPC interventions in 31 LAs from 2019-2021. Illustrating the scale of the challenge of creating referral pathways, the RPC evaluation highlighted that *"prior to being approached by the RPC programme, it was common for local authorities not to have thought about tackling parental conflict below levels amounting to domestic abuse. In many areas parental conflict had not historically been seen as a policy area or priority."* Separately, the MoJ announced early in 2021 two pathfinder pilot court sites which have the authority to pilot new ways of working with family separation, to combat both the family court demand crisis and the propensity for many troubled families to seek legal solutions to problems more requiring therapeutic support (likely because no such therapeutic offering exists). These pilots are due to run until February 2024, with subsequent roll-out anticipated if they are successful. This policy landscape illustrates both the need and political will to create better access to appropriate support for IPC and highlights the urgency of establishing an evidence base for IPC interventions.

Mentalising Based Therapy for Parenting under Pressure (MBT-PP) is a brief, manualised therapy programme designed to reduce IPC by supporting the parents to mentalise about their child's experience, and the motivations and experiences of each other (Hertzmann et al., 2016). By developing the capacity to mentalise about the other people involved in the conflict, parents learn to understand their child's perspective and the impact the conflict has

on them. Parents also learn to understand each other's perspectives such that actions which might previously have been attributed to hostile motivations are viewed in a more balanced way. The insights that parents glean into each other's and their child's experiences lead to a reduction in conflict and more adaptive ways to manage disagreements. A small-scale random allocation feasibility study compared MBT-PP to treatment as usual (a Parents' Group, 'PG') and found encouraging support for this (Hertzmann et al., 2016; Hertzmann et al., 2017). Thirty parents (15 pairs of separated co-parents who were entrenched in chronic and intense conflict over their children), completed quantitative measures and qualitative interviews (pre and post-intervention) to explore several outcome variables. Both intervention groups (MBT-PP and PG) showed statistically significant improvements in reported: 1) expressions of anger towards the ex-partner; 2) levels of stress and depression; and 3) behavioural and emotional difficulties experienced by their children. Furthermore, in both groups, attitudes towards the ex-partner improved. Following MBT-PP in particular, parents' descriptions of their ex-partners became less polarised and they were more able to accept that their co-parent was likely experiencing similar feelings and motivations to themselves (Hertzmann et al., 2016; Hertzmann et al., 2017). Importantly, whilst the study failed to detect a significant difference in the parents' ability to mentalise according to the quantitative measures, the qualitative findings suggested that nuanced shifts in this had occurred. The authors posited that the study may have only detected the first part of a process of change, with a larger, longer-term study better able to establish what was going on (Hertzmann et al., 2016). Overall, the study showed promise and suggested that a full-scale RCT would be warranted. Recently, Tavistock Relationships have provided MBT-PP as part of the Department of Work and Pensions' Reducing Parental Conflict programme, delivering MBT-PP to over 1,000 parents in 2022.

Evaluation Design

The current evaluation of MBT-PP is a pragmatic randomised controlled trial with internal pilot study. All referrals will be randomised to receive either MBT-PP or Treatment as Usual (TAU).

The trial design is simple in structure, and aims to compare the effects of MBT-PP against TAU on a range of measures. Participants (parents and children) will complete baseline measures before being randomised to receive either MBT-PP or TAU. After 16 weeks (when MBT-PP is complete) the baseline measures will be repeated (post-intervention). Three months after the end of the intervention (3-month follow-up), measures will be repeated a final time. The inclusion of a number of secondary measures enables the trial not only to answer the question of whether MBT-PP is effective in improving child outcomes as measured by the SDQ, but also to identify the mechanisms of action for these positive effects.

A concurrent implementation and process evaluation (IPE) will run throughout both the pilot and efficacy phases. The IPE will be designed to generate insights into the challenges associated with formulating the referral pathways, as well as the processes associated with the delivery of the intervention.

Intervention

MBT-PP

Tavistock Relationships' Mentalization Based Therapy – Parenting Under Pressure (MBT-PP) is a 10-week intervention for parents which is suitable for separated parents or intact couples. The 10 sessions across 16 weeks include 2 assessment sessions and 8 sessions that begin by introducing the skills and behaviours necessary for mentalizing: the capacity to hold others in mind when emotionally aroused and to avoid a swift eruption of conflict. The subsequent sessions build on this ability to think about parents' own feelings and beliefs, those of their partner, and the needs of their children, ending with a focus on how to maintain the achievements made.

Who: The target population for this intervention is parents of children experiencing high levels of persistent and unresolved conflict. The intervention is delivered to parents only – there is no direct therapeutic work with children. This evaluation focuses specifically on parents of children aged 8-14 years. Recruitment will be via referrals from Early Help in 3 local authorities: Dorset Council, Bournemouth, Christchurch, and Poole (BCP) Council, and Bristol City Council.

What: The intervention consists of MBT-PP, delivered online. After an initial assessment period, which consists of individual sessions for each parent with the therapist, both parents will take part in joint sessions, online, with the therapist. If only one parent is willing to take part, the therapist will work with that parent on their own. MBT-PP is delivered by MBT-PP practitioners, all of whom are qualified therapists, counsellors, family therapists, or child and adult psychotherapists, accredited and registered with their relevant professional bodies (BACP, UKCP, AFT etc.) and compliant with the requirements of these professional bodies, including ethical standards and professional supervision. Treatment fidelity is supported through fortnightly group supervision, offered by MBT-PP Supervisors who have received additional training. Supervisors attempt to ensure adherence to, and prevent departure from the manualised intervention. This allows TR to maintain fidelity, clinical oversight, manage risk and develop practitioners' skills further. Supervisors' work, in turn, is overseen by monthly supervision of supervisors, delivered by the most experienced MBT-PP leaders.

How much: The intervention consists of 10 sessions delivered over (approximately) 16 weeks. The first 2 sessions last up to 75 minutes, and sessions 3-7 inclusive last 60 minutes. Sessions are usually delivered weekly or fortnightly, allowing participants some scheduling flexibility. Sessions are delivered online, via secure Zoom or Teams calls, depending on client preference.

Treatment as usual (TAU)

Because of the aforementioned under-developed pathways for tackling IPC in LAs, it is likely that true TAU, that is, what would occur in the absence of this trial, will vary extremely widely. Because of the nature of family support provision by LAs, understanding the precise nature and content of all the possible interventions is not possible. For example, we would not be able to appraise the intensity or content of family support worker visits to a family home, in which the impact of IPC on the children may either become a focal point, or be tackled much more indirectly, if at all. In this scenario it would be very difficult to understand whether the active ingredients of MBT-PP are in fact unique to the intervention received in the MBT-PP arm.

Two of the partner LAs (Dorset and BCP) already use a suite of digital resources for IPC produced by OnePlusOne (OPO), a charity that focuses on the development of healthy relationships. These resources are a low intensity intervention, designed to be best used in a guided capacity, spread over several weeks, rather than as pure self-help. The suite comprises 3 programmes, 2 of which are relevant to the target group: *Argue Better* (AB), which is targeted at couples experiencing conflict, and *Getting It Right for Children* (GIRFC), which is targeted at separating/separated parents experiencing conflict. These programmes are currently in use in 72 LAs in England and the whole of Wales. The programmes are based on behaviour modelling training, which is distinct from, and shares no overlap with the psychoanalytic underpinnings of MBT-PP.

There is no single digital programme for reducing parental conflict that is suitable for both intact and separated parents. This is likely to be because digital interventions rely heavily on scenarios and examples that need to be relatable to parents' own experiences. Conversely, live, face-to-face interventions delivered by a therapist have the scope to be tailored to individual circumstances and idiosyncrasies, while still adhering to the intended therapy. This means that while MBT-PP can be used with both intact and separated parents, digital programmes (which do not involve a live therapist) cannot be so flexible.

That 2 of the partner LAs are already using these programmes offers an opportunity to standardise, as far as possible, the content of TAU to involve known content. TAU will therefore include LA staff using the OPO digital resources in their work to support families who are referred to the project but randomised not to receive MBT-PP. LA staff will use GIRFC

and AB as appropriate, depending on the parental relationship status. This means that TAU offers an appropriate intervention, targeted for IPC, but one that is far less intense and from a different theoretical standpoint than MBT-PP. While it is likely that TAU will also involve other interventions as appropriate (for example a family needing housing advice will receive housing advice), positioning the OPO programmes in TAU ought to minimise the variation of LA staff practice *as it relates to IPC specifically*, in TAU. Training will be provided in the 3 partner LAs to promote the OPO resources and best way to use them.

LA staff will not be asked to withhold any specific forms of support from those allocated to the TAU arm of the trial.

Delivery period

MBT-PP delivery will commence after a 3-month set up period, and recruitment will continue into the final quarter of the second project year. Ceasing new referrals at the end of the final quarter of the second project year ensures sufficient time for both the intervention (lasting 16 weeks) and post-intervention data collection to be completed before the data analysis and reporting phase (final 3 months of the project). The 3 month follow up data collection will run concurrently with the data analysis and reporting phase. It should be noted that during the co-design phase, both the delivery team and the evaluation team were of the opinion that ceasing referrals during the transition from pilot to efficacy would not be practical or in the best interests of the evaluation. This is due to the extensive labour involved in setting up, including securing buy-in and changing working practices of frontline staff. Cutting this off once referrals have begun to flow would be hugely detrimental and risk damaging front line staff's positive perceptions of the project, on which we are dependent for referrals. It would also not serve the goal of avoiding wasted referrals, because if the project is removed, cases that would have been referrals will not wait; they will move on to other, less targeted services, or potentially even commence legal action, which would render them excluded from participating. Hence, the project team and evaluators requested permission not to halt delivery during transition, and this was agreed.

