







# A research project for children with hard to treat behaviour problems

<b>Submission date</b> 23/05/2016	<b>Recruitment status</b> No longer recruiting	 Prospectively registered
<b>Registration date</b> 31/05/2016	<b>Overall study status</b> Completed	 Protocol added
<b>Last Edited</b> 02/03/2022	<b>Condition category</b> Mental and Behavioural Disorders	 SAP not yet added
		 Results added
		 Raw data not yet added
		 Study completed

## Plain English Summary

### 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?  
Ms Liz Graham  
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## Contact information

**Type(s)**  
Public

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Protocol/serial number**  
30713

## Study information

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

**Acronym**  
TIGA-CUB

**Study hypothesis**  
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

## **Condition**

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

### **Overall study end date**

01/09/2017

## **Eligibility**

### **Participant 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 ( $\geq 4$  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

### **Participant 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 ( $\geq 20$  on Alcohol-Use Disorders Identification Test) or drug dependence ( $\geq 3$  on Drug Abuse Screening Test), determined by the study Researcher on initial screening visit

**Recruitment start date**

01/07/2016

**Recruitment end date**

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

Leeds

England

United Kingdom

LS15 8ZB

**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?
<a href="#">Protocol article</a>	protocol	15/09/2017		Yes	No

<a href="#">Results article</a>	01/12/2018	02/03/2022	Yes	No
<a href="#">HRA research summary</a>		28/06/2023	No	No