ISRCTN90349442 https://doi.org/10.1186/ISRCTN90349442

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

Submission date
18/04/2016

Recruitment status
No longer recruiting

Registration date
06/05/2016

Overall study status
Completed

Last Edited
15/07/2019

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 Herfordshire, 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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 qualtiative 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 usng 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

Secondary outcome measures
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)

Overall study start date
01/03/2015

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

Age group

Mixed

Sex
Both

Target number of participants
Planned Sample Size: 42; UK Sample Size: 42

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
England

United Kingdom

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

Sponsor details
21 Maresfield Gardens
London

England
United Kingdom
NW3 5SU

Sponsor type
Hospital/treatment 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

Publication and dissemination plan
1. Planned publication of study protocol in the journal Pilot and Feasibility Studies
2. Planned publication of study results 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
3. 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
4. A short accessible summary of the findings for services, particularly social care services, GPs and CAMHS professionals
5. Local presentations of the findings to referrers, schools and the local authority

Intention to publish date
31/12/2018

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?
Protocol article	protocol	22/02/2017		Yes	No
Protocol file	version v2.5	25/10/2018	25/10/2018	No	No
Results article	results	10/07/2019	15/07/2019	Yes	No
HRA research summary			26/07/2023	No	No