The Supporting Parents Project (SPP): Randomised Controlled Trial and implementation process study of the Lighthouse Parenting Programme (LPP)

Protocol version	Version 2, updated 09.09.2021
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Type of Trial	RCT
Age or Status of Participants	Parents of children aged 0-12 years on a Child in Need or Child Protection plan, or in pre-proceedings.
Number of Participating Local Authorities	Five
Number of Children and Families	120-144 parents
Primary Outcome(s)	Social care risk status, Child abuse potential
Secondary Outcome(s)	Parenting Stress, parent reflective functioning, parental representations, parental epistemic trust, parent perception of child emotional and behavioural wellbeing.
Contextual Factors	Engagement and implementation factors

Summary

Maltreatment has profoundly negative and long-term impacts on a child's life. Maltreated children are at increased risk of drug misuse, serious mental health difficulties, suicide attempts, risky sexual behaviour and physical ill-health throughout later life (Norman et al., 2012). They achieve poorer educational outcomes and are more likely to participate in crime and violence in adolescence and adulthood (Gilbert et al., 2009). The availability of help for the most high-risk families remains limited in the UK (Barlow el al., 2006; Mulcahy et al., 2014).

The Supporting Parents Project (SPP) is a study which aims to evaluate the Lighthouse Parenting Programme (LPP) in Children's Social Care (CSC) for parents with children known to child protection services. The LPP is an adaptation of Mentalization-Based Treatment (MBT) and has been specifically developed for parents for whom there are serious parenting concerns. It aims to promote safe and sensitive caregiving by helping parents to understand their children's needs more clearly and repair the relationship when harmed. Its strength is in engaging hard-to-reach parents, who typically do not benefit from parenting programmes. In the LPP, parents attend a weekly Parents' Group, facilitated by two LPP practitioners, and fortnightly one-to-one sessions with an individual therapist. The programme makes use of visual and metaphorical material whereby the parent is seen as a lighthouse, providing a gentle attentive light for their child's journey and guiding them back to shore for support, help or comfort when needed.

A pilot evaluation of LPP (Byrne et al, 2019) found that it may be effective in improving parenting confidence and sensitivity and that parents valued the programme and the changes it had helped them to bring about. The Supporting Parents Project will involve a scaling up and evaluation of the programme on a wider scale in a randomised controlled trial.

The SPP is a two-arm multi-site randomised controlled trial of the Lighthouse Parenting Programme (LPP) versus Treatment as Usual (TAU) in Children's Social Care (CSC). The study will take place in five local authority CSC teams with 120-144 parents. Parents will be randomly allocated to one of two groups: TAU or the LPP + TAU. Four sites will run one LPP group of 10-12 parents and provide the usual care interventions for 10-12 parents in the TAU only group. The fifth site will recruit double the number of participants and will run two concurrent LPP groups (giving a total of 6 recruitment clusters).

The overall aims are:

1) To evaluate the effectiveness of the LPP compared with Treatment as usual in the CSC context.
2) To assess the process of implementing the LPP in CSC and the factors involved in successful delivery and treatment change.
3) To assess the costs of LPP in CSC.

The study will include an evaluation of outcomes for families, an evaluation of the implementation and process, and an evaluation of costs.

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Background and Problem Statement

Maltreatment has profoundly negative and long-term impacts on a child's life. Children who have suffered maltreatment from a caregiver show elevated rates of reactive attachment disorder (Mulcahy et al., 2014; Zeanah et al., 2004) and are at increased risk of drug misuse, serious mental health difficulties, suicide attempts, risky sexual behaviour and physical ill-health throughout later life (Norman et al., 2012). They achieve poorer educational outcomes and are more likely to participate in crime and violence in adolescence and adulthood (Gilbert et al., 2009). In the United Kingdom, there has been a call for the development of effective attachment-based interventions for families where children are at risk of maltreatment (Centre for Social Justice, 2008). The attachment relationship between children and their caregivers refers to the way in which children seek comfort and learn to adapt their behaviour to maintain proximity to their caregivers at times when they need emotional and physical safety. The quality of the attachment relationship between a child and their primary caregiver/s has been shown to be crucial in later psychosocial development (Sroufe, 2005). The child's capacity to develop a secure attachment relationship with their caregiver is dependent on that caregiver's ability to provide safe, sensitive and predictable care. Parental maltreatment is associated with insecure and disorganized attachment strategies in the child, both of which are associated with poor developmental outcomes (Baer & Martinez, 2006). Attachment-based interventions, which aim to strengthen parental sensitivity and promote child attachment security, can have wide-ranging benefits for families on the edge of care. However, the availability of interventions for the most high-risk families remains limited (Barlow et al., 2006; Mulcahy et al., 2014).

Mentalizing, the capacity to imagine mental states and to be attuned to mental states in self and others, is a highly appropriate domain for therapeutic intervention in harmful parenting. Most instances of child abuse and neglect can be conceptualised as arising from deficits, serious lapses or mis-uses of mentalizing or some combination of these factors. Some parents' own experiences of maltreatment in childhood are likely to have disorganised their attachment system and thereby disrupted the acquisition of ordinary mentalizing (Fonagy & Allison, 2012). Deficits in mentalizing, in which a parent cannot see or imagine the child's needs, may contribute to a pattern of consistent emotional or physical neglect. For instance, a parent who fails to recognise his baby as a person with wishes, desires and intentions does not provide opportunities for growth, curiosity, play or stimulation accordingly. Alternatively, in response to a baby's cries of hunger, fear or loneliness, an avoidant/dismissive parent might not be roused into empathically responding, whereas a preoccupied/conflicted parent's own unmet needs might overwhelm them (Buisman et al., 2017).

Mentalizing is an inherently imaginative mental activity, and as such, it is compromised in times of high emotional arousal. Parenting is stressful and therefore naturally leads to significant and frequent lapses in mentalizing for most people. Powerful feelings of guilt, protectiveness, humiliation, worry, love, frustration, and anger are part of the ordinary parenting experience, and in high doses can leave parents with few mental resources for staying curious. Charged states lend themselves instead to snap judgements or hasty assumptions about a child's intentions. Parenting stress has also been shown to mediate the association between maternal history of maltreatment and parental sensitivity (Pereira et al., 2012) and can impinge on the capacity to mentalize (Nolte et al., 2013). The accuracy of reading and responding to the child's communications inherently requires the ability to mentalize and sensitivity may be seen as the behavioural manifestation of the mentalization

process. Statutory health and social care services, while offering universal access, nonetheless have poor records in engaging parents who have experienced complex trauma, developmental trauma, disorganized attachments, mental health difficulties and multiple adverse childhood experiences. This is in part due to parents presenting with complex sets of difficulties- including emotional regulation - that can be challenging to professionals, but also reflects a tendency to label parents as 'hard-to-reach' rather than our services as 'difficult for some to reach'. Parents with one or more of these factors are more likely than the average parent to experience mentalizing lapses, and when they do lapse, tend to show poorer parental sensitivity and have more difficulty becoming curious and flexible again (Fishburn et al., 2017). Moments in which a parent makes a hostile misattribution about a child's intentions may result in non-accidental injury, physical chastisement or instances of emotional and psychological abuse (Richey et al., 2016).

Parents at risk of maltreating their children are often reluctant to engage in treatment or parenting interventions, refuse outright to do so or drop out. Neglect and emotional abuse in the parents' own histories often affect their development of epistemic trust, that is, their 'trust in the authenticity and personal relevance of interpersonally transmitted knowledge about how the social environment works' (Fonagy, Campbell, & Bateman, 2017, p. 177). In many cases, it can bring about a state of chronic epistemic mistrust, which manifests in parents' tendency to treat others with deep suspicion and results in a difficulty in internalising new social knowledge from others (Bateman & Fonagy, 2016; Fonagy & Allison, 2012).

