

Herts and Minds:

Evaluating the effectiveness of Mentalization-Based Treatment (MBT) as an intervention for children in foster care with emotional or behavioural problems: a phase II (feasibility) randomised controlled trial

Short title: The Herts and Minds Study

TRIAL PROTOCOL

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GENERAL INFORMATION

This document provides details regarding the setting up of, conduct, and analysis of the National Institute for Health Research (NIHR), Research for Patient Benefit (RfPB) funded study, “Evaluating the effectiveness of Mentalization-Based Treatment (MBT) as an intervention for children in foster care with emotional or behavioural problems: a phase II (feasibility) randomised controlled trial” (Short title: 'The Herts and Minds Study: Supporting the Emotional Wellbeing of Children 'Looked After' in Hertfordshire').

The Anna Freud Centre (AFC), a child mental health charity based in London, is the sponsor for this study. The AFC will be in partnership with the Hertfordshire Partnership University NHS Foundation Trust (HPFT), and The University of Hertfordshire (UH). As such, collaboration agreements will be established and exchanged between the three partner organisations. These agreements outline responsibilities and financial arrangements.

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**National Institute for
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Co-investigator: Ms Joyce Robinson

Co-investigator: Dr Sally Wood

R&D representative: Professor Tim Gale

SIGNATURES

The chief investigator (CI), HPFT and UH have discussed the protocol. The investigators agree to perform the investigations and to abide by this protocol except in cases of medical emergency or where departures from it are mutually agreed in writing.

Signature: Date:.....

Name: Professor Tim Gale
For and on behalf of HPFT

Signature: Date:.....

Name: Dr David Wellsted
For and on behalf of UH

Signature: Date:.....

Name: Dr Nick Midgley (Chief Investigator)
For and on behalf of AFC

ABBREVIATIONS AND DEFINITIONS OF TERMS

Organisations involved in the delivery of the study:

AFNCCF	The Anna Freud National Centre for Children and Families
UCL	University College London
UH	University of Hertfordshire
HPFT	Hertfordshire Partnership University NHS Foundation Trust

Personnel involved in the study:

CI	Chief Investigator
CSO	Clinical Support Officer
RA	Research Assistant
TM	Trial Manager

Further abbreviations and definitions:

CAMHS	Child and Adolescent Mental Health Service
CASUS	Child and Adolescent Service Use Schedule
CBT	Cognitive Behavioural Therapy
CHI-ESQ	Experience of Service use Schedule
CHU9D	Child Health Utility
CLA	Children Looked After
CTU	Clinical Trials Unit
CTSN	Clinical Trials Support Network
CRN	Clinical Research Network
FCO	Full Care Order
GCP	Good Clinical Practice
GBOM	Goal-Based outcome measure
ICO	Interim Care Order
LA	Local Authority
MBT	Mentalization-Based Treatment
MRC	Medical Research Council
NIHR	National Institute of Health Research
PIRG	Public Involvement in Research Group
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PSI-SF	Parent Stress Index – Short Form
RCT	Randomised Controlled Trial
RfPB	Research for Patient Benefit
RCADS	Revised Child Anxiety and Depression Scale
R&D	Research & Development Department
SAE	Serious Adverse Event

SRE	Serious Related Event
SDQ	Strengths and Difficulties Questionnaire
SE	Significant Event
SOPs	Standard Operating Procedures
SPA	Single Point of Access
SSC	Study Steering Committee
UCC	Usual Clinical Care
YP	Young Person

1. INTRODUCTION

1.1 SUMMARY

According to the most recent figures, there were 68,840 looked after children in England in March 2014, with 62% in care as a consequence of abuse, neglect and maltreatment (SFR 36,2014). Forty-five percent of looked after children have mental health problems (Meltzer et al., 2003), but the support currently available is variable and these children (and their carers) do not always get the support they need. The 2013 NICE guidelines for looked after children concluded that, *“there is a lack of robust, adequately controlled, studies completed to a high standard [and] the UK evidence base does not serve the needs of looked after children and young people as well as it might”* (p.86).

We propose to test an adaptation of Mentalization-Based Treatment (MBT), for supporting children who are in foster care experiencing emotional and behavioural difficulties, and their carers. The approach, MBT-Fostering, is based on attachment theory and neuroscientific research, and has been developed to support relationships, to promote collaboration between professionals, carers and children in care, and improve the social and emotional well-being for children in care.

1.2 OVERALL OBJECTIVE OF THE STUDY

While our longer-term objective is to undertake a randomised clinical trial evaluating the clinical and cost effectiveness of MBT-Fostering for looked after children and their carers, our initial objective is to conduct a feasibility study which will provide the information we need to design the full scale study to follow. Working closely with Hertfordshire County Council’s Looked After Children’s Service, we will recruit and randomly allocate 42 children who have been referred because of emotional and behavioural difficulties, to one of two arms of the study; MBT-Fostering or to Usual Clinical Care (UCC).

The aims of this study are to establish whether it is feasible to conduct a full-scale trial, and address any obstacles to doing so. We will share our findings with families taking part in the study, and with service commissioners, with the ultimate aim to improve outcomes for children in care.

1.3 PURPOSE OF THE STUDY PROTOCOL

This protocol is intended to be used by all study staff as the approved procedures for the conduct of the study. Every care has been taken in its drafting, with corrections and amendments made by the Chief Investigator (CI). All investigators involved in the study are expected to be familiar with the most up to date version.

2. BACKGROUND

2.1 PRIOR LITERATURE

Children Looked After (CLA) are a vulnerable group with high levels of need and at high risk of experiencing mental health problems (Ford et al., 2007; Tarren-Sweeney & Hazell, 2006). It is estimated that 45% have mental health problems and 68% have special educational needs (NICE, 2013).

According to the most recent figures available, there were 68,840 looked after children in England in March 2014, 62% as a consequence of abuse, neglect and maltreatment (SFR 36/2014). In a comprehensive survey conducted in 2002, 45% of CLA aged 5-17 met criteria for a psychiatric disorder; including conduct disorder (37%), and anxiety and depression (12%); but more recent studies have suggested that the figure could be as high as 72% (Sempik et al., 2008). Even those children without an identified psychiatric disorder tend to demonstrate significant emotional and behavioural problems (de Jong, 2010).

These children are exposed to a variety of risk factors, including maltreatment, multiple placement changes, school underachievement and peer difficulties. As the mental health problems that can arise in these circumstances are significant predictors of future, long-term maladjustment (e.g., Kasen et al., 1999; Moffitt et al., 2011; Harrington et al., 1990), tackling their emotional and behavioural difficulties promptly and effectively is a priority for health and social care professionals (NICE, 2013).

75% of children in the care system in England and Wales are in foster care (SFR 36/2014), an increase of 9% since 2010; but foster families often struggle to manage the broad and complex needs of these children, jeopardising much-needed stability and creating risk of placement breakdown. Children in care, when they present to mental health services, often do so with a complex mix of difficulties, including problems with emotional regulation, anger and oppositionality, as well as problems in close social relationships, including with carers (Schofield & Beek, 2005).

Currently, when referred, these children are likely to be offered a range of un-manualized and eclectic interventions, for which evidence is lacking with regard to their efficacy (Cocker & Scott, 2006; Luke et al., 2014). Professional support systems are also frequently identified as lacking a shared understanding of the child's needs or for a coherent approach to tackling common problems.

2.2 LIMITS OF CURRENT APPROACHES

While recent health and social care policy has prioritised the mental health needs of CLA to agencies commissioning and delivering services for children and young people (National CAMHS Support Service, 2009), the nature and form of support available is highly variable. A recent analysis of USA data (Bellamy et al., 2010) found no difference in emotional or behavioural problems between CLA receiving a professional intervention relative to controls that did not. The analysis, in line with UK experience, provided little evidence that

routine care has reliable positive effects on the outcomes for this vulnerable group.

Although some approaches may be helpful for some children in care (Luke et al., 2014), the lack of a good evidence base for children with moderate emotional and behavioural problems referred to services means that those children are neither offered nor do they consistently receive high quality care. A Cochrane Review (Turner, MacDonald and Dennis, 2007), and the 2013 NICE guidelines for CLA concluded that, *“there is a lack of robust, adequately controlled, studies completed to a high standard”* (p.86), and the guidelines also concluded that, *“the UK evidence base does not serve the needs of looked after children and young people as well as it might”* (p.86).

2.3 RATIONALE FOR THIS STUDY

Over the last ten years the Anna Freud Centre (AFC) has developed a family-based adaptation of Mentalization-Based Treatment (MBT; Keaveny et al., 2012), for use with children and their carers, based on principles from attachment theory. This approach aims to promote the quality of primary relationships, support effective and sensitive parenting and help the child and family understand and manage their emotions. It has been used with a wide range of children including foster children, with promising results from uncontrolled studies (Keaveny et al. 2012; Midgley, 2010).

Although MBT-Fostering has yet to be evaluated systematically, it includes many of the features set out in the NICE guidelines (2013) as key elements of best practice, including a focus on early intervention, and promoting well-being and resilience (recommendation 8), promoting professional collaboration (recommendations 6-7), ensuring that foster carers are included in the 'team around the child' (recommendation 6), and helping social workers to have reflective conversations with foster carers that include emotional support and parenting guidance (recommendations 35-38). The MBT-Fostering approach pays particular attention to developing reflective practice for those working with CLA (recommendations 50- 52). The focus is on improving the core components of secure attachment, including parental sensitivity, collaboration, and parental reflective capacity or 'mentalizing'.

2.4 PUBLIC AND PATIENT INVOLVEMENT (PPI)

Patient and public involvement (PPI) has been central to the design and development of the research, including providing feedback on the design of the study, instruments and assessments and the development of patient information and consent materials. PPI will continue to be central to the ongoing monitoring and management of the study, including reporting of the study results and dissemination.

The prioritisation of developing evidence-based interventions for CLA with mental health needs was born out of the recent NICE/SCIE guidelines on the emotional well-being of CLA, the committee includes patients, carers and other relevant stakeholders. As outlined in the 'background' section, the proposed intervention explicitly includes elements of care that

were highlighted by foster-carers and CLA who had used CAMH services. Feedback from service users, including a focus group with parents and interviews with children, was drawn upon in the process of adapting the MBT model to the treatment of children in foster care, leading to an increased focus on treatment goals being set in relation to the needs of young people, and on collaborative working. We consulted with the Ware foster-carers' support group (Herts), who highlighted the importance of good communication between professionals, which led us to strengthen the element of our intervention which focuses on consultation with the network and creating a 'reflective' team around the child. Two foster carers (service user representatives) were also involved in the development of the research design at each stage. They judged that the aims were relevant, the rationale was persuasive and there were no design aspects or ethical issues that should be improved or that they disagreed with.

In addition to the two foster carer representatives on the Study Steering Committee (SSC), the study will also benefit from the support of the Public Involvement in Research Group (PIRG), an effective and long-standing mechanism for involving the public in research, based at UH. The PIRG have already been instrumental in advising and providing feedback on patient information and consent materials, and they have the skills to empower others in taking part in research, including providing support and training, as necessary. We will thus ensure accessibility, acceptability and usability of the study procedures and materials, and aim to ensure that the needs and potential concerns of foster families and those in their care and of the wider public are represented and accounted for.

We have also worked closely with the targeted CLA team in the Hertfordshire Partnership NHS foundation Trust (HPFT) to ensure that the study design meets the needs of NHS users in the region; that there are sufficient referrals to ensure that recruitment to the study is successful; that clinical teams are enthusiastic about the project; and that the Trust gives full support to the project. We have liaised with the Hertfordshire Research Ethics Committee to ensure that our proposals for gaining consent to participate in the study meet their requirements (as this is a complex area when working with CLA), and have sought legal advice from the Legal Department of Hertfordshire Local Authority (LA), regarding issues of consent for CLA. We have also consulted with a social worker based in Hertfordshire, to ensure that our proposed recruitment strategy would be feasible in the local context. The project is strongly supported by the commissioner for CLA in Hertfordshire, and has support from the LA.

