

Herts and Minds: Supporting the emotional wellbeing of looked after children in Hertfordshire

Submission date 18/04/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/07/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Almost 60,000 children are in foster care in England, with over 50% placed there as a result of abuse and/or neglect. Around 45% of these children suffer from mental health problems, but there is evidence to suggest that these children (and their carers) do not always get the support they need. This study is testing a new approach (Mentalization-based Treatment, MBT) to supporting foster children with mental health problems, and their carers. The new approach has been developed to promote good communication between professionals, carers and children in care by aiming to support caring relationships, and to improve emotional well-being. The aim of this study is to test the effectiveness of this approach in a small study based in Hertfordshire, in order to find out whether a larger study would be possible.

Who can participate?

Children aged 5-16 who have been in foster care for at least 4 weeks with emotional/behavioural problems, who are due to have therapy from the Child and Adolescent Mental Health Services (CAMHS) in Hertfordshire, and their foster carers.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group take part in the Mentalization-based Treatment (MBT). This involves a course of six to twelve sessions depending on the needs of the individual participants. The sessions involve a combination of a specially-devised Mentalization-Based Assessment approach (teaching to understand the mental state of self and others) through 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 a 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. Those in the second group receive the usual care that is being offered by the CAMHS team looking after that child. This may include a range of different therapies, including play therapy, family therapy or individual therapy. At the start of the study and then again after 12 and 24 weeks,

participants (and their carers) complete a number of questionnaires in order to determine whether their emotional/behavioural issues have improved. The amount of participants who took part and remained in the study is also determined to find out whether a large-scale study would be possible.

What are the possible benefits and risks of participating?

Benefits of taking part in this study are unknown however it is possible that children will experience an improvement in mental health and behaviour. There are no notable risks involved with taking part in this study.

Where is the study run from?

Hertfordshire Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

May 2015 to January 2018

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Sarah Jane Besser
sarah.besser@kcl.ac.uk

Contact information

Type(s)

Public

Contact name

Dr Sarah Jane Besser

Contact details

Research Fellow Centre for Life Span and Chronic Illness Research
Department of Psychology
University of Hertfordshire
Hatfield
United Kingdom
AL10 9AB

Additional identifiers

Protocol serial number

20877

Study information

Scientific Title

Herts and Minds: Supporting the emotional wellbeing of looked after children in Hertfordshire

Study objectives

The aim of this study is to establish whether it is feasible to conduct a full-scale trial investigating a new approach to support foster children with mental health problems and their carers, and address any obstacles to doing so.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire and Hertfordshire National Research Ethics Committee, 29/12/2015, ref: 15/EE/0032

Study design

Randomised; Interventional; Design type: Treatment, Psychological & Behavioural, Complex Intervention

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Specialty: Mental Health, Primary sub-specialty: Learning disorders; UKCRC code/ Disease: Mental Health/ Unspecified mental disorder

Interventions

Children will be randomly assigned to one of the two treatment arms (Mentalization-based Treatment versus Usual Clinical Care). Randomisation will be managed by the Clinical Trials Support Network (CTSN) at the University of Hertfordshire, 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.

Mentalization-based Treatment arm: The MBT arm consists of a combination 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; 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 a 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

Usual Clinical Care arm: 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.

Both trial arms are delivered through direct work between 6 and 12 sessions as indicated. Participants will be assessed before treatment, and again at 12 and 24 weeks post randomisation.