Incentives

Voucher incentives will be used to thank participants (parents and CYP) in both arms of the trial for questionnaire completion and for participation in interviews (a small subset of the total sample). To minimise attrition from the research processes (completion of measures), a structured incentive system will be used. Vouchers for questionnaire completion will be provided after each data collection point and will include a bonus for complete data collection (i.e., completing all 3 time points) after the final questionnaire, to maximise participant retention.

Racial diversity and inclusion considerations

The three locations in which we will deliver this evaluation vary considerably in demographics, and we expect this to be reflected in our sample.

Table 1. Ethnicity statistics of the three LA areas

	England		Bristol (city of)		BCP		Dorset	
	N (000's)	%	N (000's)	%	N (000's)	%	N (000's)	%
White British	43,519	78.7%	357	78.1%	346	88.0%	352	94.4%
White Other	3,407	6.2%	37	8.1%	30	7.6%	13	3.5%
Mixed / Multiple Ethnic Groups	968	1.8%	7	1.5%	3	0.8%	1	0.3%
Asian / Asian British	4,396	8.0%	25	5.5%	8	2.0%	4	1.1%
Black / Black British	1,946	3.5%	23	5.0%	2	0.5%	1	0.3%
Other Ethnic Group	1,032	1.9%	8	1.8%	4	1.0%	2	0.5%
ALL	55,268	100%	457	100%	393	100%	373	100%

Source: Ethnicity statistics at local authority level - Office for National Statistics (ons.gov.uk)

Note: BCP – Bournemouth, Christchurch & Poole. ONS has Christchurch as a subsample (lower area) of Dorset. Therefore, the above stats show Dorset (minus Christchurch) and BCP adds numbers for Bournemouth, Christchurch & Poole areas.

We aim to ensure that race, ethnicity, and inclusion are a key focus throughout all stages of the evaluation, from design through to reporting. We recognise that our team is predominantly White British and hence we may require additional support in this regard to ensure that the evaluation is welcoming and inclusive to all. We will be guided by a race equity consultant, who we will hire externally. We have costed for this with agreement with YEF.

All Sheffield Hallam University staff undertake unconscious bias diversity training as part of standard operating procedures. For the purposes of this project, we additionally commit to the research team completing racial diversity training delivered by an external provider.

In order to ensure that the evaluation is as inclusive as possible, we will offer translation of all evaluation materials into other languages as required. This will be managed on an ongoing basis as required by close communication between LA project partners and evaluation team.

We will also seek feedback on our qualitative evaluation materials (participant information sheet and interview topic guide) from an external race equity expert, and parents from minority ethnic groups to check for cultural sensitivity and appropriateness, and will seek feedback on the interview process from the first five parents from ethnic minority backgrounds who attend an interview to inform our approach to subsequent interviews.

Based on the demographic data presented above, we expect that the proportion of our final sample who are of minority ethnic origin will be small and preclude formal testing of minority status as a moderator of treatment effects. We will, however, explore this issue using descriptive statistics. We will compare characteristics of participants who completed vs. did not complete the intervention, to assess whether systematic factors (e.g., deprivation, ethnicity) are associated with engagement with MBT-PP. We will employ purposive sampling in the IPE elements of the trial in order that the experiences of minority ethnic groups are heard. We will take the race equity consultant's advice on whether we also need to hire researchers who are more representative of the communities we are trying to reach to conduct the interviews, and we will manage this within our budget if so.

Impact evaluation

Primary Research Question

RQ1 Does MBT-PP (compared to TAU) delivered to parents experiencing IPC lead to lower externalising and internalising behaviours in children aged 8-14 (as measured by the SDQ 'difficulties' scale)?

Secondary Research Questions

RQ2 Does MBT-PP (compared to TAU) delivered to parents experiencing IPC lead to higher wellbeing in children aged 8-14 (as measured by the Stirling Children's Well-being Scale)?

RQ3 Does MBT-PP (compared to TAU) delivered to parents experiencing IPC lead to lower IPC reported by parents (as measured by the O-Leary-Porter Scale)?

RQ4 Does MBT-PP (compared to TAU) delivered to parents experiencing IPC lead to lower IPC reported by children (as measured by the Children's Perception of Interparental Conflict Scale)?

RQ5 Does MBT-PP (compared to TAU) delivered to parents experiencing IPC lead to lower parent anger expression (as reported by the Dimensions of Anger Reactions-Revised)?

RQ6 Does MBT-PP (compared to TAU) delivered to parents experiencing IPC lead to higher mentalising ability in parents (as reported by the Parental Reflective Function Questionnaire)?

RQ7 Does MBT-PP (compared to TAU) delivered to parents experiencing IPC lead to more positive parenting (as measured by the Parenting Scale Short Form PS-8)?

RQ8 Does MBT-PP (compared to TAU) delivered to separated parents experiencing IPC lead to better parent emotional adaptation to relationship dissolution (as measured by the EARDA)?

Mechanisms of Action Research Questions

To address not only whether the intervention works, but also how the intervention works, we will also test the exploratory mediation models depicted in Figure 1 and Figure 2.

RQ9 Is the effect of MBT-PP (compared to TAU) on externalising and internalising behaviours in children aged 8-14 (as measured by the SDQ 'difficulties' scale) mediated by parent mentalising, parent anger expression, parent report IPC, child perception of IPC, parenting style, or parent emotional adaptation?

RQ10 Is the effect of MBT-PP (compared to TAU) on wellbeing in children aged 8-14 (as measured by the Stirling Children's Well-being Scale) mediated by parent mentalising, parent anger expression, parent report IPC, child perception of IPC, parenting style, or parent emotional adaptation?

Figure 1. Examining the mechanisms by which MBT-PP may improve children's externalising and internalising behaviours

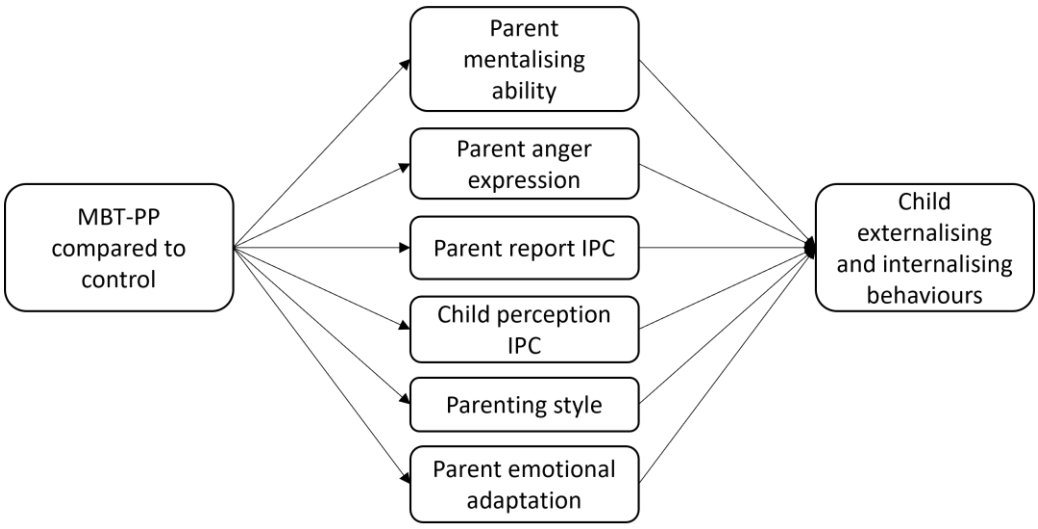
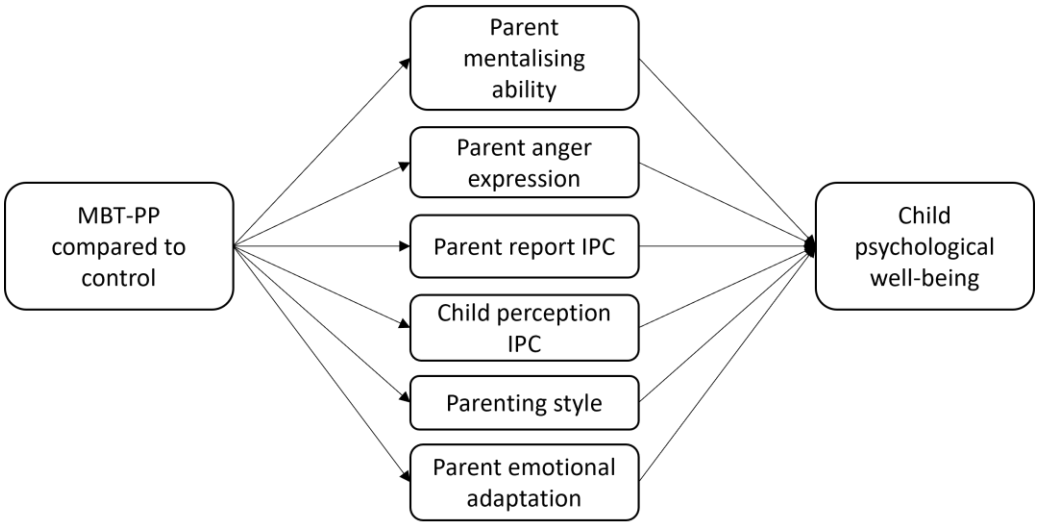


Figure 2. Examining the mechanisms by which MBT-PP may improve children's psychological well-being