An MBT approach has much to offer this population. MBT works directly with issues of trust, and there is robust evidence for its effectiveness at engaging hard-to-reach adults who have complex histories of attachment trauma or neglect, poor emotion regulation, and difficulties building stable trusting relationships (Bateman, Bolton, & Fonagy, 2013; Bateman & Fonagy, 2008; Bateman, O'Connell, Lorenzini, Gardner, & Fonagy, 2016). Confidence in the parenting role can be severely undermined when families are referred to child protection services. This can further undermine the parent's ability to provide consistent nurturing for their children and may exacerbate their heightened levels of stress. A successful intervention for families where children have been identified as at risk of maltreatment should serve to improve parental sensitivity and confidence and alleviate the amount of stress that such parents are already under.

The Lighthouse Parenting Programme aims to improve parental sensitivity and confidence, reduce stress and the risk of child maltreatment by attending to both parental deficits in mentalizing and lapses in mentalizing. It has been developed specifically for high-risk parents. The programme is designed to enhance parental mentalizing, that is, to foster in parents an active curiosity about the child's inner world and a readiness in parents to reflect on their own thoughts, feelings, and reactions. It supports parents to make sense of misunderstandings in their relationship with their child, including misunderstandings that arise from unresolved difficulties in the parent's own attachment history, it equips parents to inhibit harmful responses in those moments of misunderstanding and to repair ruptures arising from these misunderstandings in their relationship with their child. In keeping with other MBT programmes, the LPP explores parents' own attachment styles, and the attachment styles of their children, but places more specific emphasis on explicitly working with attachment in each session. The central metaphor in the programme is of the parent as a lighthouse, providing a gentle attentive light for their child's journey and a homing beacon, guiding their child back to safe harbour/shore for support, help or comfort when needed. The programme

helps parents approach their child with a curious, wanting-to-know mentalizing stance ("Illuminating Beam"). This helps them to recognise where their own mentalizing as a parent can fail and when too much certainty about their child's inner world- which can be prone to distortion- replaces curiosity ("Projecting Beam"). The programme gives parents skills to recognise such moments and, when they happen, to attempt to restore their own mentalizing to gain clearer sight of the child.

The programme has been successfully developed, implemented and tested in specialist Child and Adolescent Mental Health Services by psychological therapists and is the core model of treatment for the small numbers of families. In these services, families usually commence treatment on child protection plans, in pre-proceedings or care proceedings. The majority move to Child in Need plans or discharge on completion of the programme, and in a significant number of cases, families are successfully reunified (Byrne & Webb, 2015). A small non-randomised pilot evaluation of the programme demonstrated improvements in parental sensitivity, parenting confidence and parental stress from pre- to post-intervention with moderate to large effect sizes (Byrne et al., 2019). Interviews with participating parents indicated that most felt the programme had led them to make "life-changing" improvements in their capacity to care for their children. While this small-scale pilot (n=12) indicates potential effectiveness and value to parents, further work is needed to rigorously evaluate LPP's effectiveness in a randomised controlled trial. Furthermore, small specialist services do not have the capacity to support the large numbers of parents presenting to children's social care. The aim of this project, therefore, is to scale up and evaluate the LPP in the settings where it can have the most impact- children's social care. Frontline social care practitioners will be trained to deliver this intervention and a rigorous evaluation of the implementation process and outcomes in such a setting will be conducted.

Intervention and Theory of Change

Overview

The Supporting Parents Project is an evaluation of the Lighthouse Parenting programme- an innovative mentalization-based treatment (MBT) parenting intervention for families where children are at risk of maltreatment. The programme is an adaptation of MBT for borderline and antisocial personality disorders, with a particular focus on attachment and child development.

Aim

The Lighthouse Parenting Programme aims to prevent child maltreatment by promoting sensitive caregiving in parents. The programme is designed to enhance parents' capacity for curiosity about their child's inner world, to help parents 'see' (understand) their children clearly; to help parents make sense of misunderstandings in their relationship with their child (including misunderstandings that arise from unresolved difficulties in the parent's own attachment history); and to equip parents to inhibit harmful responses in those moments of misunderstanding, and to repair the relationship when harmed.

Why take a mentalizing approach with high-risk families?

Mentalizing is the capacity to imagine mental states and to be attuned to mental states in self and others, holding minds in mind. Mentalizing is a highly appropriate domain for therapeutic intervention in harmful parenting for two primary reasons: Firstly, we can understand most instances of child abuse and neglect as arising from deficits in mentalizing, serious lapses in mentalizing, misuses of mentalizing, or some combination of these factors. Secondly, MBT can help engage hard to reach parents, who typically do not benefit from parenting programmes. MBT works directly with issues of trust; there is robust evidence for its effectiveness at engaging adults with complex psychological and social difficulties who - like many of the parents whose children are referred to social care - have histories of attachment trauma or neglect, poor emotion regulation, and difficulties building stable trusting relationships.

Format

The Lighthouse Parenting Programme is a 20-week intervention. Parents attend a weekly Lighthouse Parents' Group (2hrs), facilitated by two practitioners, and fortnightly one-to-one Parenting sessions with one of the practitioners (1hr). The practitioners are trained in MBT skills as well as the Lighthouse model and the group and individual sessions follow a mentalizing approach. In keeping with other MBT programmes, the Lighthouse Parenting Programme explores parents' own attachment styles, and the attachment styles of their children.

Each session is at its core an MBT session. This means that practitioners will be aiming for parents to feel seen and understood and that they will experience practitioners as genuinely open and curious about their minds and are more likely to trust in what they learn from the programme. This attitude or stance, the curious, 'wanting to know' stance is called the mentalizing stance. Practitioners attend first and foremost to the issues that parents bring to each session, and aim each time to help parents understand misunderstandings, map their own and others (especially children's) behaviour in relation to their internal world, including attachment needs in the moment. The programme also makes use of a 'library' of videos, images, vignettes, role play and creative activities, in order to stimulate active curiosity and

mentalizing. These are intended to be drawn on and used as needed, rather than 'delivered' at predetermined points in the programme.

The programme uses metaphor as a way of helping parents hold complex mentalizing and attachment concepts in mind, so that these are salient later even under pressure (e.g., when dealing with a child whose behaviour a parent might find frightening, infuriating, or confusing). The central metaphor in the programme is of the parent as a lighthouse, providing a gentle attentive light for their child's journey and a homing beacon, guiding their child back to safe harbour/shore for support, help or comfort when needed.

Mode of delivery

Due to uncertainty during the Covid-19 pandemic, both groups and individual sessions will be hosted online, via video conferencing.
Group sessions: Two to three practitioners and 8-12 parents, weekly for 20 sessions.
Individual sessions: Each parent has individual MBT-P sessions with a practitioner (one of the group facilitators), fortnightly alongside the group programme.

Staff training

The clinical team who developed the programme will provide an MBT-Basic 3-day training and a 5-day Lighthouse training to teams of social workers and family support practitioners from each participating Local Authority. These teams will then deliver the Lighthouse Parenting Programme at each site.