Intervention Type

Other

Primary outcome(s)

1. Capacity to train mental health practitioners to an acceptable level of treatment integrity is assessed during therapy (sessions 1-12) via the therapists feedback form
2. Feasibility of recruitment processes and uptake to the study is determined using data collected before baseline assessment via the study screening log and monitored at regular bi-monthly meetings
3. Acceptability and credibility of MBT-Fostering as a treatment intervention for CLA is assessed using the therapist feedback form after study recruitment and follow-up is complete
4. Feasibility and acceptability to families of conducting a randomised clinical trial is measured in a 24 week post-intervention qualitative interview with foster carers and children where appropriate
5. Feasibility of collecting resource-use data, for the purpose of calculating relative cost-effectiveness, is measured using a questionnaire at baseline, 12 and 24 weeks
6. Preliminary estimate of likely treatment efficacy effect size treatment outcome measures at 24 weeks

For the feasibility RCT assessment of the treatment outcome measures will be undertaken to support effect size estimation, and to inform power estimation for the definitive trial:

1. Emotional and Behavioural difficulties are measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline, 12 and 24 weeks
2. Brief Assessment Checklist at baseline, 12 and 24 weeks
3. Carer wellbeing and carer-child relationships are measured using the Parent Stress Index – Short Form at baseline, 12 and 24 weeks
4. Beliefs and confidence about parenting skills are measured using the Parenting Efficacy Scale at baseline, 12 and 24 weeks
5. Caregiver's capacity for reflective functioning (mentalizing) is measured using The Five Minute Speech Sample at baseline, 12 and 24 weeks
6. Service user defined treatment outcomes are measured using the Goal-based Outcome Measure (GBOM) at baseline, 12 and 24 weeks
7. Negative life-events are measured using a Significant Events log at baseline, 12 and 24 weeks

Key secondary outcome(s)

1. Mental health difficulties are measured using the brief assessment checklist at baseline, 12 and 24 weeks
2. Goals of therapy are assessed using the Goals Based Outcome Measure Questionnaire, collected during therapy, and again at 12 and 24 weeks
3. Parental stress is measured using the Parent Stress Index at baseline, 12 and 24 weeks
4. Parenting style is measured using the Parenting Scale, at baseline 12 and 24 weeks
5. Confidence in parenting is measured using the Brief Parental Efficacy Scale at baseline, 12 and 24 weeks
6. Health Related Quality of Life is measured using the Child Health Utility at baseline, 12 and 24 weeks
7. Anxiety and depression are measured using the Revised Anxiety and Depression Scale at

baseline, 12 and 24 weeks

8. Service use is measured using the Child and Adolescent Service Use Questionnaire at baseline, 12 and 24 weeks

9. Experience of Therapy is measured using the Experience of Service Questionnaire at 12 and 24 weeks

10. Attendance to therapy sessions is measured using a Treatment Attendance Form at each therapy session (1-12)

11. Reflective functioning is measured using a Five Minute Speech Sample at baseline, 12 and 24 weeks

12. Therapist feedback form (pre-, during and post-training and intervention delivery)

Completion date

01/01/2018

Eligibility

Key inclusion criteria

Children inclusion criteria:

1. Primary and secondary school age children (aged 5-16)
2. In foster-care (or kinship care) for a minimum of 4 weeks
3. Referred to the targeted CAMHS team in Herts
4. Decision for the child to receive therapy from the CAMHS team, following an initial consult meeting with the professional network
5. With emotional or behavioural problems (based on a score on the SDQ ≥ 15)

Carer inclusion criteria:

Foster carers of participating children.

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Total final enrolment

36

Key exclusion criteria

1. An emergency/crisis referral, where an immediate response to a significant risk is required
2. The referral is specifically for a psychiatric assessment in specialist CAMHS

Date of first enrolment

07/04/2016

Date of final enrolment

21/05/2017

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Hertfordshire Partnership NHS Foundation Trust

Kingfisher Court

Kingsley Green

Harper Lane

Radlett

United Kingdom

WD7 9HQ

Sponsor information

Organisation

Anna Freud Centre

ROR

<https://ror.org/0497xq319>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/07/2019	15/07/2019	Yes	No
Protocol article	protocol	22/02/2017		Yes	No
HRA research summary			26/07/2023	No	No
Protocol file	version v2.5	25/10/2018	25/10/2018	No	No