Design

Table 2. Trial design

Trial design, including number of arms		Pragmatic two arm cluster RCT
Unit of randomisation		Family
Minimisation variables (if applicable)		Age group (all CYP aged 8-11 / all CYP aged 12-14 / CYP aged 8-11 and 12-14), Minority ethnic group status of one or both parents (yes / no), relationship status (separated/intact)
Primary outcome	variable	a) Child internalising and externalising
	measure (instrument, scale, source)	a) Parent reported SDQ, total difficulties scale (Goodman, 1997)
Secondary outcome(s)	variable(s)	b) Child psychological well-being c) Parent report IPC d) Child perception of IPC e) Parent anger f) Parent mentalising capacity g) Parenting style h) Parent emotional adaptation to separation (separated parents only)
	measure(s) (instrument, scale, source)	b) Stirling Children's Well-being Scale (Liddle & Carter, 2015) c) O'Leary-Porter Scale (Porter & O'Leary, 1980) d) Perceptions of Interparental Conflict-Intensity/Frequency Scale (PIC-I/F) (Kline, Wood & Moore, 2003) e) Dimensions of Anger Reactions- Revised (DAR-R; (Nederlof, Hovens, Muris & Novaco, 2009) f) Parental Reflective Function Questionnaire (Luyten et al., 2009) g) Parenting Scale Short Form (PS-8) (Kliem et al., 2019), a short form of the Parenting Scale (Arnold et al., 1993) h) Emotional Adaptation to Relationship Dissolution Assessment (Millings et al., 2020)

Baseline for primary outcome	variable	Scores at baseline (pre-randomisation) on variables listed above
	measure (instrument, scale, source)	As above
Baseline for secondary outcome	variable	Scores at baseline (pre-randomisation) on variables listed above
	measure (instrument, scale, source)	As above

Randomisation

Randomisation will be conducted on all consenting referrals (referral and consent procedure are outlined below) as they occur. Because recruitment will be rolling, classic random stratification is not feasible. We will therefore use minimisation (Scott et al., 2002; Altman & Bland, 2005) whereby allocation is random initially and then systematic to minimise differences between groups across a few specified strata within LAs, specifically, child age, parent minority ethnic group status, and relationship status (intact or separated). In the context of rolling recruitment, a minimisation approach will best ensure that the MBT-PP and TAU samples are comparable in terms of the specified strata. The minimisation will be undertaken using the MininPy software.

Participants

Participants will be referred to the project by LA staff (e.g., Early Help practitioners) through an online form. LA staff will be provided with information/training about the project detailing that it is for:

- Parents experiencing high intensity, frequent and unresolved IPC, who have at least one child aged between 8 and 14 years old
- They do not have to live together, or be in a current relationship, but should be willing to think about how they can improve their relationship with their co-parent.
- Parents will need to consent to the referral being made and have an understanding that the work will focus on the quality of the relationship with their co-parent.
- Parents must understand that:
    - This is a research project

- They will be randomly allocated to receive either support from Early Help which will involve using an online therapeutic resource or the MBT-PP intervention, which is delivered online.
- They will need to fill in questionnaires before the start, at the end, and then three months after they finish.
- They will receive vouchers to thank them for their time, once they have completed all the questionnaires.
- They will need to be willing and able to attend either 10 sessions of MBT-PP therapy or engage with the digital resources as directed by Early Help staff

Referrals will be received by the Gateway Lead (GL), who will review the referral and contact the family. Parents may also self-refer to the project by contacting the GL directly. The GL will administer the DAS-4 (in the case of self-referrals only) and screen for risk (exclusion criteria) with each parent separately.

Inclusion criteria

- Parents must have at least one child aged 8 (or turning 8 during the intervention period, i.e., not more than 16 weeks younger than 8 years) -14 (or still 14 at recruitment).
- Parents must either have been referred for support with interparental conflict by a local authority practitioner (e.g., Early Help staff) or must be classified as a distressed couple on the DAS-4 with one or both parents scoring <13.

Exclusion criteria

- Current issues with substance or alcohol misuse in either parent.
- Significant mental health diagnosis which is not currently well-managed. Further guidance will be provided by Tavistock Relationships to the GLs regarding how to define 'well-managed'.
- Current domestic abuse or violence. (If there are historic issues of domestic abuse / intimate partner violence this should be detailed in the referral.)
- Current engagement in court proceedings (e.g., care proceedings or private family law proceedings).

If inclusion/exclusion criteria permit, the GL will administer the consent procedure and ensure completion of baseline measures.

Consent procedure

The GL will explain the research project and provide participant information sheets and consent forms to parents. This process may take place in person, by phone/email, or online – to be decided in consultation with LA colleagues during the project inception phase. Once consent has been completed for both parents, the GL will assign ID numbers and send each

parent participant a link to an online questionnaire containing the baseline measures. Children (aged 8-14) of consenting parents will be supported to complete the child outcome measures by the Early Help practitioners and/or the GL, to be decided in consultation with LA colleagues. Children will be asked for their assent prior to completion of these measures. The GL will inform the research team that a new family is ready for randomisation, and the research team will check the secure online survey platform hosting all measures and randomise when the baseline measures have been completed, informing the GL of the outcome of the randomisation. The GL will then inform the relevant team (TR or Early Help), so that contact can be made with the family. Referral data (case details) and contact details will be detached and replaced by ID numbers, and communications between the GL and relevant intervention teams will be via secure (e.g. encrypted or password protected) means.

The theory of change for MBT-PP indicates that the intervention will be maximally effective when both parents engage. As such, the trial is designed based on recruitment of both parents into the trial. However, while the GL will attempt to engage both parents in the trial, should one parent be willing to engage while the other appears unwilling to consent or complete the baseline measures, the family will be accepted into the trial, randomised to one of the two conditions, and the engaging parent will begin their intervention. The GL will contact the other parent 1-2 more times at around week 3, using multiple methods where possible (phone, email, text), to invite them again to participate in the trial. Parents who join the trial (consent and complete baseline measures) at this point will be allocated to the same condition as their co-parent, and in the case of families in the MBT-PP arm, will be invited to join their co-parent for the remaining therapy sessions. In our dataset, we will record which families began the trial with both parents involved, which families had the second parent join part-way through the intervention period, and which families only had one parent engage in the intervention, so that we can conduct sensitivity analyses relating to this.

Intervention delivery

For families randomised to receive MBT-PP, Tavistock Relationship (TR) will contact the family on receipt of the allocation from the GL to arrange initial sessions with each parent. Contact will be made by telephone, and preferences for Zoom/Teams to attend MBT-PP will be discussed.

It should be noted that MBT-PP commences with a clinical assessment, which can occasionally result in the decision that the intervention is not suitable for a particular family, due to risk management (i.e. concerns that the therapeutic process may exacerbate problems, or disclosures of abuse). In such cases, the family will be deemed ineligible and will be referred onwards to other services as appropriate. However, for the purposes of the Intention-to-Treat (ITT) analyses, these families will be included according to their original allocation.

Sample size calculations

Internal pilots enable data from the 'pilot' and 'efficacy' stages to be combined in order to increase sample size (and hence statistical sensitivity). Internal pilots are best thought of as a smaller scale efficacy trial which might be undertaken to gain some evidence of promise before funding a larger scale efficacy trial. All types of pilot could provide 'evidence of promise' and also are useful for obtaining empirical estimates to help improve the precision / accuracy of power analyses for an efficacy trial. What makes 'internal pilots' distinct is the pre-specified plan to combine data from the 'pilot' and 'efficacy' stages. This results in greater restrictions on adaptations between these stages; most strongly around the intervention (e.g., how it is implemented and theorised) but also around evaluation design (primary outcome, trial design). Programmes that are well developed and have some exposure to type-3 evaluation methodologies (QED if not RCT) might be suitable for this. For programmes that may evolve between the two stages, combining the two sets of data will be less reliable. In summary, whilst 'internal pilots' can bring additional methodological benefits compared with standard ('external') pilots, this does come at a cost of reduced flexibility in adaptation.

Based on the previous small-scale randomised study of MBT-PP (Hertzmann et al., 2016), this trial design assumes that an internal pilot is suitable and effect sizes for both pilot and efficacy stages will be reported alongside the combined effect size in the final evaluation findings.

The smallest effect size that our proposed CRT design could detect with a specified statistical significance ($\alpha<0.05$, two tailed) and statistical power ($1-\beta$ = 80% or higher) is known as the Minimum Detectable Effect Size (MDES) and can be calculated using Equation 1 adapted from Spybrook et al (2016). We estimated the MDES for our design using this equation and checked this using the PowerUp! software (Dong et al., 2015).

Equation 1:

$$MDES_{2LCRT} \sim M_{J-m-2}\sqrt{\frac{1}{P(1-P)}}\sqrt{\frac{ICC(1-R^2_{Fam})}{J}+\frac{(1-ICC)(1-R^2_{CYP})}{nJ}}$$

For a CRT design, the MDES is influenced by:

- n=number of children per family (estimated as **2**); J = number of families (see below)
- P = proportion of families allocated to intervention group (=**0.50**)

- m= number of (level 2) covariates used (which will include: group membership, family-level pre-test and all variables used for minimisation, ~ **11** variables)
- M_{J-m-2} is the group effect multiplier value of the t-distribution for a 2-tailed test with alpha=0.05 & beta=0.80
- ICC is the family level ICC (proportion of variance of the outcome at level 2) ~ this is unknown but estimated at between 0.01 and 0.15 (to be updated with empirical estimates from internal pilot)
- R^2_{CYP} = proportion of within-family child level variance that is reduced by covariate(s) - pupil level explanatory power and R^2_{Fam} = proportion of between-family variance that is reduced by covariate(s) - family level explanatory power. These are also unknown and will be updated with empirical estimates from the internal pilot. For these a priori MDES estimates, we have assumed that $R^2_{CYP} = R^2_{Fam}$ and allowed the values to vary between 0.25 and 0.49 (based on an assumed pre-post test correlation of between 0.50 and 0.70).