The training provides trainees with:

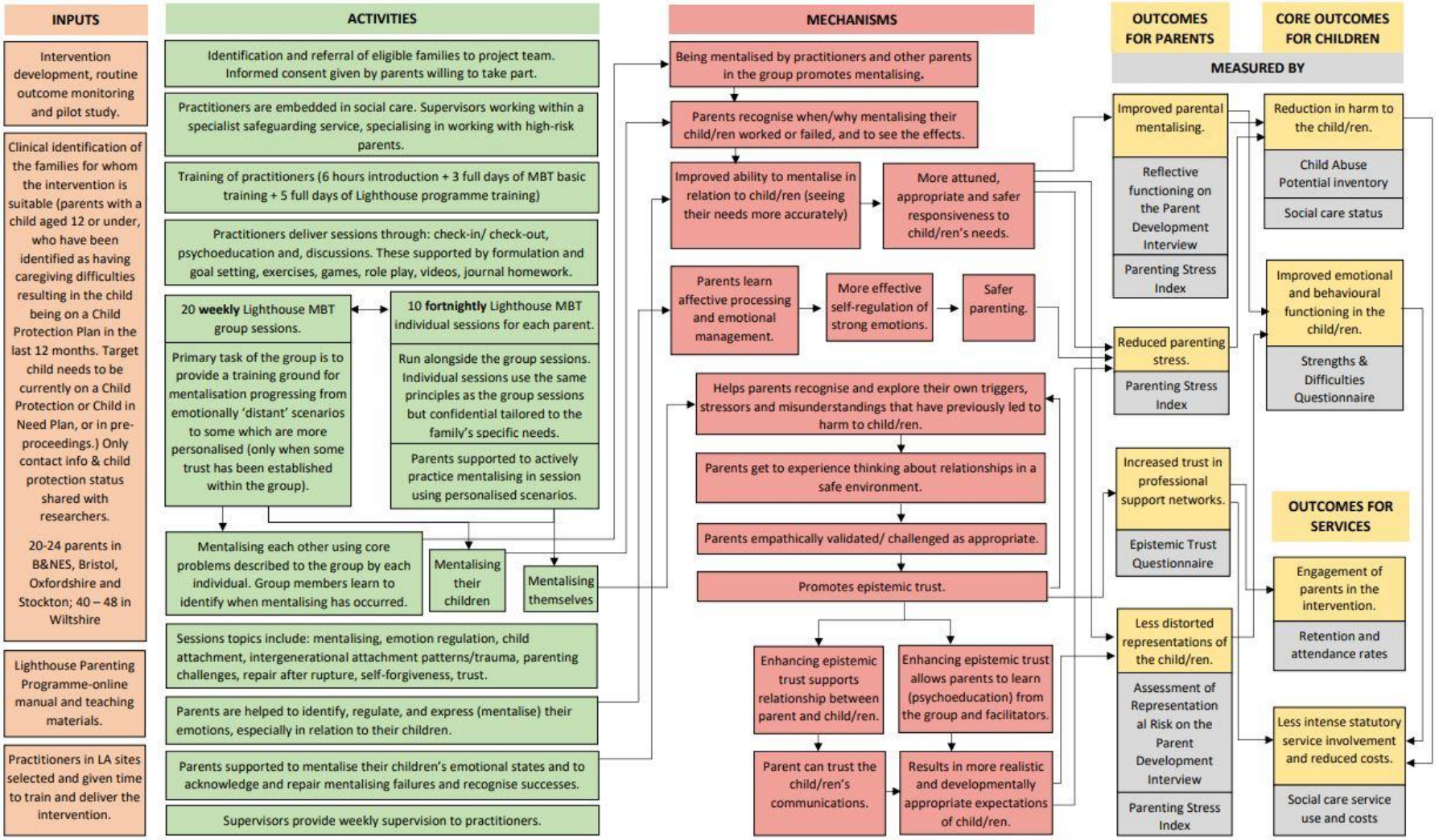
- An understanding of the centrality of mentalizing to the parent-child relationship.
- An understanding of the attachment-oriented Lighthouse metaphors, and confidence to use them in clinical practice.
- The clinical skills to enhance parents' capacity for mentalizing; in particular mentalizing their children, and mentalizing under stress.
- The clinical skills for facilitating a mentalization-based parenting group (MBT skills, group therapy skills, and Lighthouse-Parenting specific skills)
- The confidence to run the Lighthouse group programme with supervision.

The training is highly experiential, rich with video examples and role plays. Trainees are actively encouraged to reflect on their own attachments, and the impact of the work on themselves. Each person will have the opportunity to experience being in a parents' group facilitated by the trainers, in which they will participate in Lighthouse programme activities themselves.

Supervision

The trained practitioners will receive weekly (90min) group supervision with an experienced Lighthouse Parenting Programme practitioner from the clinical development team. Supervision consists of submitting videos of group and individual sessions for the supervisor to review, and a specific focus on (a) honing MBT micro-skills, with attention to the submitted video footage; (b) ongoing refinement and development of mentalization-based risk formulation for each family; (c) reflection on the impact of the work on the therapists and supporting therapists to notice their own mentalizing and non-mentalizing moments in relation to the families they are supporting.

Logic model


INPUTS
Intervention development, routine outcome monitoring and pilot study.
Clinical identification of the families for whom the intervention is suitable (parents with a child aged 12 or under, who have been identified as having caregiving difficulties resulting in the child being on a Child Protection Plan in the last 12 months. Target child needs to be currently on a Child Protection or Child in Need Plan, or in pre-proceedings.) Only contact info & child protection status shared with researchers.
20-24 parents in B&NES, Bristol, Oxfordshire and Stockton; 40 – 48 in Wiltshire
Lighthouse Parenting Programme-online manual and teaching materials.
Practitioners in LA sites selected and given time to train and deliver the intervention.
ACTIVITIES
Identification and referral of eligible families to project team. Informed consent given by parents willing to take part.
Practitioners are embedded in social care. Supervisors working within a specialist safeguarding service, specialising in working with high-risk parents.
Training of practitioners (6 hours introduction + 3 full days of MBT basic training + 5 full days of Lighthouse programme training)
Practitioners deliver sessions through: check-in/ check-out, psychoeducation and, discussions. These supported by formulation and goal setting, exercises, games, role play, videos, journal homework.
20 weekly Lighthouse MBT group sessions.
10 fortnightly Lighthouse MBT individual sessions for each parent.
Primary task of the group is to provide a training ground for mentalisation progressing from emotionally 'distant' scenarios to some which are more personalised (only when some trust has been established within the group).
Run alongside the group sessions. Individual sessions use the same principles as the group sessions but confidential tailored to the family's specific needs.
Parents supported to actively practice mentalising in session using personalised scenarios.
Mentalising each other using core problems described to the group by each individual. Group members learn to identify when mentalising has occurred.
Mentalising their children
Mentalising themselves
Sessions topics include: mentalising, emotion regulation, child attachment, intergenerational attachment patterns/trauma, parenting challenges, repair after rupture, self-forgiveness, trust.
Parents are helped to identify, regulate, and express (mentalise) their emotions, especially in relation to their children.
Parents supported to mentalise their children's emotional states and to acknowledge and repair mentalising failures and recognise successes.
Supervisors provide weekly supervision to practitioners.
MECHANISMS
Being mentalised by practitioners and other parents in the group promotes mentalising.
Parents recognise when/why mentalising their child/ren worked or failed, and to see the effects.
Improved ability to mentalise in relation to child/ren (seeing their needs more accurately)
More attuned, appropriate and safer responsiveness to child/ren's needs.
Parents learn affective processing and emotional management.
More effective self-regulation of strong emotions.
Safer parenting.
Helps parents recognise and explore their own triggers, stressors and misunderstandings that have previously led to harm to child/ren.
Parents get to experience thinking about relationships in a safe environment.
Parents empathically validated/ challenged as appropriate.
Promotes epistemic trust.
Enhancing epistemic trust supports relationship between parent and child/ren.
Enhancing epistemic trust allows parents to learn (psychoeducation) from the group and facilitators.
Parent can trust the child/ren's communications.
Results in more realistic and developmentally appropriate expectations of child/ren.
OUTCOMES FOR PARENTS
CORE OUTCOMES FOR CHILDREN
MEASURED BY
Improved parental mentalising.
Reflective functioning on the Parent Development Interview
Parenting Stress Index
Reduction in harm to the child/ren.
Child Abuse Potential inventory
Social care status
Improved emotional and behavioural functioning in the child/ren.
Strengths & Difficulties Questionnaire
Reduced parenting stress.
Parenting Stress Index
Increased trust in professional support networks.
Epistemic Trust Questionnaire
OUTCOMES FOR SERVICES
Engagement of parents in the intervention.
Retention and attendance rates
Less distorted representations of the child/ren.
Assessment of Representational Risk on the Parent Development Interview
Parenting Stress Index
Less intense statutory service involvement and reduced costs.
Social care service use and costs
MODERATING FACTORS
Family engagement – willingness of parents to attend and participate in all sessions. Failure could lead to less effective interventions for some parents and disruption of therapeutic group processes.
MITIGATING FACTORS: Practitioners to help establish trust and cohesion within the group, supervision, experts by experience can be consulted to problem-solve engagement issues.
Fidelity to the intervention model - practitioners do not adhere to MBT principles or do not deliver all components of manualised intervention. Failure may lead to less effective interventions and could therefore impact on outcomes.
MITIGATING FACTORS: Weekly supervision, videoed sessions, training is experiential and intensive, detailed and structured manual, crib sheets for practitioners.
Implementation issues – practitioner time for preparation and delivery, technological issues. May result in problems with parent engagement and practitioner fidelity to the model.
MITIGATING FACTORS: Practitioners allocated adequate time for preparation and delivery. Parents loaned the required technology if needed.