3. STUDY OBJECTIVES

The objective of this study is to establish whether it is feasible to conduct a full-scale clinical trial to evaluate the clinical and cost effectiveness of MBT for CLA who are experiencing emotional difficulties and their carers (MBT-Fostering). We propose an unblinded (see section 5.1 and 7.3) 2 arm randomised control feasibility trial (RCT), in 1 site over 24 weeks with 42 patients. This feasibility study will examine the challenges to, and establish procedures for a later large scale RCT, including the recruitment of a control group that will receive Usual Clinical Care (UCC).

3.1 AIMS

As a feasibility study the aims are:

Aim 1: to test capacity to train mental health practitioners to an acceptable level of **treatment integrity**;

Aim 2: to assess the **feasibility of recruitment processes and uptake to the study**;

Aim 3: to establish **acceptability and credibility of MBT-Fostering as a treatment intervention** for CLA;

Aim 4: to establish **the feasibility and acceptability to families of conducting a randomised clinical trial**;

Aim 5: to establish **the feasibility of collecting resource-use data**, for the purpose of calculating relative cost-effectiveness; and

Aim 6: to **constrain a preliminary estimate of likely treatment efficacy effect size** (treatment outcome measures).

3.2 OUTCOME MEASURES

The instruments, scales, assessments and interviews to be utilized are as follows:

Aim 1: The capacity to train mental health practitioners (**treatment integrity**):

- The **MBT Adherence and Competence Scale** (adapted from Karterud et al. 2013), rating both adherence and competence.
- **Therapist feedback forms**, to provide qualitative feedback about the MBT training and experience of its use in practice.

Aim 2: **The feasibility of the recruitment processes**:

- A **Recruitment Log**, including number of children referred; meeting inclusion/exclusion criteria; completing baseline assessment; randomised into the trial; and reasons for non-eligibility or non-participation. This data will help to determine how long it would take to recruit patients into a definitive trial and the necessary referral levels / number of services that should be involved.
- Focus groups with social workers, to ascertain their views of having their cases included in the study and any barriers to inclusion

Aim 3: The **acceptability and credibility of MBT-Fostering as a treatment intervention** for CLA:

- **A treatment attendance form**, recording non/attendance, and withdrawal with reasons. UCC group includes details about planned/received treatment.
- The **Experience of Service Questionnaire** (CHI-ESQ; Astride-Stirling, 2002) in child, adolescent and carer formats, assessing service satisfaction.
- The **Experience of Therapy and the Research Process Interview** (Midgley et al. 2011); a qualitative interview with foster carer (and child, where appropriate) examining the experience and acceptability of the intervention.

Aim 4: The **feasibility and acceptability to families of conducting a randomised clinical trial**

- **The Experience of Therapy and the Research Process Interview** (Midgley et al. 2011) includes the family's experience of, and barriers to participation in the trial. This qualitative data will be used alongside data from the CRF to assess feasibility and acceptability of the trial procedures themselves. This would include: a) the process of consent and randomization; b) the response rates for primary and secondary outcome measures, including retention at each of the three data collection time-points and level(s) of missing data.

Aim 5: **The feasibility of collecting resource-use data:**

- **Child and Adolescent Service Use Schedule** (CA-SUS, Barrett et al 2006); assessing resource use.
- **Child Health Utility 9D** (CHU9D; Stevens, 2012); assessing Health-related quality of life.

Aim 6: To **constrain a preliminary estimate of likely treatment efficacy effect size** (treatment outcome measures)

Assessment of the treatment outcome measures will be undertaken partly to support assessment of the suitability of the SDQ as a screening tool and outcome measure, and to support effect size estimation, and to inform power estimation for the definitive trial. The following treatment outcome measures will be used to assess the effectiveness of the intervention in the definitive trial.

Primary treatment outcome measure:

- **Strengths and Difficulties Questionnaire** (SDQ, Goodman and Goodman 2012), the routinely used clinical tool assessing emotional and behavioural difficulties in children aged 3-17 in the care system. Primary outcome for child behaviour and emotional well-being will be the carer-rated SDQ, but teacher-rated and young-person (11-17) rated versions will also be used, as appropriate.

- Secondary treatment outcome measures:
 - **Brief Assessment Checklist** (Child and Adolescent Versions – BAC-C and BAC-A; Tarren-Sweeney, in press) a caregiver-reported psychiatric rating scale, for children and young people, complementing the SDQ.
 - **Revised Child Anxiety and Depression Scale** (RCADS; Child (8-16) Version, and Parent Version; Chorpita et al., 2000), a measure of anxiety and depression already used as part of routine outcome monitoring in CAMHS in Hertfordshire.
 - The **Parent Stress Index – Short Form** (PSI-SF; Haskin et al., 2006) used to assess **carer wellbeing** and the **carer-child relationship**.
 - The **Parenting Efficacy Scale** (Woolgar et al., 2012), a measure of beliefs and confidence about parenting skills.
 - The **Parenting Scale** (Arnold et al., 2003), assessing parenting practices, including over-reactivity, a crucial focus of the study.
 - The Five Minute Speech Sample (FMSS, Magana Anato, 1983), coded using the Reflective Functioning coding Manual (Fonagy et al., 1998) to assess the caregiver's capacity for reflective functioning (mentalizing)
 - **Goal-based Outcome Measure** (GBOM; Law, 2013), assessing service user defined treatment outcomes.
 - A **Significant Events** log recording negative life-events, including placement breakdown, involvement with youth justice system and school exclusions.
 - Parent Development Interview – Revised (PDI-R short version for foster carers), assessing caregivers reflective functioning (Slade et al, 2004) will be conducted with a subset of the foster carers.

4. INTERVENTION

Following recruitment to the study ($n=42$), participants will be randomized to one of two treatment arms, MBT-Fostering or Usual Clinical Care (UCC). UCC is defined as the routine interventions the CLA team usually offers to the referred child and carers.

4.1 INTERVENTION DESCRIPTION

MBT-FOSTERING is a short-term manualized treatment. MBT-Fostering will be integrated into the therapeutic offer of the CLA Service and delivered by CAMHS therapists, employed by HPFT. Depending on the child's need, therapy is usually between 6-12 sessions.

MBT-Fostering aims to promote the quality of relationships, support effective and sensitive foster care, and help carers to help the child in their care understand and manage emotions better. The focus is on improving the core components of secure attachment, including collaboration, and parental (or carer) reflective capacity. The MBT-Fostering approach pays particular attention to developing reflective practice for all professionals working with CLA. To this end, MBT-Fostering includes three core components:

- 1) **Two sessions of psycho-education** for foster carers, including introduction of a specially-devised Mentalization-Based Assessment approach, and key ideas related to

attachment and mentalization in children with histories of trauma and maltreatment;

- 2) **Consultations with the professional network** (foster carers, social worker, school staff) based on a set of practice guidelines designed to improve reflective practice, develop a shared understanding of the child and promote collaborative working within the professional network ; and
- 3) **A six-session model of family-based therapy**, tailored to the needs of each foster family, aimed at helping foster families understand their foster child's needs and feelings, encouraging sensitive parenting and tackling problematic patterns of family interaction

MBT-Fostering will be compared to Usual Clinical Care (UCC). UCC is whatever would currently be offered by the Targeted CLA team within child and adolescent mental health services (CAMHS). The routine interventions the CLA team usually offers to the referred child and carers might include: family therapy, play therapy, Cognitive Behavioural Therapy (CBT), person centred therapy or supportive counselling depending on the child's needs.

For both MBT-Fostering and UCC, direct work is usually limited to between 6 and 12 sessions, as indicated.

4.2 TRAINING

As MBT-Fostering is a new adjunct to the suite of therapies currently offered by the CAMHS service, and the MBT intervention will be delivered by HPFT clinicians on the targeted team, MBT training will be provided to half (three) of the team. Selection for training was informed by: i) whether or not the staff member has had MBT training before; and ii) their length of time in role (experience in months/years). The six staff were paired by the service, then subsequently ordered alphabetically by the study statistician who then generated a random sequence to randomise the suggested pairs of therapists into the MBT and UCC groups.

Training will be delivered by Dr Sally Wood, who is a Consultant Family Therapist at the AFC, with expertise in MBT and work with CLA. Training will take place at the AFC in the form of a four-day group format including a three-day intensive course, with a further one-day follow-up session. Training will end with a videotaped assessment of performance (see <http://tiddlymanuals.tiddlyspace.com/>). Efforts will be made to keep 'contamination' to a minimum by means of separate supervision arrangements for the two groups of clinicians. Dr Wood will lead on the supervision of the MBT trained therapists, who will receive fortnightly supervision.

5. STUDY DESIGN

5.1 OVERVIEW

The study is a two-arm, parallel group, single centre feasibility randomised trial and will conduct the study over a 24 month period. The research assistant carrying out assessments will be blind to treatment allocation. Blinding of the therapist is not possible, and blinding of the child and Foster family is judged not to be desirable (to avoid the perception of manipulation by the study team). As the interventions in both arms of the study are accepted as effective, there is no reason to withhold the intervention allocation from the child and Foster family.

5.2 SETTING

The study will be conducted in a Targeted CAMHS service within a single NHS Trust: HPFT. Every month about 40 children in Hertfordshire come into public care because they cannot be supported by their own families, and as of August 2014 there were 1,023 children in care in the county. The CAMHS targeted team is a county-wide service which works collaboratively with Children's Services. It provides a mental health service to CLA, as well as children and families who are actively working with social workers in Children's Services. Treatment takes place at the nearest CAMHS clinic to the child and family. Alternatively, sessions can be held at an agreed venue of the family's choice.

5.3 PARTICIPANT SELECTION

A total of 42 CLA and their carers will be recruited from routine referrals to a Single Point of Access (SPA) in HPFT.

Social workers from HCC and all therapists from the targeted team will be invited to focus groups about their experiences of being involved in the research, both in delivering interventions and being part of the research team. In addition, because the SDQ has a privileged role in monitoring the mental health and wellbeing of children in care, in screening and as an outcome measure, we also plan to conduct 4-6 interviews with therapists from the targeted team about the appropriateness of the SDQ as a screening tool and outcome measure.

The Targeted CAMHS team within HPFT is a cross-county service with an annual referral rate of 170 children per year. In 2013/14, 74.6% (n=132) of children referred to the service would have met inclusion criteria for this study. Recruitment is planned for 12 months, suggesting that 32% of eligible children will need to be recruited to the study during the recruitment period.

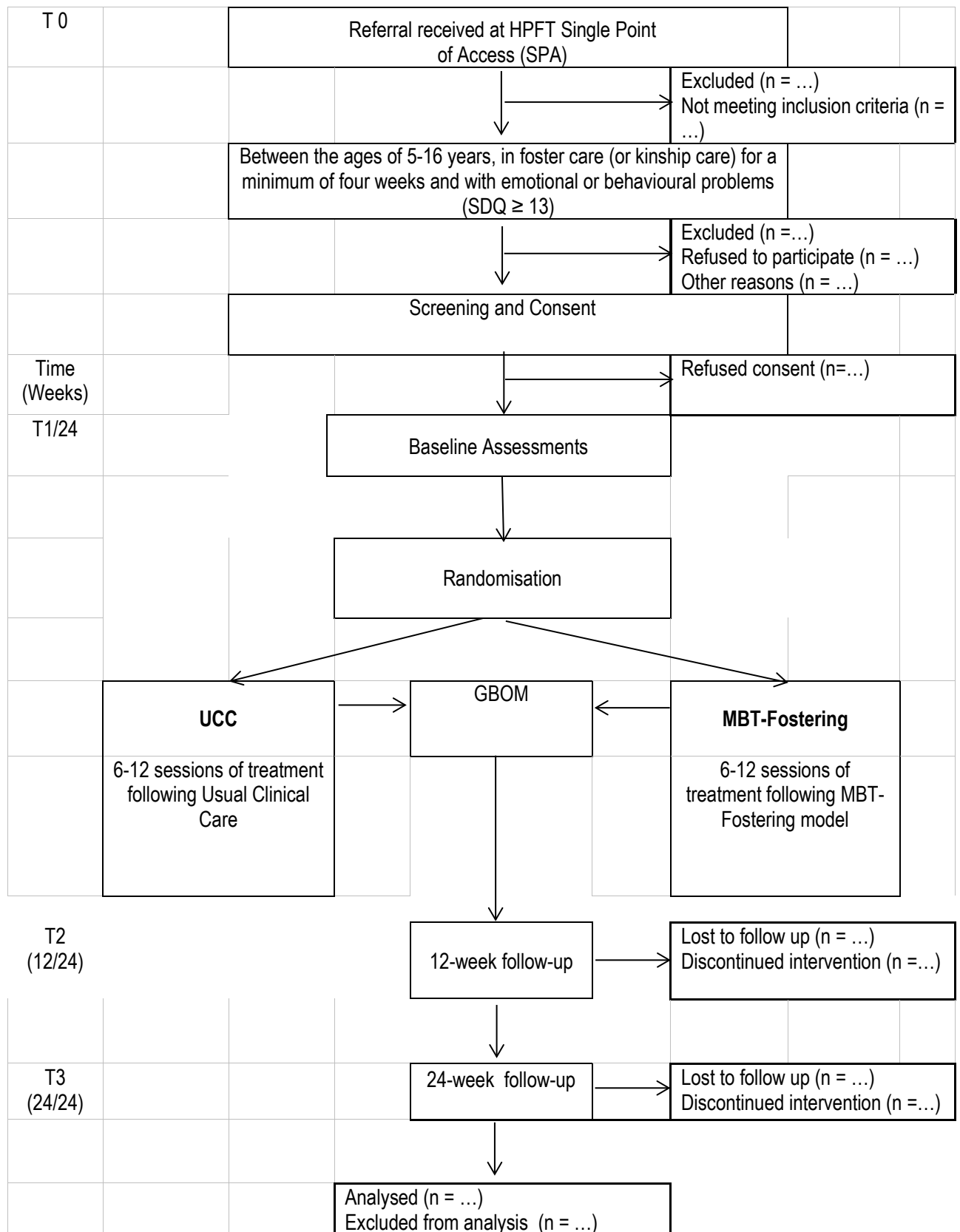
The project leads will work closely with all the teams involved to ensure continued commitment to the study. Regular monitoring of study progress will identify potential problems early, and allow any remediative action to be taken.