The number of families (J) has been allowed to vary between 200 and 350. This is the ITT sample of families without taking account of possible attrition (see below).

Table 3 shows a range of MDES estimates across 20 cells. MDES estimates of 0.22 SDs or lower are highlighted because, informed by meta-analyses of child outcomes for family therapy (van der Pol et al. (2017), parent mindfulness interventions (Burgdorf et al., 2019), and co-parenting interventions (Eira Nunes et al., 2020), we expect MBT-PP to produce a small effect on child outcomes.

Table 3. MDES estimates for a 2-level Clustered RCT with randomisation at the family level.

Total families if 2 children per family	200	250	300	350
Total Children	400	500	600	700
Covariate explanatory power (at family & CYP levels)	MDES Estimate			
R^2=0.25	0.25-0.26	0.22-0.23	0.20-0.21	0.18-0.20
R^2=0.36	0.23-0.24	0.20-0.21	0.18-0.20	0.17-0.18
R^2=0.49	0.20-0.22	0.18-0.19	0.16-0.18	0.15-0.16
Estimated MDES Range				

(assuming 0% attrition	0.20-0.26	0.18-0.23	0.16-0.21	0.15-0.20
Indicative MDES range (assuming 10% attrition)	0.21-0.28	0.19-0.25	0.17-0.22	0.16-0.21

Assumptions

The MDES calculations are based upon the ITT sample randomised following the collection of baseline data. Within the ITT sample, the only difference between the intervention and control groups will be (by design) 'random'. This enables the use of statistical theory to identify the minimum effect size that could be detected as statistically significant ($p<0.05$, two tailed) with a statistical power of 0.80 or higher. We discuss these MDES estimates (shown in

Table 3) below. Assuming zero attrition (

Table 3), if covariate explanatory power is assumed to be relatively strong ($R^2=0.49$), a sample of 200 families results in MDES estimates between 0.20 and 0.22 SDs; a sample of 250 families results in MDES estimates between 0.18 and 0.19 SDs; a sample of 300 families results in MDES estimates between 0.16 and 0.18 SDs and a sample of 350 families results in MDES estimates between 0.15 and 0.16 SDs. But, if covariate explanatory power is assumed to be weaker ($R^2=0.25$), a sample of 200 families results in MDES estimates between 0.25 and 0.26 SDs; a sample of 250 families results in MDES estimates between 0.22 and 0.23 SDs; a sample of 300 families results in MDES estimates between 0.21 and 0.21 SDs and a sample of 350 families results in MDES estimates between 0.18 and 0.20 SDs.

We recommend a total sample size (pilot + efficacy) of 350 families to best ensure that the CRT design achieves an MDES of 0.22 SDs. In the event of zero attrition, a sample of 350 families (700 CYP) has MDES estimates between 0.15 and 0.20 SDs (depending on ICC and covariate explanatory power). With the assumption of 10% attrition, the randomised ITT sample of 350 would lead to a final sample of 315 families (630 CYP). Indicative MDES estimates for a sample of 315 families are between 0.16 and 0.21 SDs. Even in the event of attrition being 20%, the final sample (of 280 families, 560 CYP) results in indicative MDES estimates between 0.17 and 0.22 SDs. These indicative MDES estimates include an assumption that attrition will be random; which is why they are labelled as 'indicative'. A missing data analysis will be undertaken to examine this assumption and, if appropriate, multiple imputation will be used to estimate missing values (within follow-on sensitivity analyses).

To combine the pilot and efficacy stage samples, the intervention needs to be as consistent as possible in both stages – although effect sizes for the two separate pilot and efficacy stages

will be reported alongside the combined effect size. Consistency in effect sizes along with the underlying Theory of Change would result in robust findings for the combined sample.

In addition to providing data to improve statistical sensitivity for the efficacy trial, the internal pilot would also be able to provide empirical estimates for both ICC and covariate explanatory power. This would allow the power analyses to be updated with empirical estimates (e.g., in the Statistical Analysis Plan).

In the pilot phase of the project we expect to reach and randomise 140 families (280 CYP). In the efficacy phase of the project, we expect to reach and randomise 210 families (420 CYP), making a total of 700 CYP over the entire recruitment phase (pilot + efficacy combined).

Table 4 has been completed assuming a total (pilot+efficacy) sample of 350 families (700 CYP). Please see above for details behind making this assumption. The estimations for pre-test/post-test correlations (family and CYP levels) and the ICC value (just family) cover a range of values. Data from the internal pilot will be used to update these with empirical estimates.

Table 4. Sample size calculations

		PARAMETER
Minimum Detectable Effect Size (MDES)		0.15 – 0.20, depending on ICC and covariate explanatory power
Pre-test/ post-test correlations	level 1 (participant)	0.50 to 0.70 (R^2 between 0.25 & 0.49)
	level 2 (cluster)	0.50 to 0.70 (R^2 between 0.25 & 0.49)
Intracluster correlations (ICCs)	level 1 (participant)	Not appropriate in this case. There will be residual variance but ICCs relate to clusters not individuals. The proportion of residual variance is assumed to be between 0.85 and 0.99
	level 2 (cluster)	0.01 to 0.15
Alpha[7]		0.05
Power		0.80
One-sided or two-sided?		Two
Average cluster size (if clustered)		2 CYP per family
Number of clusters[8]	Intervention	175
	Control	175

	Total	350
Number of participants	Intervention	350
	Control	350
	Total	700

With an attrition rate of 10%, and assuming that attrition was random, the indicative MDES estimates would be between 0.16 and 0.21 sds.

Internal Pilot Study

Internal pilots enable data from the 'pilot' and 'efficacy' stages to be combined in order to increase sample size (and hence statistical sensitivity). Internal pilots are best thought of as a smaller scale efficacy trial which might be undertaken to gain some evidence of promise before committing funding a larger scale efficacy trial. All types of pilot could provide 'evidence of promise' and also are useful for obtaining empirical estimates to help improve the precision / accuracy of power analyses for an efficacy trial. What makes 'internal pilots' distinct is the pre-specified plan to combine data from the 'pilot' and 'efficacy' stages. This results in greater restrictions on adaptations between these stages; most strongly around the intervention (e.g., how it is implemented and theorised) but also around evaluation design (primary outcome, trial design). Programmes that are well developed and have some exposure to type-3 evaluation methodologies (QED or RCT) are considered suitable for this. MBT-PP meets the criteria of being well established, and evidence of promise was found in a small-scale, underpowered RCT (e.g., Hertzmann et al., 2016; 2017). Our design assumes that an internal pilot is suitable and effect sizes for both pilot and efficacy stages will be reported alongside the combined effect size in the final evaluation findings (should the pilot continue to efficacy stage).

The aims of the internal pilot study will be to assess:

a) The extent to which the referral pathways are working, i.e., whether sufficient referrals are flowing into the project, and whether these referrals are meeting eligibility requirements
b) The acceptability of the referral pathways and consent and randomisation procedures to participants (indicated by drop out rates at these points)
c) Whether there are any signs of problematic attrition (e.g. that might indicate that the research processes or interventions are not acceptable to participants)

d) How the estimates used for the sample size calculation should be adjusted in light of data.

These aims inform the progression criteria (Appendix A), which utilise a red/amber/green classification system, whereby amber or red indicate that mitigations are required prior to progression.

Additional aims for the pilot study are:

e) To pilot the data collection methods (including examining completion time and parent views on completing measures)
f) To pilot data linking processes
g) To seek early evidence supporting the Theory of Change
h) To explore the relationship between parents' SDQ reports

Outcome measures

Certain features of the trial design mean that there is not a wide range of measures to choose from for many of our constructs. These include the age range of CYP targeted; 8-14 years is a wide age range and spans multiple developmental stages. Another feature that makes measure options limited is the fact that families may be intact or separated. Measures of IPC are typically intended for only one of these groups and are not appropriate for both. Finally, some of our constructs are only recently identified in the literature, or simply have not received a similar level of research attention as others, which means that only one measure exists (to the very best of our knowledge). Despite these challenges, we have selected a set of measures that are appropriate for the target population and have good psychometric properties.

All measures will be completed at baseline, post-intervention, and 3 month follow up.

Primary outcome

a) The Strengths and Difficulties Questionnaire (SDQ; Goodman, 1997)

Parents will complete the SDQ. The total difficulties score at post-intervention will be the primary outcome variable. The SDQ is a brief questionnaire measuring behaviours, emotions and relationships in 4-17-year-olds. It contains 25 items which break up into 5 subscales, 2 of which measure externalising problems (conduct problems and hyperactivity/inattention), 2 of which measure internalising problems (emotional symptoms and peer problems), and a prosocial behaviour subscale. A general difficulties score is based on 4 of these subscales, excluding prosocial behaviour. The parent-report questionnaire will be used in this evaluation. We will ask both parents to complete the SDQ for each of their children. We will

take mothers' SDQ score as the primary outcome variable, and treat fathers' SDQ score as a secondary outcome. We will explore the correlation between parents' SDQ scores in the pilot phase. Literature suggests that parent reports can differ (Bergström & Baviskar, 2021), and the delivery partners expect differences between mothers and fathers will be amplified in a sample with high IPC, because disagreement about children's well-being is often a topic of IPC. For this reason, it will not be appropriate to substitute mother SDQ score with father SDQ score in the primary analysis in cases where we have missing data for the mother. In non-traditional families (two mothers, two fathers, or non-binary parents), we will randomly select which SDQ to treat as primary.