Impact Evaluation

Research questions

Primary research questions

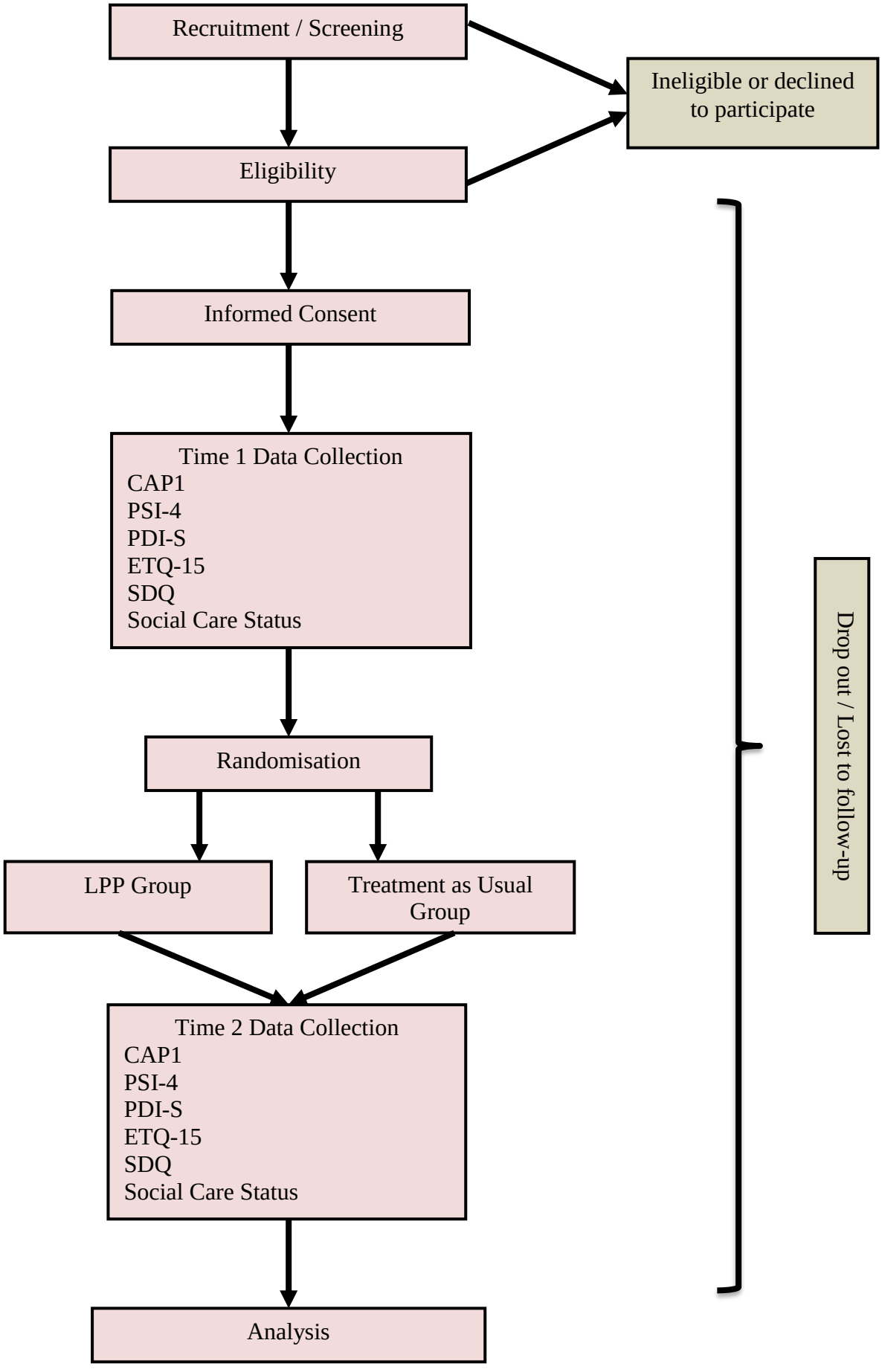
1. What is the impact of LPP on the risk of child physical harm compared to treatment as usual for parents open to children's social care services?
2. What is the impact of LPP on child social care status compared to treatment as usual for parents open to children's social care services?

Secondary research questions

1. What is the impact of LPP on parenting stress compared to treatment as usual for parents open to children's social care services?
2. What is the impact of LPP on parental reflective functioning compared to treatment as usual for parents open to children's social care services?
3. What is the impact of LPP on parental representational risk compared to treatment as usual for parents open to children's social care services?
4. What is the impact of LPP on parental epistemic trust compared to treatment as usual for parents open to children's social care services?
5. What is the impact of LPP on parent-reported child social, emotional and behavioural wellbeing compared to treatment as usual for parents open to children's social care services?

Design

Trial type and number of arms		RCT, two arms
Unit of randomisation		Parent, en bloc
Stratification variables (if applicable)		Site
Primary outcome	variable	1. Risk of parent physically abusing child 2. Whether the child is on a CiN or CP plan, or if the family has entered court proceedings
	measure (instrument, scale)	1. Child Abuse Potential Inventory (CAPI) (Milner, 1994) 2. Change in child social care status over the intervention period
Secondary outcome(s)	variable(s)	1. Stress relating to the parenting role 2. Parent reflective functioning (RF) 3. Parent representational risk 4. Parent epistemic trust in communication and communicated knowledge 5. Parent perception of child emotional, behavioural and social well-being
	measure(s) (instrument, scale)	1. Parenting Stress Index (PSI-4; Abidin,1995) 2. Parent Development Interview-Short version (PDI-S; Slade et al, 2004) 3. Epistemic Trust, Mistrust and Crudulity Questionnaire (ETMCQ; Campbell et al, 2021) 4. Assessment of Representational Risk (ARR; Sleed et al., 2021) coding of PDI-S 5. The Strengths & Difficulties Questionnaire (SDQ) (Goodman, 2001)


Recruitment / Screening
Ineligible or declined to participate
Eligibility
Informed Consent
Time 1 Data Collection
CAP1
PSI-4
PDI-S
ETQ-15
SDQ
Social Care Status
Randomisation
LPP Group
Treatment as Usual Group
Time 2 Data Collection
CAP1
PSI-4
PDI-S
ETQ-15
SDQ
Social Care Status
Analysis
Drop out / Lost to follow-up

Referral and assessment pathway

Five Local Authority Children's Social Care sites in England are participating in the trial: Bath and North-East Somerset, Bristol, Oxfordshire, Stockton-on-Tees and Wiltshire. In each site, social work teams who are working with the target population will lead on the identification and recruitment of participants. The project evaluation and delivery team will hold a recruitment workshop for referrers and managers in each site prior to recruitment starting. The project manager will work with the site coordinators to provide support for the identification and referral of families.