5.4 INCLUSION/EXCLUSION CRITERIA

1. **Inclusion criteria:**

- 1.1. primary- and secondary-school age children (aged 5-16);
 - 1.2. in foster-care (or kinship care) for a minimum of 4 weeks;
 - 1.3. referred to the targeted CAMHS team, and accepted as an appropriate referral following an initial consult meeting with the professional network;
 - 1.4. with emotional or behavioural problems (based on a score on the SDQ ≥ 13).
2. **Exclusion criteria:**
- 2.1. An emergency/crisis referral, where an immediate response to a significant risk is required;
 - 2.2. the referral is specifically for a psychiatric assessment in specialist CAMHS

5.5 STUDY FLOW CHART



6. RISKS AND BENEFITS

6.1 ANTICIPATED BENEFITS FOR PARTICIPANTS

It is our experience that children and foster carers often appreciate the opportunity to meet with a research assistant and review how things are, through filling in the questionnaires about their well-being. Young people and carers have also spoken in previous studies about the benefit they get from knowing that they will be helping other young people in similar situations to them, by helping to identify the most effective treatments.

6.2 ANTICIPATED BENEFITS FOR THE WIDER COMMUNITY

The costs of untreated emotional and behavioural problems in CLA are considerable. The long-term research aim is to identify the most cost-effective treatment strategy for these children, incorporating a range of measures to identify the intervention with the greatest potential for positive impact on health and wellbeing. By testing the feasibility of a trial to answer this research question, our study contributes information of major importance to the NHS. Potential challenges or difficulties to completing a larger-scale trial would allow us to modify and improve our research protocol, or if necessary to not proceed, if the findings of the feasibility study suggested that this intervention does not have a significant chance of improving outcomes for users of the NHS.

If the feasibility study is successful and provides the platform to continue to a full clinical trial, with positive outcomes, this would be a major step towards identifying an evidence-based intervention that could help address the needs of CLA - among the most vulnerable children in the UK, with very poor long-term outcomes, who currently make extensive use of mental health services in England and Wales.

Our hypothesis is that the outcomes will be better with MBT than UCC for equivalent cost. Given the current effect estimate, for roughly every eight families seen, at least one more family would benefit with MBT than with UCC, giving a saving to public services of up to £15,382 per family per year (minus the £2,000 cost of treatment). These savings are of course in addition to the benefit of helping more families with the distress of mental health problems. This study therefore has the potential to have direct impact on the day-to-day practice of health service staff, to bring savings to the NHS, Local Authorities, education and criminal justice sectors and benefits for some of the most vulnerable users of the NHS in England.

6.3 RISKS FOR PARTICIPANTS

For the current study, there are relatively minimal additional risks involved with participating in the research, as whether participating or not, the child will still receive a therapeutic intervention from the service, of roughly equal length, provided by a clinician of comparable experience. Children in the study will only be required to complete a minimal amount of additional questionnaires as part of the study, and these are ones that are commonly used and are unlikely to cause distress.

There may be some questionnaires that include sensitive topics that may upset participants. For example, foster carers will be asked about how they are managing the care of their foster child, and (given the emotional and behavioural problems that have led to the referral for help) it may be that some of them are struggling. Being asked about this could be upsetting for some carers. Researchers and clinical staff will be trained to deal with such situations in a sensitive and appropriate manner. The CI will be available via telephone for support in the event that any researcher finds themselves in this situation. Disclosure of information regarding the safety of the patient will be reported back to the appropriate clinical team members and/or social services (if the patient is no longer engaged with the clinical service).

6.4 METHODS OF REDUCING RISKS TO PARTICIPANTS AND OTHERS

All those participating in the study will be given clear information about the study, so that their consent to participate will be fully informed, and they will have the right to withdraw at any point, without their clinical care being affected. Where parental responsibility for a child in care is still held by the birth parent/s or other legal guardian (described forthwith as 'birth parent'), we will seek consent from them for their child's participation in the research, as well as the consent of the LA and foster carers. Children will be provided with age-appropriate information sheets and their assent obtained if they are under 13 (and written consent obtained for 13-16 year olds). Participants will be given time to consider their involvement in the study (this includes the child, the foster carer and the birth parent/s). Participants may withdraw from the study at any point. This may be indicated by the child, their foster parents or the birth parent.

All Trust and research ethics framework will be followed to ensure confidentiality of the data, and that any identifiable data (e.g. from the qualitative interviews) will be used in a way that ensures the anonymity of the patients. As part of the preparation for this application, we have liaised with members of various research ethics committees, as well as the legal department of the LA, to ensure that our proposed recruitment strategy would be in line with their guidance. Key modifications to our proposal were made in line with the guidance received, which specifically focused on gaining appropriate consent from the relevant parties in the context of children in care.

In advance of the study start date, we will submit an application via the Integrated Research Application System (IRAS) for review by the identified research ethics committee. Once this has been done, we will submit the study via the Central System for gaining NHS permissions (CSP) to ensure central and local governance review, and formal support for the study via portfolio adoption. Research and Development Department (R&D) approval will be sought before recruiting patients from HPFT. Professor Tim Gale will be contacted in this instance and the study will be considered at the R&D department's bimonthly Research and Development Committee meeting.

Regarding risks regarding data protection and protecting anonymity, no individuals outside the treating or research team will have access to patient identifiable information. Participants will be informed of this in writing (via the participant information sheet) and/or verbally. Participants will also be informed that they may withdraw their participation at any time without penalty. For the purposes of the research trial, participants will be given an anonymous code to protect the identity of the child and associated family members.

6.5 METHODS OF PROTECTING PARTICIPANT PRIVACY, DATA AND RIGHTS.

This study will be conducted in accordance with the Data Protection Act (1998) and the guidelines of the Declaration of Helsinki (1964- Updated Tokyo, 2004).

Responsibilities for data management will be clearly specified in partnership agreements, and procedures to ensure the accurate and timely processing of data will be clearly specified in a data collection guide for the study, which will be communicated to all study personnel, with training provided where necessary.

Data management will be co-ordinated from UH, and only Good Clinical Practice (GCP) certified investigators who have been approved by the study management group will be given access to data and the electronic data management system. Any other electronically stored data will be password protected. All electronically stored data will be anonymised and stored on password protected computers.

Access to the Screening/Randomisation Log, containing participant identifiable information, will be restricted to authorised personnel and will be password protected. A unique patient identifiable number (PIN) will be generated by for each new participant entered into the study, this will be a sequential number starting with 001. Paper records, including hand completed forms and questionnaires, will be stored in locked cabinets behind a locked door at the appropriate site location, including clinics. Where possible, all paper records have been designed to be anonymised.

7. STUDY PROCEDURES

7.1 SCREENING FOR ELIGIBILITY

This study will build on the existing clinical pathways for referral to the targeted CAMHS team. As part of usual clinical practice, all referrals to the targeted CAMHS team are received via the HPFT single point of access (SPA), and include a written referral, a copy of the SDQ, and confirmation from the social worker that the birth parent/s, where appropriate, have given informed consent to the clinical referral.

For the duration of the study, the referrals to the CAMHS team that meet the inclusion/exclusion criteria for the research study will also go through a process which enables all the key people in the child in care's life to gain information about the study, and to make a decision about participating based on the principle of informed consent.

7.2 PROCEDURE FOR RECRUITMENT

7.2.1 GENERAL PRINCIPLES

For this study - based on extensive review of the literature, as well as consultations with researchers in social care, as well as the Director of Social Care and the legal department of the LA - the nature of the consent that will be required for the child to be recruited into the study will be determined by the child's legal status and their age. But as a general principle, we are proposing that written, informed consent to take part in the study must be received from *at least one person holding parental responsibility for every child under 16 who meets the inclusion criteria for the study*. For children on *full or interim care orders*, this will be a representative of the LA; for children on *voluntary agreements*, this will be at least one of the child's birth parents/legal guardian.

If a child is accommodated by the LA under section 20 of the Children Act 1989, the LA will not hold parental responsibility for the child and therefore consent will need to be obtained by the birth parent/s or others who hold parental responsibility for them.

In the case of children subject to an Interim Care Order under section 38 Children Act 1989, the LA share parental responsibility with the birth parent/s. Whilst the LA is able to give consent for the child to participate in the study as their Corporate parent, given that the matter will still be within Court proceedings and therefore a final decision on the child's future has not been made, it is good practice for their parent/s to also be appropriately consulted where appropriate to obtain their views. However, the LA is able to determine the extent to which their views can be overridden if they believe them not to be in the child's best interests.

In the case of children subject to a Full Care Order under section 31 Children Act 1989, as above the LA will continue to share parental responsibility with the birth parent/s, however the LA is permitted to decide how far the parents may exercise their responsibility. The consent of the LA and the child will be obtained before a child will participate in the study, however as with those children on an Interim Care Order, the views of others who hold parental responsibility will be taken into consideration when appropriate.

In addition, informed consent will be sought from:

- a) the child's foster carer(s) and;
- b) the child him- or herself. Whilst a child under the age of 16 is not considered to be competent in law to provide consent, many children over the age of 12 will be determined as Frazer competent and will therefore be able to provide consent as to

whether they wish to be considered to take part in the study. Information about the purpose of the study will be provided to these children in an age appropriate way. The wishes of all children will be taken into consideration and they will be asked for their consent in an age-appropriate way.

Where the child is on a full- or interim-care order, a letter and information sheet will *additionally* be sent to parents, via their social worker, with details of the study and confirmation that their child will receive therapeutic care regardless of whether the child participates in the study. They will be informed that they may contact the study team if they have any objections to their child being part of the research via an 'opt-out' method of consent. This method has been used and recommended previously (Bogolub & Thomas, 2005). If the parent/s contact the research team and decide that they do not want their child to participate in the study, the child will not participate. If the LA considers that there is any reason (e.g. regarding risk or the potential of creating conflict that could be detrimental to the child's well-being) why the research team should not contact the child's parent/s with information about the research project, then the child would be excluded from participating in the study, and the reason would be noted on the Recruitment Log.

All those required to give agreement for the child to participate in the research will be given clear information about the study (see appendices for Participant Information Sheet [PIS]), so that their consent to participate will be fully informed, and they will have the right to withdraw at any point, without the child's clinical care being affected. Children will be provided with age-appropriate information sheets and given reasonable time to consider the study. Their assent will then be obtained if they are 12 or under, and written consent obtained for 13-16 year olds.