The SDQ is being used by YEF across its projects to create consistency and comparability between different evaluations. Further information about the SDQ is available here: https://www.sdqinfo.org/.

Secondary outcomes

b) Stirling Children's Well-being Scale (Liddle & Carter, 2015)

The Stirling Children's Well-being Scale (SCWBS) will be used to measure children's well-being. It is validated for use in children aged 8-15 years. It has 12 items measuring children's emotional and psychological well-being over the previous two weeks and 3 items to assess socially desirable responding. Participants are asked to rate their agreement with statements on a 5-point scale, from "Never" (1) to "All of the time" (5). All items are positively worded, e.g., "I've been in a good mood". The SCWBS has good internal reliability (Cronbach's alpha = .85), external validity, and test-retest reliability. It also has shown no evidence of ceiling effects, meaning that it ought to be able to detect positive change.

c) O'Leary-Porter Scale (Porter & O'Leary, 1980).

The O'Leary Porter Scale (OPS) will be used to assess parent-reported IPC. The OPS is a 10-item measure designed to assess overt hostility in intact couples, but it has also been used with separated couples (e.g., Owen & Rhoades, 2012; Shifflett & Cummings, 1999). The OPS assesses the frequency of overt hostility (such as quarrels, sarcasm, physical abuse) that is observed by the child. Higher scores indicate greater hostility in the relationship. Internal consistency is good, with Cronbach's alpha of 0.86 (Porter & O'Leary, 1980). We already have the author's permission to use this scale and to adapt it to suit a modern, British audience.

d) Perceptions of Interparental Conflict-Intensity/Frequency Scale (Kline, Wood & Moore, 2003)

The Perceptions of Interparental Conflict-Intensity/Frequency Scale (PIC-I/F) is a 13-item scale measuring children's views of aspects of relationship conflict. Participants are asked to indicate how true statements are for the parents' relationship on a six point scale from

"definitely false" (1) to "definitely true" (6). This measure is a short form of the 48-item Children's Perception of Interparental Conflict Scale (CPIP; Grych et al, 1992), which was developed for 9-17-year-olds. The PIC-I/F has good internal reliability (.83) and test-retest reliability over a 2-week period (.93; Kline, Wood & Moore, 2003).

e) Dimensions of Anger Reactions-Revised (Nederlof, Hovens, Muris & Novaco, 2009)

The Dimensions of Anger Reactions-Revised (DAR-R) will be used to measure parents' anger. The seven-item scale assesses anger responses and functional impairment. Participants are asked to rate how much statements have applied to them over the last four weeks, from "not at all" (0) to "very much" (4), e.g., "I often find myself getting angry at people or situations". Previous research has found acceptable internal reliabilities for this measure, with Cronbach's alphas of .68 to .77 for the anger response subscale and .68 to .82 for the anger impairment subscale in general population samples, along with evidence of convergent and discriminant validity (Kannis-Dymand et al., 2019).

f) Parental Reflective Function Questionnaire (Luyten et al., 2017)

The Parental Reflective Function Questionnaire (PRFQ) will be used to measure parent mentalising ability. The PRFQ is an 18-item measure, containing three subscales: pre-mentalizing modes; certainty about mental states; and interest and curiosity in mental states. Participants are asked to rate their agreement with statements on a 7-point scale, from "strongly disagree" to "strongly agree", e.g., "I try to see situations through the eyes of my child". Higher scores indicate higher parental mentalising ability. All three subscales have satisfactory internal consistency (Cronbach's alphas of .69, .77 and .75, respectively) and there is evidence of convergent validity (Anis et al., 2020).

g) Parenting Scale Short Form (Kliem et al., 2019)

The Parenting Scale Short Form (PS-8) will be used to measure parenting style. The PS-8 uses 8 items from the Parenting Scale (Arnold et al., 1993), which assess parenting behaviour in response to problematic child behaviour over the previous two months. Participants are asked to rate their agreement with statements on a 7-point scale between two poles, representing effective and ineffective parenting strategies. Higher scores indicate more dysfunctional parenting. Internal consistency has been shown to be acceptable (Cronbach's alpha = .75) and there is evidence of construct validity (Kliem et al., 2019).

h) Emotional Adaptation to Relationship Dissolution Assessment (Millings et al., 2020)

The Emotional Adaptation to Relationship Dissolution Assessment (EARDA) is a 10-item scale developed in the UK and validated in samples of separated parents. The EARDA has excellent convergent, discriminant, concurrent criterion-related, and incremental validity, correlates with co-parenting communication, mediates between separation characteristics and conflict,

and in a small sample, has been found to align with the professional opinion of mediators regarding parents' ability to communicate without arguing (Millings et al., 2020). Because the EARDA's focus is adaptation to dissolution of the relationship, it will only be used where parents are separated. As such, analyses using the EARDA will be regarded as exploratory, as it is not possible to estimate prior to the pilot phase how many separated vs intact families will be referred to the project. The SHU funded PhD studentship opportunity (worth £84K) provides the flexibility in staffing resource to undertake this work, and this component of the project represents added value beyond the evaluation itself.

Socio-demographic information

In addition to the validated outcome measures listed above, parents will also be asked to report socio-demographic information at baseline, e.g., age, sex, gender, ethnicity, LGBTQ+ status, education level, marital status, employment status, and postcode (so that an index of deprivation for participants' neighbourhoods may be found). This will enable examination of the extent to which economic disadvantage affects IPC. We will also ask participants to report their children's ethnicity and sex, whether their children have any special educational needs or disabilities, and whether they are looked-after children/previously looked-after children. We will collect children's dates of birth and home addresses to allow children to be matched to the records held in the National Pupil Database by the Department for Education at the end of the project.

MBT-PP administrative data

For participants allocated to the MBT-PP condition, we will also collect data from TR about the date of first contact with each family, how many therapy sessions were attended per family, how many therapy sessions were delivered and recorded per therapist, and how many hours of supervision therapists received.

Compliance

Families that complete 6 sessions of MBT-PP will be deemed compliant. In discussion with the project partners, we are currently refining how compliance is affected by parents completing different amounts of MBT-PP, i.e., if one parent completes 6 or more sessions, and the other parent completes less than 6.

Analysis

Primary analyses will address the primary research question of whether, compared to TAU, MBT-PP produces better SDQ outcomes for children. The primary outcomes will be analysed

using analyses of covariance (ANCOVA) with baseline primary outcome measures constituting the covariates. These will be mixed (multilevel) regression analyses with two levels (children clustered into families). We will run these analyses as an intention to treat analyses with all participating parents and children analysed as part of the intervention to which they were randomised. This will be the primary analysis and provide the most statistically robust evidence of the causal impact of the Tavistock programme on the SDQ primary outcome.

The primary analyses will include all CYP in the ITT sample with complete baseline/outcome data regardless of whether their family is classed as being 'compliant' (i.e. by completing 6+ sessions of MBT-PP). To estimate the impact of the Tavistock programme for CYP from families classed as 'compliant', we will undertake two analyses for the SDQ primary outcome; a per-protocol (or on-treatment) and Compliers Average Causal Effect (CACE) analysis. The on treatment analysis would restrict the Tavistock intervention group to only include CYP from families who received 6+ sessions of MBT-PP and compare SDQ outcomes with the complete CYP sample randomised to receive TAU. To accompany the on-treatment analysis, a descriptive comparison of the compliant, non-compliant CYP / family samples will be presented to examine whether it is reasonable to assume that compliant and non-compliant families are 'similar' (the validity of on-treatment analyses is based on this). If compliant and non-compliant families are systematically different, this provides clear evidence that randomness within the on-treatment analyses has been undermined. The CACE analysis would attempt to address the bias within the on-treatment analysis by adopting an instrumental variable (IV) approach using a two stage Least Squares (2SLS) analysis (Sussman & Hayward. 2010; Tilbrook et al. 2014). The first stage would model the binary compliance measure using the baseline SDQ along with additional variables at the CYP and family levels. This model will be used to generate the predicted compliance for the Tavistock programme. The second stage model will then use the predicted compliance variable in place of the group identifier to generate the CACE estimate for the Tavistock programme. In the event of the on-treatment and CACE estimates being closely aligned, we would favour the reporting of the on-treatment estimate for communicability reasons because it is less abstract / technical compared to CACE. However, if notable differences between the on-treatment and CACE estimates are observed, we would favour the CACE estimate because of this attempts to address the potential bias within on-treatment (i.e. families who comply being different from families that do not comply). STATA IVRegress will be used for this IV approach for estimating CACE.

Secondary analyses will address the secondary questions of whether, compared to TAU, MBT-PP produces: reduced IPC, lower child perception of IPC, improved parenting style, reduced parent anger expression, improved parent emotional adaptation to the situation, and improved CYP psychological well-being.

Mediation analyses using structural equation modelling will be employed to test whether IPC, lower child perception of IPC, reduced parent anger expression, and improved parent emotional adaptation to the situation are significant mechanisms by which MBT-PP improves CYP adjustment (parent report SDQ scores).

Descriptive statistics will be used to compare the demographics of the sample to the local populations of the LAs. Dropout analyses will be used to assess whether there were systematic differences between participants who were and were not compliant with MBT-PP.

Quantitative data will initially be analysed to establish the extent and nature of any missing data (i.e. MCAR, MCR MNAR). An appropriate imputation solution will be implemented and the ITT analyses will be re-done using this imputed data as sensitivity analyses.

