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A research project for children with hard to treat behaviour problems

Submission date
23/05/2016

Recruitment status
No longer recruiting

Registration date
31/05/2016

Overall study status
Completed

Last Edited
02/03/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
When a child has a behaviour problem, the first treatment that is usually tried is a parenting programme or sessions on child behaviour management techniques. These work for many people but they don't work for everyone. Some children have what are called 'hard to treat behaviour problems'. Currently, there is little research looking into how best to help these children. Some researchers think a therapy called 'Child Psychotherapy' might help. This is already available in the NHS, but the therapy itself takes a long time. This study is looking at a brief version of this Child Psychotherapy treatment so that children and their parents/carers don' t have to go to so many sessions. The aim of these study is to find out whether it is feasible to carry out a larger study investigating whether this brief version of Child Psychotherapy is better than the 'usual treatment' offered.

Who can participate?
Children aged 5-11 years old, and their main caregiver, who have been referred to CAMHS with a behaviour problem.

What does the study involve?
Participants are randomly allocated to one of two groups. The children (and their caregivers) in the first group take part in 12 weekly 50 minute therapy sessions. The children (and their caregivers) in the second group continue to receive usual care for the duration of the study. At the end of the study, the amount of participants who agreed to take part and those who completed the study are recorded.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The study is run from the Clinical Trials Unit at the University of Leeds (UK)

When is the study starting and how long is it expected to run for?
March 2016 to September 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
30713

Study information

Scientific Title
Trial on Improving Inter-Generational Attachment for Children Undergoing Behaviour Problems

Acronym
TIGA-CUB

Study objectives
The aim of this study is to investigate the practicability of implementing a confirmatory, randomised controlled trial (RCT) comparing Child Psychotherapy (CP) to Treatment as Usual (TaU), as a second-line intervention for children aged 5-11 with treatment resistant conduct disorders and inter-generational attachment difficulties and for their primary carers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 17/03/2016, ref: 16/YH/0055

Study design
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: Children, Primary sub-specialty: Neurosciences; UKCRC code/ Disease: Mental Health/ Behavioural syndromes associated with physiological disturbances and physical factors

Interventions
Participants will be randomised on a 1:1 basis to receive either Manualised Child Psychotherapy or Treatment as Usual.

Child Psychotherapy: Both the primary carer and child will each attend 12, weekly 50 minute therapy sessions, as prescribed by the TIGA-CUB Child Psychotherapy manual.

Treatment as Usual: Participants receive the usual care offered by local CAMHS teams. This treatment is likely to be highly diverse and may involve group and/or individual and/or primary carer and/or family based work, delivered by a range of practitioners from a variety of professional backgrounds and theoretical orientations.

Participants will be contacted for follow-up at 4 months post-randomisation.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment rate is measured by recording the proportion of dyads who consented to participate at the study end
2. Attrition rate is measured by recording the proportion of dyads completing the study out of

those randomised to follow-up at the study end
3. Adherence is measured by recording the proportion of dyads randomised to the intervention arm successfully completing the required number of therapy sessions specified in the manual (or fewer, as determined by the CAPT) at the study end

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/03/2016

Completion date
01/09/2017

Eligibility

Key inclusion criteria
1. Children aged 5-11 years old at baseline
2. Presenting to CAMHS, or re-referred within CAMHS, with a clinical conduct disorder (≥4 on Strengths and Difficulties (SDQ) conduct sub-scale)
3. Child's current primary carer* has been offered a first line group or individual parenting programme or other structured parenting intervention in primary care or within CAMHS, and has attended at least one session, but the child's conduct disorder persists and the child has been referred to CAMHS or re-referred within CAMHS for further treatment.

*The term 'primary carer' denotes the adult most involved in parenting the child.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Children with a clinical diagnosis of Autistic Spectrum Disorder (ASD), including Asperger's
2. Children with a clinical diagnosis of severe Learning Difficulties (LD)
3. Children medicated for Attention Deficit Hyperactivity Disorder (ADHD), unless they have been on a stable medication dose for 3 months or more (children with un-medicated ADHD are eligible if other inclusion criteria met)
4. Looked After Children (LAC) (including adopted children):
4.1. who are not in kinship foster care or special guardianship, or
4.2. who are not in kinship foster care or special guardianship which is stable (> 6 months)
5. Children under/at risk of Safeguarding or Court procedures
6. Children whose primary carer has severe mental health difficulties, determined by usual

CAMHS procedures using clinical judgement (baseline GHQ-12 will be monitored for primary carers with severe mental health difficulties not identified by CAMHS)
7. Sibling has been randomised to the TIGA-CUB trial (as CP involving two CAPTs, which would be required for two children, may not be available in some of the services involved in the trial)
8. Primary carer is actively receiving a parenting programme within CAMHS for the child's sibling
9. Primary carer lacks capacity to comply with trial requirements, e.g. as a result of a LD, due to research burden or due to insufficient proficiency in English
10. Primary carer has severe adverse parental functioning e.g. alcohol dependence (≥20 on Alcohol-Use Disorders Identification Test) or drug dependence (≥3 on Drug Abuse Screening Test), determined by the study Researcher on initial screening visit

Date of first enrolment
01/07/2016

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
Clinical Trials Research Unit
Leeds Institute of Clinical Trials Research
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
Leeds and York Partnership NHS Foundation Trust

Sponsor details
First Floor, South Wing
St Mary's House
St Mary's Road
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England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00n635c12

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
Planned publication of study results in a peer reviewed journal

Intention to publish date
01/09/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as participants have not consented for their data to be used in further research.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/09/2017		Yes	No

Results article	01/12/2018	02/03/2022	Yes	No
HRA research summary		28/06/2023	No	No