The initial identification of participants will be done by the data management teams who will apply the criteria to current cases and develop a shortlist of potential participants. As some of the inclusion/exclusion criteria (see below) require professional judgement and knowledge that will not be available from the data records, case-holding social workers will then further screen and shortlist potential participants based on their knowledge of the families. Following this screening process, case-holding social workers will give the potential participants information about the study and will invite them to join. If the parent agrees, the social worker will make the referral. Referrals will be made consecutively until sufficient numbers of participants have consented to participate in that site cluster (n = 20-24). We have estimated that, following careful screening and support from the referring social workers, approximately 70-80% of parents who are referred will consent to participate.

Referrals will be made online to the research team through a secure website link. A researcher will then contact the potential participant to provide them with further information about the study and, if the parent wishes to participate, will take informed consent. Once a parent gives consent, baseline (Time 1) data will be collected.

Participants will be randomly allocated to the LPP or TAU treatment group after Time 1 data has been collected at that site. The interventions will be delivered locally in each site. Each site- apart from Wiltshire- will run one LPP group of 10-12 families and provide the TAU interventions for 10-12 families in the control condition. Wiltshire will recruit and provide interventions for twice as many participants and will run two concurrent LPP groups. At the end of the intervention period (Time 2) data will be collected by the research team. Time 2 will be immediately after the end of the LPP, approximately 7 months following random allocation.

Data collection procedure

The research team will collect data from participating parents at Time 1 (immediately after consent, before randomization) and at Time 2 (the end of the intervention period) approximately 7 months later. Each participating parent will complete the battery of measures, even if they are a co-parent with another participant. All research interviews will be done online over Microsoft Teams. The research interviews will be independent of the interventions and the researchers conducting the interviews will be blind to allocation status at Time 2. The social care teams will ensure that participants have appropriate technological resources to facilitate online meetings and some funding is available for families needing additional support. During the interviews, the researcher will go through the demographic form (Time 1 only), all questionnaires, and a semi-structured interview. It is likely that two or more appointments will be needed to complete the measures. In total, the research interviews will last about 90 minutes to 2 hours at each time point. All participants will be

given a voucher to the value of £25 for each time point that they participate in as a compensation for their time (£50 value if they participate at Time 1 and 2).

Randomisation

Adults with shared parenting responsibilities may wish to be referred to the study at the same time (e.g. biological or step-parents, co-habiting partners, separated parents). In these cases, each parent or caregiver will complete all measures individually, but to prevent contamination, they will be randomised together. All participants who have any shared caregiving responsibilities and who wish to participate in the trial at the same time will be randomised to the same group (i.e. this could be two or more people). The dependency in the data will be accounted for in the analyses. Any linked co-parents will be referred to here as a "family".

As LPP is a group-based intervention, randomisation will be done en-bloc in six clusters (four LA sites will have a single cluster and one LA site will have two clusters). Allocation will be done at the family level and will be stratified by site. Randomised permuted blocks of size 4 will be used at each site to allocate participants to either LPP (n=10-12 per cluster) or TAU (n=10-12). To maintain allocation concealment, allocation will be done en-bloc after 20-24 cases in that site after families have completed baseline assessments. This will be done on a site-by-site basis, as recruitment is completed for that cluster. Group assignment will be conducted by an independent statistician in a separate organisation who will be blind to all participant data. They will conduct the randomisation using R. The code for randomisation will be provided to them. Case IDs which uniquely identify the family will be entered into a secure web portal by the researchers. The statistician will notify the Project Manager of the outcome of the randomisation procedure within 24 hours of receiving the case list and the Project Manager will let the participants and referrers know the outcome. In this way, the research assistants responsible for data collection will remain blind to allocation status.

Participants

The inclusion and exclusion criteria were decided by a working group involving the Lighthouse clinical team, social care partners and the evaluation team. These criteria, which are listed below, are based on clinical considerations of the parents who would be able to engage safely in MBT and group-based interventions, ethical considerations, and practical considerations for conducting an RCT in CSC.

Inclusion Criteria

1. Parent has at least one child aged 0-12 years (the 'target child/ren)'.
2. Parent has been identified as having caregiving difficulties which has resulted in the child being:
   - on a Child Protection Plan, or
   - on a Child in Need Plan, or
   - in pre-proceedings

Exclusion criteria

1. The target child is currently in care proceedings.
2. The referring professional considers the family likely to proceed to care proceedings in the next 6 months.

3. The referring professional considers the parent to be unsuitable for a group-based intervention as they may compromise the safety of others in a group setting. For example, this may be the case if they have a diagnosis of Anti-Social Personality Disorder.
4. The parent has been a perpetrator of sexual abuse or has a history of sexual predatory behaviour.
5. The parent has been a perpetrator of sadistic abuse of children (deliberate physical harm/ torture).
6. The parent has severe learning difficulties.
7. The parent currently has acute psychosis.

Sample size / MDES calculations

MDES (standardized)		0.5
Baseline/Endpoint correlations	Child	N/A
	Participant	0.6
	Social Worker	N/A
Intracluster correlations (ICCs)	Family	N/A
	Group	0.01
	Site	0
Alpha		0.05
Power		0.8
One-sided or two-sided?		Two-sided
Level of intervention clustering		Treatment group
Average cluster size		11
Sample Size (families)	Intervention	68
	Control	68
	Total	136

Five sites will participate in the trial. Four sites will run a single LPP group with 10-12 families each, and one site (Wiltshire) will run two concurrent groups with twice as many participants in each arm. This will provide a total of six clusters of 20-24 families each (N= 120 – 144). The minimum detectable standardised effect size was calculated on this basis. The design is a partially clustered randomised controlled trial. Power analysis was conducted using formulae

published by Moerbeek & Teerenstra (2016). It was assumed that 136 eligible families would be randomised, with 68 participants in six LPP groups, and 68 assigned to TAU. We allowed for 20% loss to follow-up, such that per LPP group at least nine participants and overall at least 54 control participants are assumed to provide post-treatment data, with an achieved sample size of 108. The within-cluster correlation was estimated to be 0.01 and the within-participant correlation to be 0.6. A power analysis assumed the outcomes would not be related to site, which is conservative; within-site correlation would increase the power, as each site would act as its own control. Based on these parameters, the minimum standardised effect size detectable with 80% power is 0.5. The actual power would be 80.6%.

We determined whether 0.5 was a realistic effect size to expect. The LPP pilot evaluation (Byrne et al., 2018) did not include the CAPI as an outcome measure, but the Parental Stress Index yielded a standardised before-after effect size of 0.61. Ethier et al. (2000) used the CAPI Abuse Scale to evaluate two interventions for families at risk of child neglect and observed before-after effect sizes of 0.85 and 0.41, respectively. We expect most study participants to have CAPI scores at or above the cut-off for elevated risk of abuse (215). Pre-treatment standard deviations for an at-risk population were estimated to be around 80 (Ethier et al., 2000). We expected that TAU was unlikely to result in meaningful change in CAPI scores, but that LPP participants would experience reductions in CAPI score of around 40 (one-point reduction in approximately half of the 77 scale items). This would translate to a standardised effect size of 0.5.

Outcome measures

Primary outcome measures

The primary outcomes will be measured by:

- Child Abuse Potential Inventory (CAPI; Milner, 1994), a parent-report measure developed to estimate the risk of a parent physically abusing a child (Chaffin & Valle, 2003; Walker & Davies, 2010) at time 2. This is the most clinically relevant and psychometrically robust measure available to capture what we consider to be a primary aim of the intervention being evaluated- to reduce the risk of harm to the children. The internal consistency, test-retest reliability, concurrent validity and predictive validity are well established (Chaffin & Valle, 2003; Walker & Davies, 2010).
- Social care status. This will be recorded for each child of participating parents at both timepoints, including whether the child is on a Child in Need or Child Protection plan, or if the family has entered court proceedings. Change for each child of the parent participant will be measured as step up (a negative outcome), step down (a positive outcome) and no change in terms of risk status as recorded by social services, measured from baseline to the primary endpoint. This “hard” measure of risk status will complement the self-reported measures, as recommended good practice in conducting RCTs for this population (Tanaka et al, 2010).