Any parametric test assumptions will then be evaluated and violations to assumptions will be addressed as appropriate (e.g. through data transformations).

Data will be aggregated across the pilot and efficacy studies either pooling the data or using meta-analytic techniques, depending on any design changes that occur from pilot to efficacy, to produce the overall impact estimates of the efficacy study with internal pilot.

All planned statistical analyses will be set out in the Statistical Analysis Plan (SAP) prior to any analysis taking place.

Longitudinal follow-ups

It is possible that the effects of MBT-PP are not seen immediately that the therapy finishes, but take some time to embed into the family system in a way that effects change. We therefore plan to conduct a 3-month follow up. This will take place 3 months from the last session of MBT-PP, or, for those in TAU, 7 months (the length of MBT-PP + 3 months) after the baseline measures. All baseline measures will be repeated.

The analytic procedures employed to analyse the follow up data will be the same as those used to analyse the post-intervention data (but with an additional time point). All analyses will be fully specified in the SAP.

Implementation and process evaluation

Implementation Research Questions (RQs)

RQ1 What are the key factors that influence successful delivery of and engagement with MBT-PP? (This will include collecting data on barriers and facilitators to implementation,

from both clients and therapists, including contextual and wider structural factors that might differentially affect minorities.)

RQ2 What compliance, contamination, and fidelity issues are present in the trial?

RQ3 What does the trial indicate about scalability? Can MBT-PP be delivered at scale?

Process RQs

RQ4 How does MBT-PP affect parents and children? What are the mechanisms of change?

Research methods

Throughout the IPE, we will purposively sample so that 50% of participants are from minority ethnic groups. The purpose of this sampling strategy is to ensure that we can understand how wider structural factors affect minority groups' engagement with the intervention and whether the intervention is sufficiently tailored and sensitive to minority groups.

We intend to conduct qualitative interviews with parents, MBT-PP therapists, Early Help practitioners and Gateway Leads to answer the IPE research questions. In each of these cases, participants will be provided with a specific participant information sheet and provide consent prior to participating in an interview. Interviews will be conducted by a member of the SHU research team who is experienced in conducting sensitive research and clinical interviews, or additional researchers if deemed appropriate by the race equity consultant. Interviews will either take place online using video conferencing software or by telephone, according to each participant's preference. The interviews will be semi-structured, following an interview schedule specific to the type of participant (parent, MBT-PP therapist or Early Help practitioner). Interviews will be audio-recorded and transcribed.

Parent interviews

Qualitative interviews with parents with a sample of parents (n = 30) who have undergone MBT-PP will be used to explore engagement with MBT-PP and the psychological changes that parents experience as a result of MBT-PP. These interviews will use open questions to explore the impact of MBT-PP and how this was achieved, including whether parents experience a change in their mentalising abilities and ways of expressing anger, and whether and how the conflict in their co-parenting relationship has changed. For parents who are separated from their co-parent, the interviews will also explore how, if at all, MBT-PP has affected their emotional adaptation to the separation. Interviews will also use open questions to explore the issues that brought parents to MBT-PP (i.e., sources of conflict), how suitable MBT-PP was for their needs, and barriers and facilitators to engaging with MBT-PP.

Parents who have completed MBT-PP will be invited to take part in a remote interview about their experiences with MBT-PP. We will recruit participants from the three different LAs involved in this project, and where possible, we will purposively sample to ensure a broad demographic spread. Parents participating in an interview will be asked to confirm their sociodemographic details (e.g., age, ethnicity) collected as part of the baseline quantitative data. Parent interviews will explore barriers and facilitators to engaging with MBT-PP (RQ1), the activities undertaken as part of MBT-PP and how parents understand and use these (RQ2) and the psychological changes arising from MBT-PP (RQ4).

We will also interview a sample of parents who have undergone TAU (n = 15). These interviews will examine the nature and content of the support received in TAU, to support the fidelity assessment (RQ2), which is described below..

CYP interviews

Qualitative interviews with children of parents who have undergone MBT-PP will be used to explore children's experiences and their perceptions of IPC, and whether and how these have changed as a result of their parents undergoing MBT-PP.

We will interview a sample of children (n = 20). A child-friendly participant information sheet will be provided to parents and children in advance. Informed consent for these children to participate will be sought from their parent, and assent will be sought from the children on the day of the interview. The Gateway Lead or Early Help practitioners will support children to access a remote interview with a member of the SHU research team. We anticipate that this might involve coordinating with the child's school or other community venue to ensure that the child can access the interview in a secure environment, where they will not be overheard by their parent and therefore will feel more able to speak freely. Child interviews will explore emotional/behavioural difficulties, wellbeing and their perceptions of IPC, and whether and how these have changed as a result of their parents undergoing MBT-PP (RQ4).

Therapist interviews

All therapists (n = 12) who provide MBT-PP for TR will be invited to participate in an interview. Therapist interviews will explore the activities that were carried out while working with MBT-PP clients (RQ2), barriers and facilitators to delivery of MBT-PP (RQ1) and perceptions of the impact of MBT-PP on clients (RQ4).

Treatment as usual provider interviews

We will conduct qualitative interviews with a sample of the LAs' practitioners who provide TAU (n = 12). All practitioners who provide TAU in this project will be invited to participate in an interview. These interviews will explore the activities that were carried out while providing TAU (RQ2) and the processes involved in identifying and referring parents to the trial (RQ3).

Gateway Leads interviews

We will interview the Gateway Leads (n = 3) to explore barriers and facilitators to conducting the trial (RQ3), specifically focussing on establishing referral pathways and buy-in from Early Help staff. Each of the Gateway Leads will be invited to participate, and will be provided with an information sheet in advance. Consent will also be obtained prior to participation.

Therapy recordings

To evaluate treatment fidelity, we will audio-record therapy sessions (and this will be stipulated in information sheets and consent forms), create a fidelity checklist (see below) and rate a proportion of therapy sessions for fidelity to the MBT-PP manual.

Treatment fidelity analysis

We will draw on the Bellg et al. (2004) treatment fidelity framework to explore issues of compliance, fidelity and contamination (RQ2). The framework describes aspects of fidelity: i) Design (e.g. standardising the treatment dose for each participant); ii) Training (e.g. standardised training for intervention deliverers); iii) Delivery (e.g. adherence to treatment protocol and minimising contamination); iv) Receipt (e.g. participant comprehension of the intervention); and v) Enactment (e.g. Participants using the skills they have learnt from the intervention in appropriate life settings). Given that the MBT-PP programme is already established and manualised and people are already trained to deliver the programme, we will focus on the assessment of the latter three aspects of fidelity.

Development and piloting of a fidelity checklist

We will devise a prototype fidelity delivery checklist for the MBT-PP intervention, based on the manual for the intervention and the theory of change, so that we establish the key active ingredients of the intervention and agree how these will be operationalised within the intervention delivery. We will pilot the checklist using a sample of three audio-recorded intervention delivery sessions during the first 20 referrals. Two researchers will independently code the fidelity of intervention delivery using the prototype checklist when listening to audio-recordings of the sessions. Coders will then meet to compare coding and to discuss any required refinements to the checklist.

Assessment of delivery fidelity

We will monitor adherence to the treatment protocol in the following ways:

1. Monitor the number of sessions delivered, when they are delivered and the length of each session.

2. We will code one intervention delivery session for each of the therapists. To do this a researcher will listen to one selected audio-recording of a delivery session and will use the fidelity delivery checklist to code the fidelity.
3. During qualitative interviews with therapists, we will seek to understand capability, opportunity and motivational barriers and facilitators to intervention delivery.
4. During qualitative interviews with those who delivered TAU, we will explore whether they delivered any of the key active ingredients of the MBT-PP intervention (i.e. contamination), as outlined in the fidelity checklist.
5. During the qualitative interviews with parents who received TAU, we will explore whether parents received any of the active ingredients of MBT-PP.

Assessment of Receipt and Enactment fidelity

We will explore the extent to which participants received the intended intervention and enacted the suggested methods to manage disagreements during interviews post intervention. Specifically, the interviews will explore:

1. Parent participants' understanding of the intervention and how it works (capability).
2. The extent to which parents intend to use the methods taught to them during the intervention and how confident they feel to be able to use them (motivation).
3. Barriers and facilitators to using the methods with a particular focus on the kinds of situations in which they successfully used the methods and times when they did not.

Qualitative Analysis

Qualitative data will be analysed using Thematic Framework Analysis (Braun & Clarke, 2006). The frameworks we will use will reflect the research questions that we pose (see table 5) and include:

1. *Bellg et al.'s (2004) treatment fidelity framework*
   This considers five different aspects of fidelity: Design; Training: Delivery; Receipt and Enactment (see Treatment Fidelity Analysis).
2. *Michie et al.'s (2011; 2014) COM-B model* which proposes that for any Behaviour to occur an individual must have sufficient Capability, Opportunity and Motivation.
3. *Theoretical Domains Framework (TDF; Cane et al., 2012)* fits alongside COM-B and describes 14 domains representing key theoretical constructs related to behaviour change as follows: Knowledge; Skills; Memory, attention and decision processes; Behavioural regulation; Social/professional role and identity; Beliefs about capabilities; Optimism; Beliefs about consequences; Intentions; Goals; Reinforcement; Emotion; Environmental context and resources; and Social influences.

4. *Theoretical Framework of Acceptability (TFA: Sekhon et al., 2017)* describes seven constructs that reflect the extent to which people delivering or receiving an intervention consider it to be appropriate as follows: Affective attitude; Burden; Ethicality; Intervention coherence; Opportunity costs; perceived effectiveness; Self-efficacy.