7.2.2 SPECIFIC PROCESS OF RECRUITMENT

Children are referred, as per usual practice, to the Single Point of Access (SPA) team in HPFT where SPA staff will determine whether they are suitable to be accepted by the targeted CAMHS team. The research team will be forwarded emails from the SPA so as to remain informed of those referrals coming into the Targeted CAMHS team. If necessary, a member of the research team may attend the SPA in person to screen referrals. A patient identification number for the study will be allocated to all referrals at this point. The research team will record details on the Patient Identification Log and Patient Recruitment Log.

For all children referred to the Targeted CAMHS team, an initial consult meeting is offered to the professional network, at which the referral is reviewed and a decision is made about whether it is appropriate for the Targeted CAMHS team to offer an intervention. Until that meeting has taken place, it cannot be confirmed whether the child is eligible to enter the study. However, in order to avoid a delay in accessing treatment, the preliminary work on seeking consent from the responsible adults will begin alongside the process of setting up a consult. In order to avoid any unnecessary burden on the child, the process of discussing the research with the child, and seeking their consent/assent to participate, will only take place after the consult meeting has confirmed that the child is to be offered an intervention

by the Targeted CAMHS team, and only if/when the appropriate adults have already given their consent for the child to participate in the study.

7.2.3 FOR ALL CHILDREN REFERRED TO THE TARGETED CAMHS TEAM VIA THE SPA, A MEMBER OF THE RESEARCH TEAM WILL:

i) review the referral letter and SDQ to assess whether the child meets the inclusion/exclusion criteria for the study.

In cases where they do, a member of the research team will:

ii) alert the administrator of the Targeted CAMHS team that the child is a potential participant in the study. As per usual clinical practice, the referral will then be discussed at the weekly Targeted CAMHS team meeting (or earlier, where clinically indicated) and a decision will be made about whether to offer an initial consult meeting to the professional network.

iii) if the clinical team decides to offer a consult meeting, a date will be arranged, and the referrer informed. If the clinical team decide not to proceed with offering a consult meeting, the child will be excluded from the study and the reason noted.

iv) if a consult meeting with the professional network is being offered, a member of the research team will access the child's referral form to ascertain details of the acting social worker and will make contact with them in the first instance to provide information about the study, and to begin the process of identifying who would be responsible for giving informed consent for the child to participate in the study. As set out below, this will vary somewhat depending on their legal status.

On making contact with the Social Worker, a member of the research team will:

iii) explain the study to the Social Worker and clarify that the referral does meet the initial inclusion criteria for the clinical service and that a consult meeting for the professional network is being set up to confirm whether the Targeted CAMHS team will be offering an intervention.

The research team's next steps will depend upon the child's legal status. Given the complex situation regarding parental responsibility for CLA, the process outlined below was worked out based on detailed legal advice from the Legal Department of Hertfordshire County Council.

7.2.4 FOR ALL CHILDREN ON A FULL CARE ORDER OR INTERIM CARE ORDER (I.E. NOT THOSE VOLUNTARILY IN CARE, E.G. UNDER A SECTION 20 AGREEMENT) THE CSO/ MEMBER OF THE RESEARCH TEAM WILL:

i) begin the process of seeking written, informed consent from an appropriate member of the LA, who carries appropriate responsibility to decide whether the child should be allowed to participate in the study. This consent will be provided by an officer of the LA who has knowledge of the child's background and issues and of the study along with sufficient

authority to give consent for the child to be considered for the study. Under the LA's scheme of delegation, the authority to provide consent for routine medical treatment is delegated to LA Team Managers.

ii) where consent from the LA is obtained, the research team will establish with the Social Worker whether the child's parent/s are already aware of the referral that has been made to the Targeted CAMHS service, and check if there is any reason (e.g. regarding risk or the potential of creating conflict that could be detrimental to the child's well-being) why the research team should not contact the child's parent/s with information about the research project. If the Social Worker considers that it would not be appropriate, then the child would be excluded from participating in the study, and the reason would be noted on the Recruitment Log;

iii) If the LA agree that the child's parent/s can be contacted, the research team will send a standard letter and information sheet to the parents, informing them that their child has been referred to the Targeted CAMHS team and that a meeting with professionals (the consult meeting) will be going ahead to establish whether the service will be offering some sort of therapeutic support for their child's emotional/behavioural issues. The letter will explain that a parallel clinical study will be taking place and that their child may be selected to take part in the study. The letter will include detailed but easy to understand information about the nature of the study and they will be advised that regardless of whether their child is part of the study or receives support via to normal method, they will receive the necessary support that the child requires. The letter will also contain information stating that the research team are willing to discuss it further with them if they were to have any concerns and they will be given the opportunity to object to their child participating in the study via an 'opt out' method. This method has been used and recommended previously (Bogolub & Thomas, 2005).

If no response has been received after seven days, the research team will proceed with the child's involvement with the study, as long as a clinical decision is made at the consult meeting to offer a service, and appropriate consents are received from the LA, the foster carer and the child him/herself. Although seven days is a relatively short period of time, this time-period has been set in order to prevent any delay in the child receiving a service. However, in line with the principle of consent being on-going, any birth parent who contacts after this seven day period will be responded to as above, and if objections are raised, their child will be withdrawn from the study, but continue to receive a clinical service from the targeted CAMHS team.

iv) Where the parent/s respond to this letter, the research team will offer to meet them in a suitable location and answer any questions about the study. If parents do object to their child participating in the study, the LA can then consider the reasons for the objection to determine whether the wishes of the parents should be overridden if they are deemed not to be in the child's best interests. However in most cases, we would anticipate that the child will not participate in the study if the birth parent/s raise any objections; however the child will continue to be offered a clinical service by the Targeted CAMHS team.

v) Alongside the above process, the research team will contact the foster carer's Supervising Social Worker, to give them information about the study, so that they are aware that an invitation to participate in the study will be going to the foster carer in due course. In addition, the Social Worker will be asked to provide the foster carer with information about the study, and invite them to contact a member of the research team if they have any questions or concerns about the study. Once consent from the LA is obtained, the research team will then proceed to contact the foster carer (either before or after the consult meeting has taken place, depending on how quickly the LA makes a decision, and taking into consideration the foster carer's preference), and arrange a meeting where they can explain the study in full to the foster carer, and seek informed, written consent to participate, if the Targeted CAMHS team do offer a service following the consult meeting. If the foster carer has a partner who is also planning to be involved with the child's therapy, then consent to participate will be sought from both carers.

vi) Where the LA does not give consent for the child to enter the study, or the foster carer does not wish to participate in the study, this will be noted on the Recruitment Log and the child will not join the study.

The above process of recruitment to the study will occur concurrently with the referral to the service, and the setting up of a consult meeting, so as not to impede the child's access to the service in a timely manner. All clinical referrals must be offered a meeting with a professional from the CAMHS team within four weeks of receiving the referral, so it is essential that the process of seeking informed consent for participation in the study does not delay the referral process.

vii) If all responsible adults, and the foster carer, have given their consent, and the Targeted CAMHS team have decided that it is appropriate to offer an intervention following the consult meeting with professionals, then an information sheet for the child will be given to the foster carer by either a member of the Targeted CAMHS team or a researcher and the foster carer will be encouraged to discuss the study with the child. Then a member of the research team will contact the foster carer and arrange a visit to meet with the child. At that visit the study will be explained in full to the child (at a level appropriate to their age and level of understanding) and the research team will seek appropriate assent or consent to participate in the study.

viii) If the child does not give consent or assent to enter the study, this will be noted on the Recruitment Log and the child will not join the study. If they do give consent or assent, then the member of the research team will proceed with the Baseline Assessment, with both child and foster carer.

ix) If the Targeted CAMHS team decide that it is not appropriate to offer an intervention at the 'consult' meeting, then the research team will contact the relevant parties to inform them that the child will not be entering the study.

7.2.5 FOR ALL CHILDREN ON A VOLUNTARY PLACEMENT (SUCH AS A SECTION 20 AGREEMENT), THE CSO/MEMBER OF THE RESEARCH TEAM WILL:

i) establish with the Social Worker that the birth parent/s are already aware of the referral that has been made to the Targeted CAMHS service, and check if there is any reason (e.g. regarding risk or the potential of creating conflict that could be detrimental to the child's well-being) why the research team should not contact the birth parent/s with information about the research project.

ii) If the Social Worker does not raise any risk issues regarding contacting the parent/s, then the Social Worker will be asked to contact the birth family with an information sheet about the study, explaining that their child has been identified as possibly taking part in a study taking place in the Targeted CAMHS service. The Social Worker will inform them that the research team will be in contact to explain the study in more detail. If the birth family say that they do not wish to be contacted about the study, then the Social Worker will inform the research team, and the child would be excluded from participating in the study, and the reason would be noted on the Recruitment Log.

iii) Four days after the Social Worker has contacted the birth family (and if the Social Worker has not informed the research team that the family do not wish to be contacted), the research team will follow this up with a phone call to the parent/s (or where parents are separated or divorced, the parent whom the LA recognises as the primary carer), in which they will arrange for a meeting, where they can provide further information about the study, answer any questions about the study, and seek informed, written consent for their child to participate in the study.

iv) If the parent/s cannot be contacted within a reasonable time-frame (i.e. without introducing any delay to the child receiving treatment), do not wish to meet, or (having met with a member of the research team), do not wish their child to participate in the study, then the child will not participate in the study (and the reason will be noted), but they will continue to be offered a service by the Targeted CAMHS team, as per usual clinical practice.

v) Alongside the above process, the research team will contact the foster carer's Supervising Social Worker, to give them information about the study, so that they are aware that an invitation to participate in the study will be going to the foster carer in due course. In addition, the Social Worker will be asked to provide the foster carer with information about the study, and invite them to contact a member of the research team if they have any questions or concerns about the study. If the parent/s give consent for their child to participate in the research study, the research team will then proceed to contact the foster carer (either before or after the consult meeting has taken place, depending on how quickly the LA makes a decision, and taking into account the foster carer's preference), and arrange a meeting where they can explain the study in full to the foster carer, and seek appropriate consent to participate, if the Targeted CAMHS team do offer a service following the consult meeting. .

The above process of recruitment to the study will occur concurrently with the referral to the service, so as not to impede the child's access to the service in a timely manner. All clinical referrals must be offered a meeting with a professional from the targeted CAMHS team within four weeks of receiving the referral, so it is essential that the process of seeking informed consent for participation in the study does not delay the referral process.

vi) If all responsible adults, and the foster carer, have given their consent, and the Targeted CAMHS team have decided that it is appropriate to offer an intervention following the consult meeting with professionals, then a member of the research team will contact the foster carer and arrange a visit to meet with the child. At that visit the study will be explained in full to the child (at a level appropriate to their age and level of understanding) and the research team will seek appropriate assent or consent to participate in the study.

vii) If the child does not give consent or assent to enter the study, this will be noted on the Recruitment Log and the child will not join the study. If they do give consent or assent, then the member of the research team will proceed with the Baseline Assessment, with both child and foster carer.

viii) If the Targeted CAMHS team decide that it is not appropriate to offer an intervention at the 'consult' meeting, then the research team will contact the relevant parties to inform them that the child will not be entering the study.