Secondary Outcome measures:

The secondary outcomes will be measured by:

- Parenting Stress Index (PSI-4) (Abidin, 1995), a well-validated measure of stress relating to the parenting role. This is a possible mechanism of change for the families, and the pilot study demonstrated possible benefits in this domain.
- Parent Development Interview - Short Version (PSI-S) (Slade et al, 2004), a shortened version of the Parent Development Interview. It can be used to code parental reflective

functioning (Slade et al., 2004). The intervention explicitly aims to improve parental reflective functioning, and this is considered the most likely mechanism of change. The interviews will also be coded with the Assessment of Representational Risk (ARR; Sleed et al., 2021), an additional coding system for the PDI that measures features of parenting representations that are associated with attachment disorganization.

- Epistemic Trust, Mistrust and Credulity Questionnaire (ETMCQ; Campbell et al, 2021), a self-report measure of parent's epistemic trust in communication knowledge. Epistemic trust has been linked to mentalization and the pilot study indicated that parents receiving the LLP reported improved trust in social care professionals. Understanding whether LLP is associated with increased parental trust in social care services and professionals will be relevant to the study aims and expected mechanisms of change.
- The Strengths & Difficulties Questionnaire - Total Difficulties score (Goodman, 2001), a measure of child emotional, behavioural and social well-being. The parent-report version will be administered in relation to the "target child" (see inclusion criteria above). If more than one child meets the criteria to be the target child, participating parents will each be asked to identify one child (the one they are "most concerned about") and outcome data will be collected in relation to that child.

The researchers administering and scoring the data will be blind to intervention allocation. If the participant reveals their allocated intervention group to the researcher, this will be recorded.

The interventions are unlikely to cause harm to the participants. In the event of an escalation of child protection issues being required, either through changes in child or family behaviour or disclosure of new information during the intervention or research sessions, clear safeguarding pathways and policies will be in place between all project members and families.

Analysis plan

This study is a multi-site randomised controlled trial with clustering in the treatment arm but not in the control arm. The primary outcome is CAPI Physical Abuse Scale score at follow-up, controlling for baseline CAPI score. Our aim is to estimate the mean difference in outcome between the participants in the treatment groups and the control participants. The primary analysis will use a partially clustered mixed effects model allowing for heteroscedastic individual-level errors, thus allowing the outcome variance to differ between treatment and control groups (Flight et al 2016). The between-cluster variation in the treatment group will be modelled as a random effect. The model will also control for site, child age, other baseline characteristics, and baseline CAPI score via fixed effects without interactions. Thus our target estimand is the average treatment effect across sites. Since there are only five sites and six treatment groups, this study is not powered to investigate differences in treatment effects between sites or groups. We will explore whether a model that additionally controls for clustering of participants in families (in the case of co-parent participants) is estimable and, if so, we will use the BIC criterion to investigate if this improves the model. If both are the case, we shall add a random intercept for family to the model equation. The null hypothesis of no treatment effect will be evaluated using a t-test on the coefficient of the treatment indicator, using a two-sided significance level of 0.05. The primary analysis will be intention-to-treat, such that all participants randomised to the treatment arm are analysed as such even if protocol violations occur. A per-protocol analysis will also be carried out.

The analysis model (stated here without the random effect for family, for simplicity) is:

$$Y_{ijk} = \beta_0 + \sum_{k=1}^{4} \beta_k s_k + \gamma Y_{0ijk} + \sum_{g=1}^{G} \delta_g X_{gijk} + \theta t_{ijk} + t_{ijk} u_{jk} + (1 - t_{ijk}) r_{ijk} + t_{ijk} \varepsilon_{ijk}$$

- Y_{ijk}: outcome at endpoint for participant *i* in treatment group *j* in site *k*
- participants: $i = 1, \ldots, n_j$
- clusters: $j = 1, \ldots, m+6$, where *m* is the number of control participants and 6 is the number of Lighthouse groups; control participants are each treated as their own cluster in this type of model (Flight et al 2016)
- *sites:* $k = 1, 2, 3, 4, 5$
- s_k identifies the sites; s_5 is the reference site
- β_0 is an intercept; here it estimates the mean outcome score for a control participant with average baseline score in the reference site
- the coefficients β_k represent differences in outcomes between sites (but <u>not</u> differences in the treatment effect)
- Y_{0ijk} is the participant's (mean-centred) baseline score on the outcome measure
- γ is the slope coefficient relating Y_{0ijk} to Y_{ijk}
- X_g, g = 1, …, G, are baseline covariates (child age, child social care status at baseline, parent age, parent gender, parent education, and baseline values on secondary outcomes), and δ_g are the slope coefficients relating to these covariates;
- t_{ijk} is the treatment indicator (t = 0 for the control participants, t = 1 for Lighthouse participants)
- θ is the treatment effect
- $u_{jk} \sim N(0, \sigma_u^2)$ is a random intercept for cluster j (estimated for the treatment clusters only)
- $r_{ijk} \sim N(0, \sigma_r^2)$ is an individual error term for the control participants
- $\varepsilon_{ijk} \sim N(0, \sigma_r^2)$ is an individual error term for the Lighthouse participants

If some values at the primary endpoint are missing, the following strategy will be employed: 1) Evaluate likely processes of missingness and assess their potential for causing bias; 2) Conduct a complete cases analysis as the primary analysis; (3) Conduct information-anchored sensitivity analyses using controlled multiple imputation under MNAR assumptions to gauge the sensitivity of the trial results to potential violations in the MAR/MCAR assumptions (Cro et al., 2016; 2019).

If values on baseline covariates are missing, we will employ the following strategy: if the overall percentage of missing covariate values is smaller than 20 %, we will use the missing indicator method for covariates (i.e. mean imputation and inclusion of a missing value indicator variable). If the overall percentage of covariate values is 20 % or larger, we will use multiple imputation of missing covariates.

For methodological interest, we will also estimate an analogous analysis model ignoring partial clustering (Model 1 in Flight 2016) to gauge the effect of this form of model misspecification on findings from partially clustered trials. We will also report the observed intra-cluster correlation to inform future studies.

The co-primary ordinal outcome “social care status” will be assessed at baseline and at the primary endpoint. For this outcome, the unit of analysis is the target child. The information from both timepoints will be used to construct a three-level outcome: step down, no change, step up. 'Step down' means a move towards less social care oversight (e.g. a step down from "Child Protection Plan" status to "Child in Need" status). This will be modelled via a mixed effects multinomial regression model (with 'no change' as the reference category) with a random intercept to account for clustering of participants, and fixed effects for site and treatment. We hypothesise that participation in the Lighthouse programme increases the chance of a 'step down' in the child's care status, and reduces the risk of a 'step up', relative to the control group.
As a sensitivity analysis, we shall also analyse the full 8-category social care status variable as an ordinal outcome at the primary endpoint, controlling for social care status at baseline. All other aspects of the mixed effects model (random intercepts and fixed effects) will be handled the same as in the main analysis.