To address RQ1 regarding the key factors that influence successful delivery of MBT-PP, we will develop a framework using the COM-B model and TDF to identify barriers and facilitators for both clients and therapists, and the TFA to address intervention acceptability for parents. We will compare the themes identified across cases to identify similar or contrasting themes and to explore patterns between themes and participant characteristics (e.g., sex, ethnicity, disadvantage).

To address RQ2, regarding compliance, contamination, and fidelity, we will apply the Treatment Fidelity Framework, as outlined above.

To address RQ3, regarding scalability, we will utilise both the COM-B model and TDF regarding barriers and facilitators, and also a more inductive approach to capture structural issues in interviews with GLs, therapists, and EH staff.

To address RQ4, we will draw from COM-B, TDF and TFA to explore parents and children's experiences of receiving MBT-PP and the impact it has had.

Table 5 illustrates the mapping of theory, participant group, and research question.

Table 5. IPE methods overview

Interview participants	Theories/models informing analysis framework	Research questions addressed	Implementation/ logic model relevance
Parents who received MBT-PP **n 30**	Framework analysis based on Theoretical Domains Framework Theoretical Framework of Acceptability, and fidelity checklist.	RQ1, RQ2, RQ4	Perceptions of inputs, activities and impacts of MBT-PP. Understanding of causal mechanisms and contextual factors. Beginning these interviews in the pilot phase will surface any problems that need rectifying for the efficacy phase.

Parents who received TAU n=15	Treatment fidelity framework.	RQ2	Assess contamination in TAU.
CYP **n = 20**	An open, inductive coding approach will be taken to surface CYP's experiences connected to their parents' engagement with MBT-PP.	RQ4	Perceptions of impacts of MBT-PP. Understanding of causal mechanisms. Beginning these interviews in the pilot phase will surface any problems that need rectifying for the efficacy phase.
MBT-PP therapists **n = 12**	Framework analysis based on Theoretical Domains Framework and fidelity checklist.	RQ1, RQ2, RQ3, RQ4	Perceptions of inputs and impacts of MBT-PP. Understanding of causal mechanisms and MBT-PP therapist contextual variables. Beginning these interviews in the pilot phase will surface any problems that need rectifying for the efficacy phase.
Early Help practitioners (n) **n = 12**	Framework analysis based on Theoretical Domains Framework and fidelity checklist.	RQ2, RQ3	Beginning these interviews in the pilot phase will surface any problems that need rectifying for the efficacy phase.
Gateway Leads **n = 3**	Framework analysis based on Theoretical Domains Framework and inductive coding regarding organisational issues.	RQ3	Conducting these interviews in the pilot phase will inform any changes needed to the referral pathways for the efficacy.

Cost data reporting and collecting

Cost data will be collected from the delivery partner, as it will refer solely to the delivery of MBT-PP, rather than TAU, in line with YEF guidelines. Cost data will be gathered every 6 months and will capture actual, rather than estimated, spend.

Cost data will be gathered using therapist diaries and salary information from the delivery partner. Because the number of therapists delivering MBT-PP is relatively small (n=12), we will aim for cost data on the entire workforce. Because the 12 MBT-PP therapists will be

delivering the intervention in 3 different LAs, but all online from one central organisation (the delivery partner) gathering these data from the perspective of the delivery partner ought to be straightforward. Cost data will also be gathered on therapist training, supervision, and overheads such as ITC requirements.

Ethics and registration

The process for obtaining ethical approval is via Sheffield Hallam University (SHU) which has established research ethics policies and procedures aligned with legal requirements and research societies' standards of good practice (https://www.shu.ac.uk/research/quality/ethics-and-integrity). The project team will follow these procedures, including operating to standardised protocols concerning anonymity, confidentiality, informed consent, rights to withdraw, and secure data privacy.

Ethics applications and reviews are managed through the SHU ethics review system. We will submit a summary of the study methods and procedures along with all participant facing documentation (including participant information sheets, consent forms, measures and interview schedules/topic guides). Applications are assigned anonymously to three trained reviewers who make a decision and recommendations as to whether the study should be approved and if any amendments need to be made. Where necessary amendments are submitted until all reviewers are satisfied that the projects meets the required standards.

The trial will be registered at www.controlled-trials.com and assigned an International Standard Randomised Control Trial Number (ISRCTN) which will be included in the protocol and all publications and reports about the trial.

The trial registry will be updated with outcomes at the earliest opportunity at the end of the project..

Data protection

One of the aims of the General Data Protection Regulation (GDPR) is to empower individuals and give them control over their personal data.

Sheffield Hallam University undertakes research as part of its function for the community under its legal status. Data Protection laws allow us to use personal data for research with appropriate safeguards in place under the legal basis of public tasks that are in the public interest. Information about the University's legal status, constitution and public tasks can be found here: https://www.shu.ac.uk/about-us/governanceand-strategy/governance/legal-status-and-constitution.

We will always inform potential participants about the information we wish to collect from them and how we will use it. We will seek their consent for the collection and use of their data in specific research projects. The research ethics committee will agree an appropriate consent procedure to ensure participant rights are protected. Full details will be provided to participants (as well as their parents/legal guardians in the case of CYP) in an information sheet.

Research in the University is governed by policies and procedures and all research undergoes ethical scrutiny to ensure that it is conducted in such a way as to protect participants' interests and is of a high standard. https://www.shu.ac.uk/research/ethics-integrity-and-practice

We will only collect information that is essential for the purpose of the research. Research data is treated as confidential and will be identifiable only via ID numbers. The key linking ID numbers with individuals will be stored securely and separately from the research data, and accessible only by authorised individuals in the research team.

The privacy of personal data is paramount and will not be disclosed unless there is a justified purpose for doing so. The University NEVER sells personal data to third parties. Data may be shared with:

- Immediate project team who are authorised to work on the project and access the information. This may include staff at Sheffield Hallam University or collaborators at other organisations authorised to work on the project. This will be clearly identified in the information sheet. Our research may be audited and access to the data may be required. The University puts in place safeguards to ensure that audits are conducted in a secure and confidential manner.
- In the case of complaints about a research project the Head of Research Ethics may require access to the data as part of our Research Misconduct Procedure.

The University takes a robust approach to protecting the information it holds with dedicated storage areas for research data with controlled access. For particularly sensitive projects the University puts into place additional layers of security. The University has a high level of data security and follows the NCSC "10 Steps to Cyber Security" framework to structure security planning and operations. Through information strategy, policy and process the University is aligning to the ISO27001 standard. Alongside these technical measures there are comprehensive and effective policies and processes in place to ensure that users and administrators of University information are aware of their obligations and responsibilities for the data they have access to. By default, people are only granted access to the information they require to perform their duties. Training is provided to new staff joining the University and existing staff have training and expert advice available if needed.

Research data will be prepared for archiving in the YEF evaluation data archive at the end of the project. Two data sets will be created. One file will contain just children's identifying data. This will be submitted to the DfE, where personal data will be removed. This will be replaced with DfE's pupil matching reference numbers (PMRs) and then submitted to the ONS for storage in the YEF archive. The second file will contain the evaluation data. This will be submitted direct to the ONS, and stored in the YEF archive. It will contain unique identifiers that allows it to be connected with the DfE PMRs. Both data sets will be held securely in the YEF archive by the ONS.

Future approved researchers will be able to access the data for approved research projects and link it with the DfE's National Pupil Database (for data on school exclusions and academic performance) and the Police National Computer (for criminal justice information).

We will collect information on racial and ethnic origin which falls under the category of special category data under GDPR UK. In compliance with GDPR UK (article 9) we will seek explicit and separate written consent from participants to the collection and processing of these racial data.

Stakeholders and interests

Project Team roles and responsibilities (all affiliated to Tavistock Relationships):

Andrew Balfour - Tavistock Relationships (TR), CEO

Sarah Ingram - Associate Director responsible for partnerships and delivery: TR Project leader and YEF Contact, responsible for project management and good governance, delivery accountability, working with SHU colleagues to offer feedback on progress to LAs

Maria Franchini - MBT lead: responsible for MBT-PP delivery, fidelity, supervision and further trainings as required.

Evaluation Team roles and responsibilities (all affiliated to Sheffield Hallam University)

Prof Abigail Millings – Evaluation lead, oversight of every aspect of the trial.

Sean Demack and Prof John Reidy – Evaluation statisticians. Sean will lead on the primary and secondary outcome analyses and John will lead on the mechanisms of action analyses.

Dr Charlotte Coleman - advisor for IPE with a focus on working with CYP.

Prof Maddy Arden – treatment fidelity, compliance, and contamination.

Dr Elaine Clarke – trial management, day-to-day tasks, allocation, data collection infrastructures, data management, interviews, (supported by the team of CeBSAP researchers).

Anna Stevens – advisor for data amalgamation and cleaning processes.

Risks

Please see risk register in Table 6.