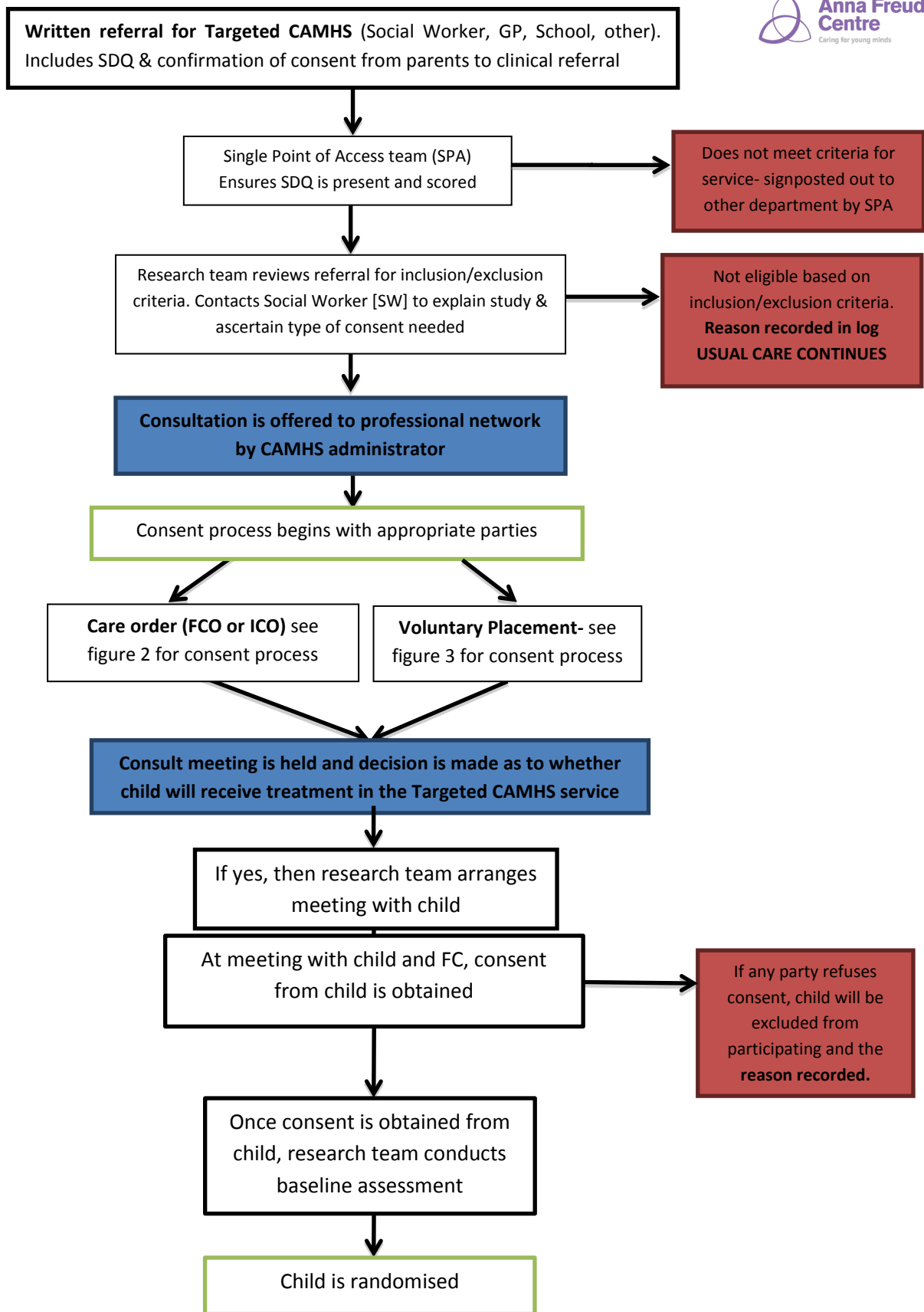


Figure 1. Flowchart from child referral to randomisation

Recruitment process for children on Voluntary Placement

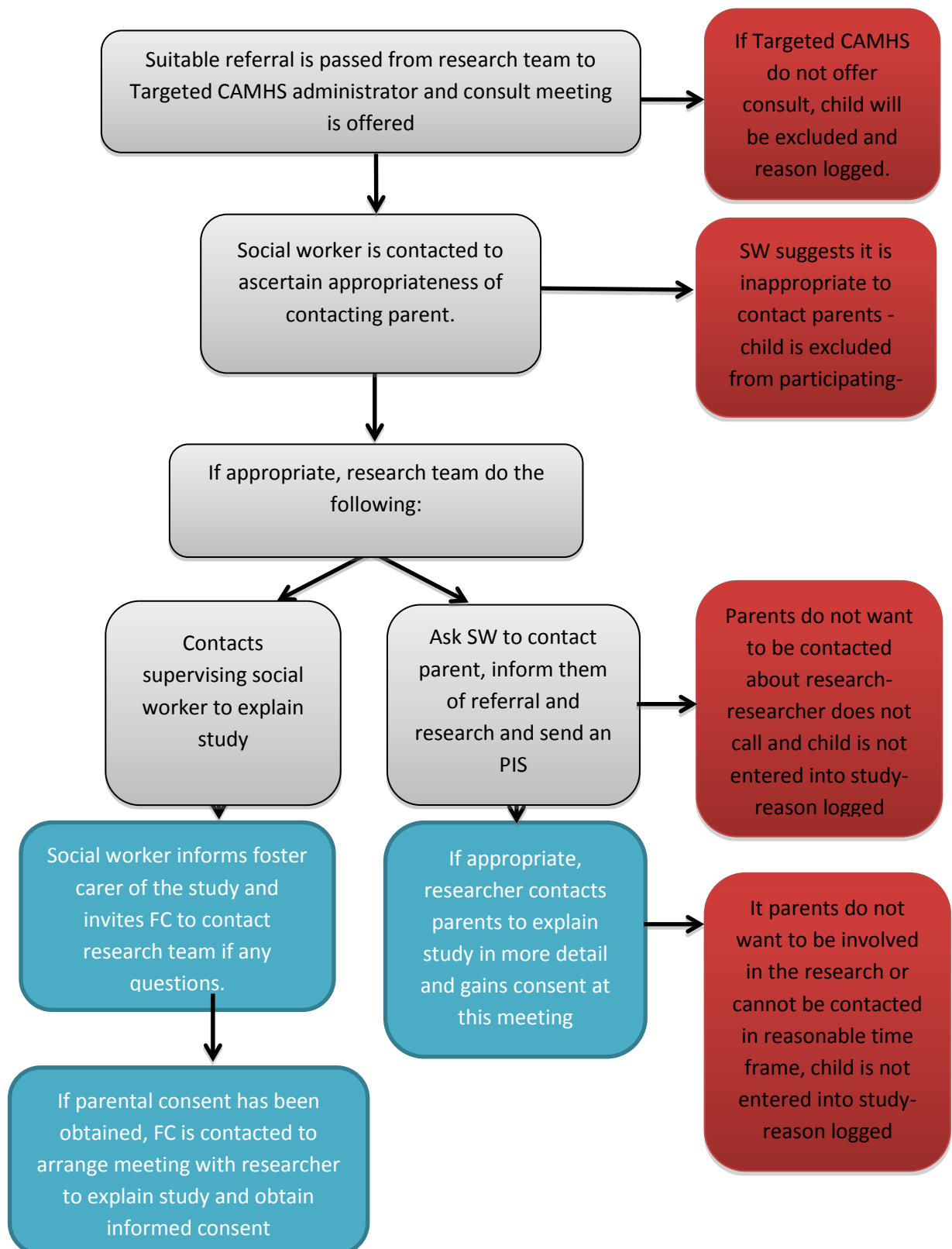


Figure 2. Recruitment process for children on voluntary care order

Recruitment process for children on care order (Full or Interim)

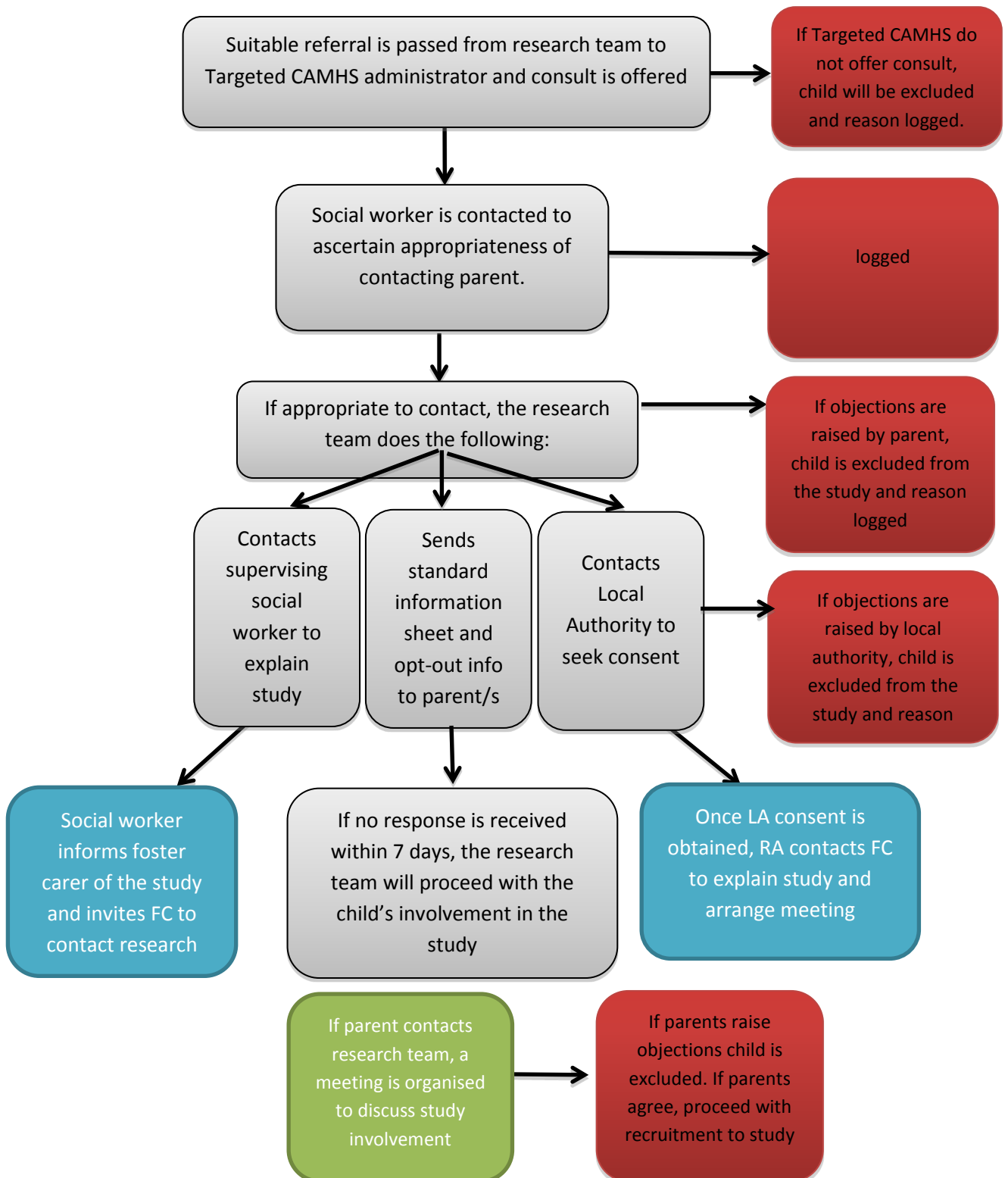


Figure 3 Recruitment process for children on full or interim care order

7.2.6 WITHDRAWAL OF CONSENT

At any point after consent has been given by a child, the carers, or the parents the study participants can request to be withdrawn from the study by contacting either the RA or the Trial Manager (TM), or the CI. This will be clearly explained on the Consent forms, with contact details provided. In these circumstances the research team will inform the administrator of the Targeted CAMHS team of the change, and the child will remain under the care of the Targeted CAMHS team, with treatment provided as appropriate.

Should any of the participants withdraw from the study treatment (MBT-Fostering or UCC) itself, as delivered by the Targeted CAMHS Service, the research team will ask the participant to continue to complete the study assessments. The research team will explain that it is possible to withdraw from the study treatment, but where possible completing the study assessments (up to 24 weeks) is valuable information that will help to decide whether the treatment intervention is useful or not, & whether the research team should try to proceed to a full-scale trial. By continuing to complete the study outcomes, the participants will be providing valuable information that will be valued by the study team, and the NHS.

7.2.7 CHANGE OF FOSTER CARER

As the children in this study are in the care system, it is possible that they will have a change of carer during the period that they are involved in the study, either because of a placement breakdown (resulting in a move to another foster carer), or as a result of a planned change (e.g. due to planning for permanency, the child could be moved to live with a potential adopter, or enter kinship care, or be returned to the care of their birth parent/s).

As best practice for the Targeted CAMHS team is to continue their therapeutic work with children, where appropriate, when such a change of carer takes place, such children would also be eligible to continue in the research study. However, as the carer also takes part in the research, we would seek informed consent from the new carer, following the same protocol as set out above (sections 7.2.4 and 7.2.5 above). If that consent is given, then any 12 and 24 week assessments which have yet to be completed will be carried out with the child's current carer, even if that means that the baseline measures and the follow-up measures are not completed by the same person. A note will be made on the CRF to indicate when a different carer has completed any of the follow-up assessments.