Secondary Analysis:
All interval-scale secondary outcomes will be analysed according to the same principle as the CAPI primary outcome. Parents' responses to the PDI will be scored using the Reflective Functioning Scale, which is an ordinal variable and will be analysed using a multilevel ordinal logistic regression. We will also code the PDI transcripts on the Assessment of Representational Risk (ARR) coding system, which gives a composite score of risk in parental representations (Sleed et al., 2021). As the ARR is a relatively new measure, we will conduct an exploratory analysis of these scores, starting with the assumption that this is an interval variable and that it can be modelled in the same way as the primary outcome. The unit of analysis for secondary outcomes is the parent, expect for the SDQ score, where the unit of analysis is the child. We will use the Benjamini-Hochberg procedure for controlling the false discovery rate for deciding whether to declare ‘statistical significance’ in the secondary (but not the primary) outcomes.

Analysis of Harms
The trial is evaluating a non-invasive psychotherapeutic intervention that has been piloted and developed clinically over many years. However, we cannot assume that there will not be any unexpected adverse events. For example, parents may improve their ability to mentalize in relation to their child, which would most likely reduce the risk of harm to the child, but may also inadvertently lead to guilt about previous parenting behaviours and therefore poorer emotional wellbeing.

We will monitor and record any reports of harm during the trial in several ways. Firstly, the outcome measures will capture any deterioration on a broad range of variables, including reports of harm to the children, increased social care concern about the child’s safety, parental wellbeing and the parents’ view of their relationship with their child. Secondly, data from qualitative interviews will be used to consider a range of experiences with the intervention, including potentially negative experiences. Finally, adverse events will be monitored, discussed and recorded by the clinical supervision team.

Exploratory Analysis
It is important to consider the longer-term outcomes of complex interventions for high-risk families beyond the treatment period. Although this is not included in the current protocol, we will build into the design the option of continuing to follow-up participants beyond the

funded period. This will enable us to keep open the possibility of collecting longer-term outcomes in future.

Contextual Factors Analysis

This study is not powered for quantitative contextual analysis. With regards to this, we intend to use information from the qualitative interviews.

Implementation and process evaluation

Aims

The IPE will address the overall aims of investigating model fidelity, examining the acceptability of the LPP to service users, and exploring potential facilitators and barriers to implementation of the LPP in a Children's Social Care setting.

Research Questions

The specific questions to be addressed will be:

Model fidelity

i) To what extent are CSC practitioners able to stay 'on model' in the delivery of the LPP?
ii) Depending on the levels of model fidelity, what changes to the training, supervision and implementation may be needed to improve LPP model fidelity?

Acceptability

iii) What were the retention rates of parents in the LPP intervention?
iv) How did parents experience the LPP and what were the barriers or facilitators for parents to engage with the LPP?

Implementation and potential for scalability

v) From the perspective of project site staff, what were the barriers and facilitators of implementation?
vi) How would any identified barriers and facilitators inform future planning for commissioning and delivery of the LPP on a wider scale?

Design and Methods

Fidelity

Fidelity to the model will be assessed using the LPP Fidelity Scale. All sessions will be video-recorded as part of the routine supervision process. Randomly selected segments of video-recordings (20 minutes of 3 sessions per group) will be analysed and rated by members of the LPP development team.

In order to examine what changes to the training and supervision may be needed, the LPP practitioners and, separately, the supervision team will take part in two focus groups at the end of the delivery phase. During these focus groups, overall levels of model fidelity will be reviewed, including any items on the scale which had the lowest mean ratings, and practitioners and supervisors will be asked their views on how well the model was adhered to, how the training and supervision supported treatment fidelity and any adaptations that should be made to improve model fidelity.

Acceptability

The retention and attendance rates in the LPP will be assessed as proxy measures of the acceptability of the intervention. Retention will be assessed by facilitator views on whether or not the parent "dropped-out" of the intervention. Attendance of more than half of the

group and individual sessions will be taken as a potential indicator (alongside those mentioned below) that participants felt the intervention was acceptable. Record forms will be provided to each site to keep accurate data on attendance and retention of families in both treatment arms during the delivery phase. This data will be used as one marker of treatment acceptability as indicated by parent engagement in the relative interventions.

At the end of the intervention period, a sub-group of parents who took part in the LPP will be invited to participate in semi-structured interviews about their experiences of the support they received. Purposive sampling will be used to select one parent who completed the LPP and one who did not (or who attended fewer than 50% of sessions) in each site. These parents (n = 12) will be invited to participate in individual semi-structured interviews with a member of the research team. The interviews will explore parents' experiences of the intervention offered, how acceptable they found it, and any facilitators or barriers they found in engaging with the programme. For those who stopped attending the LPP, or who had low attendance, there will be an exploration of reasons for stopping/non-attendance, and of potential barriers to participation. Interviews will be conducted using a semi-structured format, audio-recorded and transcribed.

Implementation and potential for scalability

An online survey will be emailed to all stakeholders in the Local Authority sites (facilitators, case workers and managers) to gain their views on barriers and facilitators of implementation, and to gather views on the scalability of the programme at the end of the delivery phase.

Once the online survey is completed, a single problem-solving workshop, including members of the research team, and selected site facilitators, case workers, and managers, will be organised, in order to review the findings of the survey and discuss potential ways in which any identified barriers could be overcome.

Analysis

Fidelity

The LPP Adherence and Competencies Scale will be used by the LPP training and supervision team (experts in the model) to rate adherence. Each item is rated on a six-point scale, and ratings of ≥3 (indicating behaviour/action exhibited in some instances) are taken as indications of adequate adherence for that competence. The mean and range of ratings will be presented and interpreted descriptively.

Focus group interviews with LPP practitioners and the supervision team will be who attended the LPP will be transcribed, and the data will be analysed using Framework Analysis (Parkinson et al., 2016), a qualitative method which emphasizes how both a priori issues and emergent data-driven themes should guide the development of the data analytic process. In line with guidance on Framework Analysis, three members of the research team will work together on data analysis, and a consensual approach will be taken to ensure the rigour of the analysis.

Acceptability

Retention rates (% completing the intervention) will be described and compared with retention rates for other interventions in the TAU condition. Between group analyses, comparing the characteristics of the parents who complete the intervention with those who do not, will be carried out to check for attrition bias. This will provide further information on which parents were more likely to find the programme acceptable.
Semi-structured interviews with parents who were part of the LPP arm of the study, to explore the acceptability of the LPP, will be transcribed and Framework analysis will be used, as described above, to analyse the data.

Implementation and potential for scalability
The survey will be analysed descriptively, and will be used as the basis for the problem-solving workshop.

Cost evaluation

A full costing of the LPP from a CSC perspective will be carried out. This will entail recording data from all sites about the staff time required and any other costs related to delivering the intervention. The unit cost per family will be estimated, based on the average costs across all sites.

In addition, we hypothesise that the introduction of an intensive parenting intervention like LPP will reduce the level of concurrent input needed compared to the Treatment as Usual condition (for example, Social Worker or Family Support Worker appointments, other parenting interventions, care proceedings), thus offsetting some of the direct costs of LPP. Therefore, service use data will be collected from each CSC site for all families in both treatment arms for the duration of the intervention period. Basic costs (from a CSC perspective) will be estimated for families in both arms. This will enable an estimate of the *additional* unit cost per family.

LPP is a relatively intensive intervention which is likely to appear costly. An important question is whether or not these costs are offset by the reduction in other concurrent or future costs- not just to CSC services, but to society as a whole. The potential savings of reducing the risk of maltreatment to children could be immense (Ferrara et al., 2015).

Ethics & Participation

The study has been reviewed and approved by the University College London research ethics committee (Project ID Number: 9593/002).

Ethical issues are clearly set out in the participant information sheet, consent form and privacy forms for the study. Each state that participating is voluntary, and participants can withdraw at any time without giving a reason and without it affecting any benefits that they are entitled to or their legal rights. Participants can withdraw from the research and continue to receive their allocated intervention. Potential participants will be told about the potential

benefits and difficulties associated with participation in the trial before giving their consent. They will also be informed that all data will be treated confidentially and only used for the purposes explained to them. The limits to confidentiality will also be carefully explained. Detailed information regarding data security will be set out in the data privacy forms approved by the Data Protection officer at AFC. All data will be held in accordance with GDPR guidelines, 2018. A full data protection impact assessment has been carried out and will be under regular review.