Table 6. Risk register

Potential Risk Identification	Initial potential risk status			Preventative measures	Reducing the impact	Revised risk status		
	Likelihood	Impact	Risk			Revised Likelihood	Revised Impact	Revised Risk
Project specific risks								
Low recruitment	medium	medium	medium	Gateway Lead posts in each of the 3 LAs will oversee recruitment. Relationship building and significant project promotion activity by Tavistock Relationships with the LA staff will raise the profile of the project. In the event of low recruitment, we will explore the option of expanding to additional LAs.	Trial design can be adapted as necessary.	low	low	**low**
Attrition	medium	medium	medium	Encouraging compliance through strong rapport, advance notice and clear communication. Full	We use a dedicated project management/administrative support team to ensure a close	low	low	**low**

				investigation of causes of attrition in the in the pilot stage. Incentives for each questionnaire completed and an additional bonus incentive for completing all questionnaires.	positive working relationship with all stakeholders in the trial. Any attrition will be recorded using a consort flow diagram and taken into account at the analysis stage.			
Deliverer staffing difficulties	medium	high	mediu m	The deliverer should ensure that cover is available in the event of staff absence or departure	Each therapist could have a designated cover to pass clients onto in the event of illness or departure. Such staffing changes will be recorded and taken into account in the analysis as changes in therapeutic relationships may affect outcomes.	low	medium	**low**
Generic risks								
Covid 19 related disruption	High	mediu m	high	Team will closely monitor any evolving pandemic-related scenarios. Intervention delivery is all online so should not be affected. All staff are able to work remotely.	Team are used to working flexibly and responsively to changes to projects, timescales and participant needs. In consultation with YEF, team able to put forward revised evaluation plans based on various future scenarios	low	low	**low**
Staff absence/departure (e.g. due to long term illness)	low	high	mediu m	Team is of sufficient size, with any staff absences handled by colleagues who are highly experienced researchers. Centres involved have very low staff turnover and the same team see projects through from inception to completion in almost every instance, when this is not possible we have capacity to meet our commitments.	We have a large number of experienced research staff within SHU, who can be brought into the project with short notice if necessary. We feel this offers good contingency for unexpected staff absence.	low	low	**low**

Slippage and deadlines not met	low	high	mediu m	All team members experienced working on projects with tight deadlines. A well developed and agreed project plan would be followed. Robust and dedicated project management and progress monitoring plans mean that timelines are clearly understood with agreed responsibilities and deadlines. Regular team meetings will review progress and plan forward.	Projects are assessed continuously so potential problems are quickly identified. Regular contact will be maintained between SHU and YEF project managers to quickly anticipate and address emerging problems. Where a deadline is seen to be problematic this would be discussed at the first instance with YEF.	low	medium	**low**

Evaluation of Tavistock Relationships MBT-PP to improve child outcomes by reducing inter-parental conflict: a pragmatic efficacy randomised controlled trial with internal pilot

Evaluation protocol

Evaluating institution: Sheffield Hallam University
Principal investigator(s): Dr Abigail Millings

Timeline

Dates	Activity	Staff responsible/ leading
Jan-Feb 2023	Set up phase. Diversity training for whole team, preparation of all participant facing materials and data collection instruments, review of these by race equity consultant and YEF, application for ethical approval, piloting of materials with representative participants, data sharing agreements, safeguarding processes.	AM & EC, with input from rest of Evaluation Team
March 2023-April 2024	Pilot baseline data collection. Referrals that come in from March-Dec will have post-intervention data included in the pilot study primary outcome analysis. Referrals coming in Jan-April will have baseline data only included in the analyses to address the aims of the pilot study regarding recruitment and acceptability.	AM & EC, with input from rest of Evaluation Team

May-June 2024	Transition. Evaluators prepare draft report on pilot, for submission end of May. YEF make progression decision by late June.	SD, JR, with input from rest of Evaluation Team. AM & EC, with input from rest of Evaluation Team
July 2024-Dec 2024	Reflect on feedback from report. Make any alterations necessary to procedures. Efficacy baseline data collection. IPE data collection.	AM & EC, with input from rest of Evaluation Team
Jan-April 2025	Efficacy post-intervention data collection IPE data collection.	AM & EC, with input from rest of Evaluation Team
May-Dec 2025	Complete 3 month follow up data collection. Complete IPE data collection. Analysis and reporting.	AM & EC, with input from rest of Evaluation Team. SD, JR, with input from rest of Evaluation Team.

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Evaluating institution: Sheffield Hallam University
Principal investigator(s): Dr Abigail Millings

Appendix A: Progress Criteria

Project Implementation

Area	Question	Assessment method	Progression criteria	Red Amber Green
1. Fidelity	Are therapy sessions being recorded?	Calculate percentage of therapy sessions delivered that are recorded.	% therapy sessions recorded	≥75% 74-50% <50%
2. Eligibility/ Referral	Do enough referrals received meet the eligibility criteria?	Calculate the percentage of referrals received during months 9-16[a] of the pilot that were eligible to take part in the study.	% referrals received that met the eligibility criteria	≥75% 74-50% <50%
3. Dosage	Do MBT-PP clients attend enough therapy sessions?	Calculate percentage of clients who attended under six and over six MBT-PP sessions.	i) % clients who were discharged having attended less than six sessions of MBT-PP	≤25% 26-50% >50%

			ii) % clients who were discharged having attended six or more sessions of MBT-PP	≥75% 74-50% <50%
4. Practitioner training	Have MBT-PP therapists received enough training?	Report amount of the five days post-qualification training on MBT-PP received by therapists.	Number of days' training in MBT-PP received by therapists	All therapists have received full 5 days of training in MBT-PP prior to delivering MBT-PP. One or more therapists have received only 3 or 4 days of training in MBT-PP prior to delivering MBT-PP. One or more therapists have received less than 3 days of training in MBT-PP prior to delivering MBT-PP.
5. Supervision	Do MBT-PP therapists receive enough supervision?	Calculate mean hours of supervision per month for MBT-PP therapists.	Mean hours of supervision per month per MBT-PP therapist (pro-rata if part-time).	All therapists delivering MBT-PP receive 1.5 hours per month One or more therapists delivering MBT-PP receive less than 1.5 hours, but more than 59 minutes per month One or more therapists delivering MBT-PP receive less than 1 hour per month.
6. Practitioner capacity	Do MBT-PP therapists have the capacity to work with clients as intended?	Calculate percentage of families (or individual parents, if parents are attending therapy separately) that are contacted by the therapist within 2 weeks of being allocated to a therapist.	% families contacted by a therapist within 2 weeks of being allocated a therapist	≥75% 74-50% <50%

[a] First two months of referrals not included while referrers learn pathway. Project then delayed by set up difficulties, leading to a 4 month extension, hence percentage of eligible referrals to be counted from month 9-16.

Evaluation Measurement

Area	Question	Assessment method	Progression criteria	Red Amber Green
7. Overall recruitment to evaluation.	Have enough families been recruited? Is the project on track to meet the recruitment needed for the efficacy study?	Comparison of actual vs. required recruitment.	i) In months 3-12, 140 families are expected to have been recruited and randomised.	≥75% of target (105 families)
				74-50% of target (70-104 families)
				<50% of target (<69 families)
			ii) % of recruited families where both parents are participating	≥80% of recruited families (112 families)
				55-79% of recruited families (77-111 families)
				<55% of recruited families (<77 families)
8. Attrition from MBT-PP.	Have enough families that started MBT-PP completed the treatment protocol?	Therapist report of whether families were discharged before completing the treatment protocol i.e., before reaching the 'ending and signposting phase' of treatment.	% families who attended session 1 who were discharged before completing treatment protocol	<30% of families who attended session 1
				30-50%
				≥50%
9. Attrition from the evaluation.	Have enough parents and CYP completed the post-treatment outcome measures? Does attrition differ systematically between study arms?	Comparison of actual vs. expected attrition from the evaluation (completing post-treatment outcome measures).	i) Attrition of Parent 1 (provider of primary outcome measure) across study arms.	≤10% of those recruited and randomised
				11-30%
				>30%
			ii) Percentage of Parent 1s who were lost from evaluation who were in MBT-PP condition (aiming for approx. half).	45-55%
				35-44% or 56-65%
				<35% or >65%

			iii) Attrition of Parent 2s (who completed baseline measures) across study arms.	≤10% of those recruited and randomised
				11-30%
				>30%
			iv) Percentage of Parent 2s who were lost from evaluation who were in MBT-PP condition (aiming for approx. half).	45-55%
				35-44% or 56-65%
				<35% or >65%
			v) Attrition of CYP (who completed baseline measures) across study arms.	≤10%
				11-30%
				>30%
			vi) Percentage of CYP who were lost from evaluation who were in MBT-PP condition (aiming for approx. half).	45-55%
				35-44% or 56-65%
				<35% or >65%

Measurement and findings

Area	Question	Assessment method	Progression criteria	Red Amber Green
10. Acceptability/		Calculate proportions of participants allocated to each condition.	% participants allocated to MBT-PP	45-55%
				35-44% or 56-65%

feasibility of randomisation.	Did randomisation work? Were there any problems?	Reflections on randomisation process from SHU, TR and LAs.		<35% or >65%
			Degree of problems reported with randomisation process.	No problems.
				Minor problems, refinements to processes needed.
				Significant problems, major changes to processes needed.
11. Data quality.	Is the baseline and post-treatment primary outcome measure data of high quality?	Calculate amount of missing data within SDQ responses that have been collected	% missing data within the 25 SDQ items completed by parents at baseline and post-treatment	≤10%
				10-30%
				>30%
12. Effective use of core measures.	Is there an effective mechanism in place to collect the outcome measures?	Report mechanisms for collecting outcome measures.	Mechanisms in place to collect outcome measures from parents and CYP.	A Gateway Lead is in post in each LA to liaise with evaluator for the completion of baseline, post-treatment and follow-up outcome measures.
				There is a not a Gateway Lead currently working in each LA, but alternative arrangements to support data collection have been/are being made where necessary.
				There is not a mechanism in place to support data collection in each LA.

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Home Office

youthendowmentfund.org.uk

hello@youthendowmentfund.org.uk

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