If the new carer does not give consent to participate in the study, the child will be withdrawn from the study, and the reason noted on the CRF. However the child will continue to receive therapeutic support from the Targeted CAMHS team, unless a clinical decision is made otherwise. In line with GCP, and the principle of on-going informed consent, the research team will also confirm with both the LA and the child whether they continue to give agreement to participate in the study, following this change of placement. If they do not give consent to continue participating in the study following the change of placement, the child will be withdrawn from the study, and the reason noted on the CRF.

Table 1: Schedule of Assessments

	Screening	Baseline (Week 0, T1)	Weeks 0-12	Week 12 (T2)	Week 24 (T3)	Time to complete
Demographics	X					20 mins
SDQ	X	X / X / X*		X / X / X*	X / X / X*	5-10 mins
Five Minute Speech Sample		X		X	X	
Brief Assessment Checklist		X		X	X	5 mins
Goal-Based Outcome Measure			X / X***	X / X***	X / X***	Goals set at first therapy session, then 5 mins to score each goal (up to 3 goals).
Parent Stress Index - SF		X		X	X	10 mins
The Parenting Scale		X		X	X	10 mins
Brief Parental Efficacy Scale		X		X	X	2 mins
Child Health Utility 9D		X / X		X / X	X / X	7 mins
RCADS		X / X		X / X	X / X	5 mins
CA-SUS		X**		X	X	20 mins
CHI-ESQ				X / X	X / X	5 mins
Experience of Therapy and the Research Process Interview					X / X	1 hour +
Therapist Feedback Form		X			X	5 mins
Treatment Attendance Form			X	X	X	2 mins
Recordings of sessions – MBT and UCC arm			X			At each session
MBT Adherence and Competence Scale					X	
Significant Event Log		X		X	X	2 mins

X – Child X – Carer X -Therapist X – Teacher X – Social worker

X – MBT Trainer and External Assessor

* If consent given to contact teacher - Collected by phone or post; ** completed using information from carer and social worker;

***Goals set with therapist

****recorded by RA using goals set at start of study by therapist.

7.3 RANDOMISATION METHOD AND BLINDING

Individual participant randomisation will be utilised for the duration of the study with children assigned to one of the two treatment arms (MBT versus UCC). Randomisation will be managed by the Clinical Trials Support Network (CTSN) at UH, and will be requested and actioned electronically via the online secure data management system. Randomisation will be stratified by age (above or below 11 years) and sex, and otherwise randomly allocated.

Randomisation will occur immediately, or as soon as possible, after consent has been received, all screening procedures have been completed and after completion of baseline measurements. *The randomisation request will be made online by a member of the research team who has been trained in the screening/randomization process, and will happen automatically.* Once this has occurred and the request to randomise has been actioned, an email will automatically be sent to the Targeted CAMHS team administrator and to the TM notifying the treatment arm the participant has been assigned to. The SPA will then refer the child onto the clinical team for the appropriate treatment.

Six therapists were engaged in the study, and were placed into 3 pairs based on experience, ranging from band 7 senior to newly qualified social workers. The Therapists were then randomly allocated to a treatment arm within each pair (one to each arm).

This is a partially blinded study as it is not possible to blind the therapists to treatment allocation, and for pragmatic reasons a decision has been made not to blind the child and foster family (see section 5.1). The RA and the CSO collecting and coding the research data and the study statistician will be the only team members blinded to treatment allocation, therefore randomisation code breaking will not be necessary during the study.

7.4.1 BASELINE ASSESSMENT

The Baseline Assessment will be conducted by the research team and will follow the consenting process with the child. The visit will take place at a time and place convenient to the foster carer, either at foster carer's home or at an HPFT site, and is estimated to take 2 hours.

During the Baseline Assessment Visit, if informed consent or assent has been obtained from the child, the participants will provide fuller information about their demographic status and history as outlined in CRF. This basic data set will be followed by completion of the baseline outcome assessments.

The research team will administer the following questionnaires in-person with the foster

carer.

- The specific **Brief Assessment Checklist**. For children aged 5-11 the BAC-C will be completed; for adolescents aged 12-16 the BAC-A will be completed.
- the **RCADS** (parent version)
- the **PSI-Short Form**
- the **Parenting Scale**
- the **Brief Parental Efficacy Scale**
- the **Five Minute Speech Sample**
- **SDQ – Parent version** (If the score obtained from the baseline SDQ form is less than 13, the child will still be eligible)
- the **CA-SUS**
- the significant events log

The following questionnaires will be administered by the research team with the child, in the presence of the carer:

- The **CHU9D** (for children aged 5-7 years the proxy version will be completed and for children aged 8-16 years the self-complete version will be used)
- **SDQ – YP version** (for children over the age of 11)
- **RCADS** - Child version (for children aged 8-16)

If the child and carer have consented to involve the teacher in the study, the research team will send out the SDQ by post to the child's teacher requesting they complete it and post it back. If the form is not returned within two weeks, the research team will follow up with a telephone call and if possible complete the form over the telephone with the teacher.

The research team will complete the **Recruitment Log** detailing the consents obtained and any information as to why consent was not granted or the child was not to be randomised.

7.4.2 TREATMENT PHASE (0-12 WEEKS)

As part of routine practice, the therapist agrees with the child and the carer the goals, usually up to three, for the therapy. These goals are written down and recorded on a **Goal Based Outcome Record Sheet** (*source data*). Goals are reviewed periodically throughout the therapy sessions, and a measure of progress is made through the use of a simple **Goal Base Outcome Measure (GBOM) Scoring Sheet**. For the purpose of this study, the RA/CSO will score the GBOM with the carer and child, at T2. This is estimated to take up to 5 minutes. The GBOM Scoring Sheet will also be administered in person at T3.

The therapist will complete the Treatment Attendance Form over the period of therapy (0-12 weeks) for all participants, for all therapies (MBT and UCC), as well as attendance at key meetings such as the Network meeting or Choice meeting. If the participant did not attend scheduled therapy this will also be recorded with a reason, where possible. Therapists will

schedule time on a regular basis (within ten days of the relevant events) to complete the attendance form, which will be uploaded onto the study database.

For those participants randomised to all trial arms, if the participant has consented to sessions being recorded, the therapist will record each treatment session. The audio file of each session will be uploaded onto a secure file management system held at UH. At the end of the study recordings for two of the families, selected randomly will be reviewed by independent raters using the adapted MBT Competence and Adherence Scale to establish both treatment integrity and treatment differentiation.

7.4.3 12 WEEK FOLLOW-UP (T2)

The 12 Week Follow-up visit will occur 12 weeks from randomization, which may or may not be after treatment has been completed. A location convenient to the patient and their carers will be arranged with the RA or CSO. This assessment will consist of the outcome assessments completed at the Baseline Visit, in addition to the SDQ sent to the child's teacher. The RA will also administer the GBOM Scoring Sheet (estimated to take up to 5 minutes), the Experience of Service questionnaire (estimated to take 5 minutes), and record any significant events which may have occurred in the preceding weeks (estimated to take 2 minutes to complete) since the last assessments. A subset of participants will be invited to be interviewed for the PDI-R. The 12 Week Assessment will take about 1 hour to complete. For participants who agree to the Parent Development Interview, the duration of the assessment will be an additional 45 minutes to 1 hour.

Where necessary the RA or CSO will liaise with the carer and the social worker after the visit to complete the outcomes.

7.4.4 FOLLOW-UP (T3) – 24 WEEKS

At 24 weeks from randomisation (T3) the final Follow-up Visit will take place, at a convenient location arranged with the child and carers. Assessments at the Follow-up Visit will include the set of outcomes included in the 12 week visit, and will also include a review of significant events in the child's life during the period of the study. The visit will also include a semi-structured interview in-person with the carer (and the child, where appropriate) about their experience of therapy and the research process. With consent, the interview will be recorded. In the event that consent is not granted to record the interview, notes will be taken by the research team. The interview will take place after all other assessment measures have been completed. Overall the Follow-up Visit will take approximately 2 hours.

Where necessary the RA will liaise with the carer and the social worker after the visit to complete the outcomes.

7.4.5 END OF ALL TREATMENTS

Once all therapies have been completed, the Trial Manager will arrange a focus group with all therapists who have taken part in the trial. The aim of this focus group will be to examine in-depth the therapists' experiences of taking part in the study, including any issues regarding the recruitment process, the impact on the service, and obstacles to data collection. In addition, those therapists who were part of the MBT arm of the study will be asked about their experience of training and supervision, and the acceptability of the MBT model for their work with CLA and their foster carers.

Furthermore, one of the study RAs will arrange a set of interviews with all of the trial therapists to assess the suitability of the SDQ as both (a) a screening tool to identify children requiring treatment and (b) as a suitable outcome measures for the Herts and Minds future definitive trial. A selection of approximately 16 cases (young people) will be identified for discussion with the therapist. These will be children who were screened for inclusion in the Herts and Minds study and offered treatment but did not meet the SDQ cut-off scores for selection into the study. All the interviews will ensure confidentiality of the young person and family involved.

In addition, the Trial Manager will arrange a series of focus groups with social workers and their team managers, from the teams who were involved in referring children to the targeted CAMHS team. The aim of this series of focus groups will be to explore in-depth the social workers' experiences of being involved in the trial, to include the level of engagement of social workers and the barriers to research involving foster children in the social care system. These focus groups will be run at six monthly intervals rather than waiting until the end of recruitment, to take account of the high level of staff turnover within the social care setting.

7.4.6 RISK DISCLOSURES

If any risk disclosures occurred, the TM or RA will discuss these and contact a Principal Investigator if risk is significant and/or imminent, for further discussion. If during office hours, TM or RA will inform the child's social worker, or a member of the social work team, in writing (and over the phone if immediate action required) of the disclosure.

7.5 SAFETY

SIGNIFICANT EVENTS AND SERIOUS ADVERSE EVENTS

The concept of 'adverse events' derives from medical trials, and in the context of psychological interventions, the term can be limiting. For example, it is possible that the same event (e.g. placement breakdown) may be considered to be either a positive or an adverse outcome depending on the context in which the event occurs. The team have therefore decided to redefine these events as "Significant Events" which will be recorded,

and then interpreted appropriately within the context of the outcome for the patient and carers.

7.5.1 DEFINITIONS OF SIGNIFICANT EVENTS

CLASSIFICATION OF EVENTS

For the purpose of this study, a Significant Event (SE) is defined as one of the following:

- A change of placement.
- A significant change within placement.
- School exclusion, permanent or fixed-term.
- A change of school.
- Identification of learning difficulties or diagnosis of a developmental disorder.
- Involvement with the criminal justice system.
- A change of social worker.
- A change of contact arrangements.
- Return to care of birth family.
- Other change in care order.
- Disclosure e.g. maltreatment/abuse.
- Other key transition/experience of loss.

DATA COLLECTION PROCEDURES FOR SIGNIFICANT EVENTS

Significant Events review will be performed by the RA at baseline and at the 12 and 24 week visits. The assessment of SEs will not differ between the intervention and the control group. Interpretation of the meaning of the events will be undertaken in collaboration with the social worker and the carer. Significant events will also be recorded by the therapists during the treatment period. Events which are recorded on the significant events log will be retrospectively assessed to ascertain whether the event is considered to have had a positive or negative impact on the child. The judgement of whether the event was positive or negative (e.g. a change of school) will be collected from the foster carer, at the final research visit at week 12 and week 24. The key objective, and one which is often missed in studies of psychological interventions, is to record significant events that could be indications of harm that are temporally related to the study interventions. As well as collecting a list of significant events from the foster carer, and their view on the impact of the event on their foster child (positive, negative, neutral) they will also be asked to state whether they believe the event was a result of the treatment received from CAMHS. Through collecting this information we can record the extent to which the study intervention leads to harm and the type of harm experienced, to decide whether one kind of intervention leads to an increased experience of harm compared to another type of intervention, and ultimately to decide whether the benefits of an intervention outweigh the harms experienced.