Registration

The trial protocol has been pre-registered with the OSF:
Sleed, M., Fearon, P., Midgley, N., Martin, P., Byrne, G., & Zywek, L. (2021, July 15). The Supporting Parents Project: A randomised controlled trial of the Lighthouse Parenting Programme. https://doi.org/10.17605/OSF.IO/GXYS9

Data protection

Purpose of data processing
As the project will be evaluating delivery and impact of a clinical intervention, it will require collecting, processing and sharing personal data. The purpose of the research is to understand the effectiveness of the Lighthouse intervention for delivery to future service users. All participating individuals will be involved in a study which has the potential to really make a difference for parents who are struggling and their children and to generate local learning about new ways of supporting families. Data will be used with the data subjects' knowledge and with ethics approval to ensure we manage it appropriately, including data minimisation and privacy by design. Parents or caregivers will be taking part voluntarily. It is not expected that their capacity to make decisions about data processing will be impaired. They will be provided with an information sheet and data privacy notice which detail what data is collected and how it is stored and used. Participants can freely object to the use of their data, and can withdraw from the study at any time, at which point any identifiable data would be deleted (data that had already been used in analysis could not be deleted, as it would have been de-identified and included in aggregate data analysis). Participants would expect us to use the data in the ways we have described in order to meet the aims of the research study laid out in the information sheet and consent form.

The collection of participant data is essential to achieve the aims of the study. We will ensure that study data is only accessible to authorised study personnel, that data processing agreements are in place and observed and identifiable study data is not shared outside of the specified teams. A privacy notice will be provided at the point where potential participants are invited to participate.

The research team will follow AFC policy on the management of data rights requests and participants will be provided with the opportunity to raise questions or concerns in the intervention or data collection sessions.

Categories of personal data

The evaluation data will come from participants and social care records. The types of data that will be collected and processed as part of the study are:

- Contact details for parents (name, address, email address, telephone number)
- Special category data (ethnicity, health data and sexual orientation, potentially safeguarding history data where held on the social care record or provided by the data subject and family social care record data e.g. index child's social care status, date of most recent case review, reports of harm to the child since the last follow up, and details of service input)
- Questionnaires
- Interview data (audio-recordings)

Referrals (with contact details) will be sent from social care teams to the evaluation team. Demographic, questionnaire and interview data will be collected directly from data subjects at two points, pre- and post-intervention. Data will be collected from the subject's social care record at two points, pre and post intervention.

Role of key parties

Data protection for the study will be overseen by AFC and a data protection impact assessment has been carried out. Three groups are involved: 5 LA Social Care teams (sites), the intervention team and the research evaluation team, who will share data between each other as necessary and may act as Controllers or Processors depending on the activity and purpose.

The LA will be the Controller of and maintain responsibility for the usual care and intervention delivery and data. They will make referrals and share care records with the research evaluation team. Controller to Controller data sharing agreements are in place for this. The intervention team will share anonymised fidelity ratings with the evaluation team. We will have a MOU in place for this. The Anna Freud research evaluation team will be responsible for the collection and processing of outcomes data, collecting data directly from participants and receiving additional data from LA agencies, including the intervention team and Social Care teams. The funders, WWCSC, will be joint data controllers with the AFC for all evaluation data.

Legal basis for data processing

The lawful basis for collecting personal data is Art 6(1)(f) "Legitimate Interest". The minimal data necessary will be collected and used in a way that participants would expect and not in a way that would infringe their rights and freedoms. We will also collect health and ethnicity data and safeguarding data, relying on Article 9(2)(j) and DPA 2018 condition Schedule 1(Part 1)(4) which permits careful use of sensitive data for research purposes, where it is in the public interest. What we learn from the study will be used to help improve services for families in children's social care future.

Data transfers, storage, and retention

Data transfers will be made securely through Microsoft Teams and Microsoft Forms. Only the evaluation team will have access to data from all participants. Individual channels will enable data sharing between each site and the evaluation team, and only relevant, named personnel will have access to these channels.

All data will be stored electronically. Data will be held in a restricted access folder and will be pseudonymised. The key will be held separately. Personally identifiable data will be held for

10 years, and thereafter will be deleted. After this retention period, the data will be fully anonymised and retained in WWCSC's archive for research purposes.

Personnel

Delivery Team

Leigh Zywek: Head of Service Safeguarding, Bath and North East Somerset Council. Responsible for supporting and enabling each Local Authority to recruit, release, and support staff to be assigned/seconded to the programme.
Gerry Byrne: Developer of the Lighthouse MBT-Parenting Programme. Responsible for the delivery of the interventions and training and supervision of practitioners.
Project manager: will support all members of the delivery team to follow the timeline, principally liaising with the participating LAs to ensure timely recruitment.

Evaluation Team

The proposed study will be held within the Child Attachment and Psychological Therapies Research Unit (ChAPTRe), a partnership between the AFC and UCL, which carries out innovative clinical and experimental research related to children's mental health.
Dr. Michelle Sleed: Senior Research Fellow at AFC and Principal Investigator of the SPP. Responsible for overseeing the study evaluation.
Prof. Nick Midgley: Co-Director of ChAPTRe and Professor of Psychological Therapies with Children and Young People in the Research Department of Clinical, Educational and Health Psychology at UCL. Senior Researcher on the evaluation team providing expertise on the delivery of RCT and the evaluation of mentalization-based treatments in children's social care.
Prof. Pasco Fearon: Professor of Developmental Psychopathology and Clinical Psychologist at UCL, Co-Director of ChAPTRe, Co-Director of UCL's Clinical Psychology Doctoral Training Programme, Director of the AFC Developmental Neuroscience Unit and a Visiting Professor at the Child Study Center at Yale University. Senior Researcher on the evaluation team providing expertise in mentalisation-based clinical trials and evaluations and early child development interventions in low resource settings.
Dr. Peter Martin: Lecturer in Applied Statistics at the Department of Applied Health Research at UCL. Senior researcher providing statistical expertise and conducting analysis.
Experts by experience: Graduates of the LPP will be employed to review all procedures and materials and their advice will be sought to help problem solve operational issues arising. This will be an important way of ensuring that the service user perspective is represented in all aspects of the evaluation.
Research assistants: A team of research officers/assistants will carry out the data collection and assist with the processing of data.

Timeline

Dates	Activity	Staff responsible/ leading
07.21	Project set-up: - Ethical approval - Trial protocol drafting and registration - Contracts and data sharing agreements with sites - Project team recruited	PI
07.21	- Recruitment period begins	All
08.21	- Recruitment of families completed.	Delivery team
09.21	-Baseline (T1) outcome data collection complete. - Randomisation of families complete.	PI, statistician
12.21	- Interim report	All
05.22	- Model fidelity rating by supervisors. - Focus groups conducted with LPP practitioners and supervisors.	Clinical team, Evaluation team
06.22	- Follow-up (T2) outcome data collection complete. - Interviews conducted with LPP parents. - Collection of cost-related data from social care teams. - Stakeholder survey completed.	PI, evaluation team
09.22	- Data analysis finalised. - Final report complete and submitted to WWCSC.	Statistician All

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Annex: Record of protocol deviations

Any changes to or deviations from this protocol after its publication will be recorded below.

Details of changes	Date	Reason
Inclusion criteria: Parents of children who are currently on a Child in Need Plan can be included in the study, even if the child has not been on a Child Protection Plan in the previous 12 months (as previously required).	09.09.2021	This would increase the pool of eligible study participants and therefore increase referral rates, especially in the smaller local authorities where recruitment has been slow. It was also agreed at the project steering group that this was a clinically important population to include in testing the effectiveness of the LPP.