7.5.2 DEFINITION OF SERIOUS ADVERSE EVENTS

A Serious Adverse Event (SAE) is an untoward and unexpected occurrence in the participant, to include any of the following:

- results in death;

- life threatening;
- requires hospitalisation, or prolongation of existing hospitalisation;
- results in persistent or significant disability or incapacity.

SERIOUS RELATED EVENTS

Serious Related Events (SREs) are events that result from the administration of the research procedures.

SERIOUS ADVERSE EVENT MONITORING

The assessment of SAEs will not differ between the intervention and the control group. SAEs will be monitored at all research visits (baseline, week 12 and week 24) by the research team (Kiri Jefferies-Sewell, Karen Irvine and Sarah Jane Besser). In addition the clinical team will collect data regarding serious adverse events for the duration of the treatment (sessions 1-12), using the items found in Table 1.

REPORTING OF SERIOUS ADVERSE EVENTS

If there is a SAE reported during research visits, a member of the research team will complete a SAE form and send it to the trial manager (Sarah Jane Besser) and Solange Wyatt, who will send it to the chief investigator.

If there is a serious adverse event reported during a therapy session, the allocated therapist is responsible for completing a serious adverse event form. They are also responsible for considering, together with the team manager (Janet Arris) or a senior member of the clinical team (e.g Anne Matthews) whether an adverse event is serious and may be related to the study intervention, and for coding the severity of each adverse event recorded for the duration of the study period for each research participant. In the event that there are queries about whether an event is serious or related to the study intervention, the issue can be raised with the Chief Investigator (Nick Midgley) via the Trial Manager (Sarah Jane Besser).

All serious adverse events will be reported by the Trial Manager to the REC and the Sponsor (Anna Freud Centre). In addition, the trial Steering Committee will also be notified. In some extreme cases, the trial steering committee might decide to suspend a study if there are indications that the intervention is leading to serious adverse events (a Serious Related Adverse Event).

7.6.1 DATA AND SAFETY MONITORING

A Study Steering Committee (SSC) will be set up to monitor progress and advise, meeting five times (0, 6, 12, 18, 24 months).

The SCC will be chaired by Professor Eamon McCrory, Research Department of Clinical, Educational and Health Psychology, UCL. The SCC will consist of the CI and principal investigators, a statistician, the TM, a health economist (Dr Sarah Byford), two PPI representatives (Anthony Keohane and Kevin Wright), a senior clinical psychologist (Dr Duncan Law) and an experienced researcher from the field of children in care (Professor

Alan Rushton).

The SSC will monitor progress of the study, including recruitment, data completeness and losses to follow up and ensure that there are no major deviations from the protocol.

The SSC will closely monitor progress of the study. They will review recruitment at least 3 months after recruitment of the first participant, in the middle and end of the study or when deemed necessary. They will discuss the need to stop the study if deemed appropriate. The SSC will also be responsible for monitoring patient safety. There is no reason to expect that the intervention (MBT) will lead to additional risk beyond the routine risk experienced by patients who receive usual clinical care. Therefore a separate Ethics Committee considering patient safety is not considered necessary.

To ensure the safety of staff, all researchers working on the study will follow the Lone Working Policies of HPFT and UH, as appropriate.

8. STATISTICAL PLAN

8.1 SAMPLE SIZE DETERMINATION AND POWER

The sample size of 42 is primarily calculated to *test consistency with desired primary outcome effect size*. Following Cocks and Torgerson (2013) a sample size sufficient to reject a lower limit for the effect size of 0 is estimated (assuming one sided $\alpha=0.05$, $1-\beta=.80$). Assuming $sd = 7$ in the SDQ is representative, with a lower limit = 2 for meaningful clinical change, the effect size = .29. This gives a definitive sample size $N=386$. To reject an effect size of 0 a sample size of 32 (16 in each arm) is required, or 42 families (21 per arm) allowing for 30% drop out. Recruitment is expected to take place between Month 2 and Month 14.

8.2 ANALYSIS PLAN

The purpose of the statistical and qualitative analysis is to evaluate the feasibility of undertaking a full clinical trial. The strategy employed is therefore to describe aspects of the data following the 6 aims outlined above; the approach to each aim is described in turn.

Aim 1: Evaluation of treatment integrity

The primary data considered will be an adapted version of the MBT Adherence and Competence Scale (ACS) (Karterud et al, 2013). The adaptation consists of a shortened version of the MBT ACS, which is a better fit with the version of MBT (MBT-F) in the therapist training manual. The data for each therapist ($N=3$) will be tabulated to determine whether the therapists are consistently achieving at least 80% of the target therapeutic qualities on the scale. Should any of the therapists not achieve the target set, the qualitative data will be evaluated to determine the extent to which the reasons could potentially compromise a training regimen for therapists. Furthermore, the MBT ACS will be revised and updated as the research team progress with coding the therapy sessions.

The purpose of this is to ensure that by the end of this feasibility study, we are left with a measure of MBT adherence and competence that is suitable for the adaptation of MBT which is used in the present study.

Aim 2: Feasibility of recruitment

The recruitment data will be presented in terms of absolute numbers and by proportions. In particular the conversion of children presenting to the SPA into children randomised to the study will be estimated as a key indicator of the feasibility of undertaking a full trial. The reasons for being excluded from the study at each point will be tabulated. The reasons for drop-out or exclusion will be examined for any consistent trends that may be addressed in the study design.

Aim 3: Acceptability of MBT as an intervention

For this aim the primary data will be the extent to which children and carers attended therapeutic sessions as scheduled, and the Experience of Service Questionnaire (CHI-ESQ). The analysis will tabulate therapeutic attendance, using both median and range data, and seek to determine particular trends where possible. It may be possible to evaluate the extent to which non-attendance is related to particular demographic or clinical factors crudely via regression models, or via stratification of the sample given the limited sample size. Listing and classification of significant events during the children's treatment may also help to highlight different effects on attendance patterns.

The acceptability of MBT-Fostering as an intervention will also be assessed qualitatively, using the *Experience of Therapy and Research Process Interview*. A thematic analysis (Braun and Clarke, 2006) will be conducted, to identify which elements of the intervention were experienced as acceptable or non-acceptable, and this will inform further development of the MBT-Fostering intervention model if a full clinical trial is undertaken.

Aim 4: Feasibility and acceptability of recruitment & research procedures

The primary aim of this evaluation will be to examine data completion and retention across the study once the child has been randomised to a treatment arm. Data completion rates will be documented across all the outcome measures, and by treatment arm, and by time point. The analysis will seek to determine whether data completion falls below 75%, and potential differences between treatment arms, responding groups (children, families, teachers), and by sub groups (sex, age [<11 or >11]), or any other demographic or clinical factor.

The study allows for a 30% drop out at the last follow-up, and the data will be examined similarly for trends in the drop-out of children and their families. This will be tabulated according to treatment, and sub group as outlined above. Drop-out will be matched (tabulation) to the attendance data, and to significant events to determine the extent to which drop out is determined by these factors. Regression models may be evaluated whether these factors are potentially informative and the study sample size allows.

The acceptability of randomisation, as well as other elements of the research design, will also be assessed qualitatively, using the *Experience of Therapy and Research Process Interview*. A thematic analysis (Braun and Clarke, 2006) will be conducted, to identify which elements of the research design were experienced as acceptable or non-acceptable. In addition to the process of randomisation, this will include the assessment burden, and the appropriateness of each of the research measures (e.g. whether the parenting measures were felt to be appropriate for the experience of foster carers). This will inform the design of if a full clinical trial is undertaken.

Once transcribed, all FMSS and the PDIs will be double-coded, blind to both treatment arm and assessment time point, in order to evaluate:

- i) the inter-rater reliability of the FMSS-RF
- ii) the convergent validity of the FMSS and the PDI as measures of RF

And if the FMSS-RF does demonstrate good reliability and validity, then the study will additionally evaluate:

- i) the baseline level of RF among a group of foster carers in the UK whose foster-children have been referred to child and adolescent mental health services because of emotional and behavioural problems; and the association between baseline RF and measures of parental stress or parenting style;
- ii) whether there was a change in RF among foster carers following either MBT or UCC, and whether this change was associated with changes in parental stress or parenting style; and
- iii) whether there was any indication of a differential change in RF between those foster carers receiving an MBT intervention compared to those receiving UCC.

Aim 5: Resource use data

A similar approach to evaluating (non) completion of the resource use scales (Child and Adolescent Service Use Schedule CA-SUS), and Child Health Utility 9D) will be applied as for Aim 4. In addition, an evaluation of the meaningfulness of the data collected on the CA-SUS compared to the costs incurred by the children involved in the study will be undertaken. The extent to which the costs appropriately capture the burden that the children present to the NHS and Social Care will be considered.

Aim 6: Likely effect size of the intervention

The preliminary effect size estimated for this study is based on an assumed minimum difference in the SDQ of 2 points given an $sd = 7$ typical of this sample of children. This gives a conservative estimate for an effect size of .29, and the sample size is estimated to enable a lower limit of 0 to be rejected. Part of the analysis will consider whether the SDQ or one of the secondary outcomes is the most appropriate outcome measure for the study. All other potential suitable primary outcomes have a potential effect size $> .29$.

The analysis will seek to estimate the effect size from the observed data, with an estimated lower limit as suggested by Cocks and Torgerson (2013). The primary data assessing the

suitability of the SDQ will come from interviews with the therapists and from data completion rates of the outcomes measures. Analysis of the therapist interviews will involve a thematic analysis examining the performance of the SDQ as intended.

Evaluating the feasibility of a full scale trial

Principle determinants of whether a full scale trial can be undertaken will follow evaluation of each of the study aims as outlined. In addition, the study team will work with the NIHR CRN to determine the feasibility of recruiting sufficient children into a full trial. In particular, given that a sample size of approximately 400 will be required, the study data will provide information about the number of study centres required. Consideration will also be given to the recruitment process to ensure that the maximum number of children can take part in the study.

Translation of the study materials where required may raise particular issues. Although it is unclear currently how many cases are likely to require translation, the number is likely to be small.

On a case-by-cases basis where translation has been used, verbal feedback from the translator will be collected by the research team to confirm any particular issues with the translation required. Where specific issues are identified with any of the study materials, further evaluation of the issues raised will be undertaken. The data collected for these cases will also be examined to determine any particular patterns for missing data, and the relationship of this missing data to identified issues with translation, or the relationship with identified issues in the study more generally.

Bringing together all the study data will allow trial feasibility to be considered, including:

- The potential to train therapists to deliver the intervention as envisaged, and the costs involved.
- That the external validity of the study is maximised by ensuring that drop-out from the study is within acceptable limits (30%), or that changes can be convincingly made to the study procedures to allow for improved retention in the study.
- That the internal reliability of the study data is maintained. Data completion for the study measures, and completion of the therapeutic intervention (attendance) will be evaluated to ensure that the completion rate is good (>75%) and that there are no obvious biases in data completion by any particular sub group. The qualitative evaluation will be considered in informing particular changes that can be made to maximise the study procedures to improve data completion.
- That the study procedures are examined more broadly, using both qualitative and quantitative data to inform development of the study design, so that success of a full scale trial will be maximised.

The final report will summarise the data to support clear decision to proceed to a full trial, and to inform development of the study procedures to maximise the quality of the trial design.

9. DATA HANDLING AND RECORD KEEPING

Data for this study will be collected in-person, electronically, over the telephone, via digital recording and from source documents. Logs will be kept of all processes and events. All endeavours will be made to ensure that all data is recorded, stored, transferred and, where necessary, converted efficiently and accurately. In accordance with the Research Governance Framework for Health and Social Care (2005), which states that each individual involved in conducting the study will be qualified by education, training and experience to perform his or her respective task(s), which, where they are involved in recording or handling data will include being GCP trained.

All steps on the conduct of the trial will be documented in order to allow step-by-step retrospective assessment of quality of the data and the performance of the trial. The Case Report Form (CRF) has been designed to reflect and support the flow of the study, and act as a check list with forms recording details of actions taken, dates and individuals responsible.

The allocation of responsibilities for record-keeping and handling of data are specified in the partnership agreement document and all members of the study team, including the therapists, will have access to a copy of the study's protocol, and local guidance documents will be developed where necessary to ensure consistency and continuity to the study processes.

With respect to blinding, the statistician and RA will be the only team members blinded to treatment assignment, and all endeavours will be made to ensure this is maintained through all steps of data processing up to the moment when the decision to break the code is formally taken, which will be at the end of the study when the RA completes the Experience of Therapy and the Research Process Interview. Given it is likely that rapport will have been established between the RA, the carer and child throughout the course of the study, the risk of bias in relation to the potential to compromise the quality of the interview data was felt to be minimal.

All hard-copy data will be stored in locked filing cabinets at either the study site (HPFT), AFC or UH premises. All non-clinical paper records will subsequently be transferred to UH at appropriate time points. All clinical paper records will be stored securely, and subsequently destroyed at HPFT following standard Trust procedures. All CRFs and signed consent forms will be collected from the study site (HPFT) at the end of the study and stored in a locked cabinet, behind a locked door at UH. Anonymised data will be archived by AFC/UH for 5 years after the study completion. Investigators will not disclose patient data in any form to anyone not involved directly in the study.

The electronic data management system being utilised for the purpose of the study, Qualtrics (<http://www.qualtrics.com/>), is a powerful online system that enables data to be

securely uploaded and managed from different sites. Qualtrics' servers are protected by high-end firewall systems, and vulnerability scans are performed regularly. All services have quick failover points and redundant hardware, and complete backups are performed nightly. Complete penetration tests are performed yearly. All Qualtrics' client data are considered confidential, and treated as such, with no specific designation (such as personal health information (PHI), personally identifiable information (PII), or public information).

UH will manage the administration of the study database, with levels of access determined by the Study Management Team. Policies for data access will be reviewed by the Study Steering Committee. Access to database will be by password only by authorised personnel. Where an electronic device is being used to capture, enter or communicate CRF data, all efforts will be made to ensure that any delegated individuals to enter CRF data have signed a signature form/sheet to declare that their electronic signature is the equivalent to a handwritten signature. After this signature has been obtained, the CI/study team will ensure that access rights and logins are kept securely.

Where data is transferred from hard-copy to electronic format, procedures will be established to ensure accuracy, verification checks and sign-off. Clear procedures for ensuring transfer of source data to study data will also be specified.

10. SITE MONITORING

The sponsor (AFC), in collaboration with the CTSN (UH) will ensure that the study is adequately monitored according to ICH GCP4. As indicated in the delegation log, the TM (UH) will ensure that the progress of the study is conducted, recorded and reported in accordance with the protocol, the risk assessment, GCP Guidance, and the applicable regulatory guidance.

The TM and CI will conduct a risk assessment prior to the commencement of the trial, to identify risks associated with the trial that have an impact on the safety and right of the study participants or the integrity of the trial results. The risk assessment will inform the monitoring plan. The CI, PI and TM and an independent monitor will agree on a monitoring plan, which will be endorsed by the sponsors.

The TM and monitor will ensure close communication to ensure ongoing monitoring of the TMF, correct recording and reporting of protocol breaches or violations and handling of data queries.

The TM and monitor, in agreement with the CI and the Sponsor, will agree the number of on-site visits required to monitor the study. The TM will run the Trial Initiation visit at the main site, and will organise ongoing remote site monitoring as specified in the monitoring plan.

The TM will report on monitoring visits to the PI, CI and Sponsor, including any actions required at the site. The TM and CI will support the PI at the site to ensure any corrective

and preventive actions (CAPA) are carried out. The TM will file the monitoring form and any CAPAs in the TMF.

11. STUDY ADMINISTRATION

11.1.1 STUDY MANAGEMENT

The CI, Dr Nick Midgley, will be accountable to the sponsor (the AFC) and will hold overall responsibility for the trial, including submission of required progress reports to the NIHR and NHS ethics committee, deliverables, financial statements and the correct use of funds.

The core study management team will consist of Dr Nick Midgley, Professor Pasco Fearon and Dr David Wellsted, who together will take responsibility for monitoring the overall progress of the study, including both data and budget management, and supervising the RA(s). The TM will manage the day-to-day running of the study, with the RA under the supervision of Dr Midgley and Dr Wellsted, with the support of the Clinical Trials Support Network (CTSN).

Co-investigators who will provide support to the study in relation to their specific areas of expertise include Joyce Robinson, who will provide senior clinical oversight of the study within the Trust, and Dr Sally Wood, who will lead on MBT training and supervision of the therapists. The CTSN will provide data-management and ongoing data monitoring, including randomisation procedures, setup of the online database and secure management of confidential patient-data.

11.1.2 Study Steering Committee

A Study Steering Committee (SSG) will be set up to monitor progress and advise, meeting five times (0, 6, 12, 18, 24 months), and will be responsible for monitoring patient safety. The SSG will be chaired by a research experienced academic (Eamon McCrory, Professor of Developmental Neuroscience and Psychopathology at UCL), will include the co-applicants and two PPI representatives (foster carers). Other expertise will cover Health Economics (Professor Sarah Byford, Institute of Psychiatry); Clinical (Dr Duncan Law, Clinical Psychologist) and Fostering and Adoption Research (Prof. Alan Rushton).

11.2 STUDY TIMETABLE

The study has been planned to be completed in 24 months. To enable the study progress to be monitored, the following milestones have been identified. The supporting Gant Chart lays out the timelines for different aspects of the study in more detail.

Mile Stone 1: Month -3 to Month 2:

Research plan: Staff recruitment, study set-up and preliminary approvals.

Deliverables: Recruitment of the trial team. Establishing contractual arrangements between the study sites. Trial documents (e.g. TMF, protocol, PIS, ethical approval from the REC and setting up trial databases). Training of MBT therapists. R&D approval.

Mile Stone 2: Month 2 to Month 14:

Research plan: Recruitment & Randomisation.

Deliverables: All referrals to targeted CAMHS team (approx. 130) screened; 42 families recruited and randomised.

Mile Stone 3: Month 2 to Month 17:

Research plan: Intervention Period.

Deliverables: 42 participants complete either MBT or TAU; all data to end of intervention uploaded to database.

Mile Stone 4: Month 8 to Month 20:

Research plan: Follow-up.

Deliverable: All data from follow-up period collected and uploaded to database. All data verified.

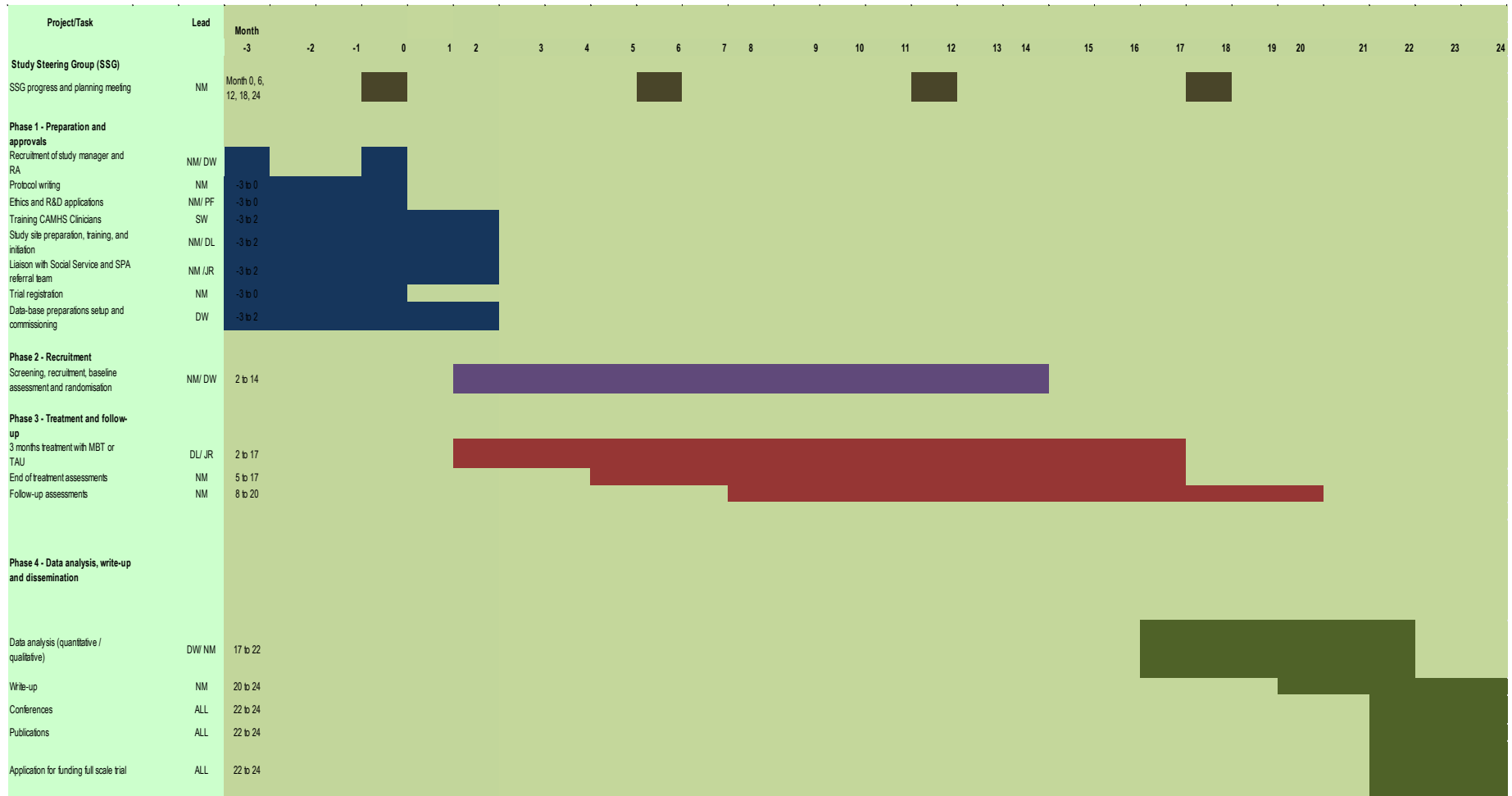
Mile Stone 5: Month 17 to Month 24:

Research plan: Analysis and dissemination.

Deliverables: Following end of intervention period, 7 months to complete data analysis and preliminary journal/conference write-up. Statistical and qualitative analysis of study data and health economic modelling. Report on trial outcomes. Abstract submission for conference posters/oral presentation. First draft of journal manuscript. Final study report to NIHR.

Assuming positive feasibility outcome, the preparation of a grant application for a large-scale clinical trial.

Study Gant Chart.



12. REPORTING AND DISSEMINATION

Given the pressing need for novel interventions for CLA (Thabane et al., 2010), the findings of this feasibility study will be disseminated to both the clinical and scientific community, and to patients and service users in the following ways:

12.1 TO THE PROFESSIONAL COMMUNITY

- A journal article in a relevant clinical/academic journal (e.g. *Journal of Evaluation in Clinical Practice* or *BMJ Medical Research Methodology*), with a particular focus on learning outcomes *in relation to the conduct of feasibility studies*. The protocol itself will be submitted to a journal such as *Trials*.
- Practitioner conference presentations, such as the CAMHS New Savoy Conference, and social care conferences, such as the annual conference of the British Association of Adoption and Fostering (BAAF); and by publication of a peer-review article in a journal, which will reach the community of practitioners, such as *Adoption and Fostering*.
- A short accessible summary of the findings for services, particularly social care services, GPs and CAMHS professionals.
- Local presentations of the findings to referrers, schools and the LA.

12.2 TO PATIENTS AND SERVICE USERS

- In collaboration with lay-members/foster carers within the steering group, we will provide a report on the study to those families who participated in the study, making clear what the outcomes of the study have been and how they will inform the next stages of the evaluation process (see below).
- Lay-members/foster carers within the steering group will be supported to present our findings to foster carer groups locally and nationally and to relevant charities

In the *shorter term*, developments in the model of MBT as an intervention for CLA and their carers (and how best to provide training to clinicians to deliver this intervention) will be used to inform existing trainings delivered to CAMHS professionals both nationally and internationally, and revisions to the treatment manual will be made freely available to clinicians on our web-based manual, at www.tiddlymanuals.com.

In the *medium term*, the information derived from this study is intended to support an application to test the efficacy of MBT in a definitive trial. Should the feasibility study suggest that a larger-scale trial is appropriate, the trial data will be used substantively to support an application to the Health Technology Assessment (HTA).

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