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Parents and Young Children under Extreme Stress - PYCES

Submission date
18/11/2013

Recruitment status
No longer recruiting

Registration date
18/11/2013

Overall study status
Completed

Last Edited
17/06/2021

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
Following horrific or life-threatening events around 10-15% of young children develop post-traumatic stress disorder (PTSD). The symptoms of this are distressing nightmares, flashbacks, anger outbursts and disturbed play. These can cause major disruption to all areas of the childs functioning and, if left untreated, can persist for many years. As yet there are no established and clinically validated treatments for this disorder in young children. Trauma-focussed cognitive behaviour therapy is a psychological intervention that is effective in treating the disorder in older children and adults. This study evaluates the effectiveness of a developmentally appropriate form of trauma-focussed cognitive behaviour therapy which we have developed for children as young as 3 years.

Who can participate?
This study aims to recruit 60 children (boys and girls) aged 3-8 years who have been involved in or witnessed a traumatic event like a car crash or an assault. It does not matter how long ago the event happened.

What does the study involve?
All children involved in the study will have an initial assessment (a parent will complete some interviews and questionnaires, and the child will do tasks). If the child is diagnosed with PTSD, then they will be invited onto the study. They will be randomly allocated to have the treatment straight away (12 weekly sessions) or to wait for 12 weeks. Children assigned to the wait-list are still able to access any help outside of this study. Both groups will be assessed half way through the 12 weeks (by parents completing some more questionnaires). At the end of the treatment /waiting period all children will have another assessment parent interviews and questionnaires, and child tasks. If a child still has PTSD at the end of the waiting period, they will then be offered the treatment.

What are the possible benefits and risks of participating?
The main benefit to children who do have PTSD is that they will be offered psychological treatment (trauma-focussed cognitive behavioural therapy). Even participants who are assigned to wait for 12 weeks will receive this treatment (if they still have PTSD) sooner than they may receive help from their local Child and Adolescent Mental Health Service. Children who do not

have PTSD will still have a thorough assessment. The children and their parents may appreciate this and the opportunity to discuss the trauma in a non-judgemental, confidential and empathetic setting.
The treatment involves talking about the frightening event, and this can sometimes be upsetting. However, other studies have shown that the treatment works well and treats PTSD in older children and adults. Participants will be given breaks whenever they need them, and will be reminded that they are free to leave the study at any time. Clinical psychologists within the team will be available for follow-up phone calls and meetings with people who need them. We have found previously that any distress experienced during therapy is short-lived and outweighed by the benefit of successfully treating PTSD.

Where is the study run from?
This study is run from the MRC Cognition and Brain Sciences Unit in Cambridge. We recruit participants from all over East Anglia several Emergency Departments are involved in our screening study and anybody can refer a child to us, for example schools, nurses, GPs or parents.

When is the study starting and how long is it expected to run for?
July 2013 to October 2017

Who is funding the study?
National Institute of Health Research, UK.

Who is the main contact?
Dr Ben Goodall Trial Coordinator and the main Clinical Psychologist working on the project ben.goodall@mrc-cam.ac.uk
Isobel Chadwick is the Assistant Psychologist isobel.chadwick@mrc-cam.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
14964

Study information

Scientific Title
A pilot randomised clinical trial of trauma-focused cognitive behaviour therapy for posttraumatic stress disorder (PTSD) in young children aged 3-8 years (PYCES)

Acronym
PYCES

Study objectives
PYCES is a randomised controlled trial assessing the effectiveness of trauma-focused cognitve behavioural therapy (CBT) as an intervention for post-traumatic stress disorder in 3-8 year olds.

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=14964

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East of England Cambridge South, January 2013, ref: 12/EE/0458

Study design
Interventional randomised controlled trial; Design type: Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Anxiety; Disease: Post-traumatic stress disorder (PTSD)

Interventions
Random allocation to have the treatment straight away (12 weekly sessions) or to wait for 12 weeks.

Trauma-Focused CBT, Manualised 12-session developmentally appropriate trauma-focused cognitive behavioural therapy.

The treatment is delivered by highly trained Clinical Psychologists who have extensive experience of working with young children. This treatment involves both the child and a parent /caregiver. It is delivered over 12 weekly sessions and involves learning about PTSD, recognising feelings, thinking and talking about the trauma and training in coping skills. The therapist will set homework each week, to consolidate the material covered in session. Three sessions take place with the child and parent together. The remaining sessions are divided into two halves; the first half involves the therapist and child only. The second half involves just the therapist and caregiver and provides an opportunity to discuss any problems and the homework. Booster sessions will be provided to the child or parent/caregiver if necessary.

Follow Up Length: 12 months

Study Entry : Registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Determine efficacy of TF-CBT as an intervention for young children with PTSD; Timepoint(s): End of study

Key secondary outcome(s)
1. Assess feasibility and acceptability of the intervention; timepoint(s): end of study;
2. Assess mediators and moderators of outcome; timepoint(s): end of study
3. Assess the course of PTSD symptoms on young children over the first 3 months post-trauma; timepoint(s): end of prospective study
4. Compare cognitive variables of children with PTSD vs non-PTSD trauma-exposed children; timepoint(s): end of study
5. Investigation of genetic factors in PTSD onset and in treatment response; timepoint(s): end of study
6. Preliminary health economics analysis; timepoint(s): end of study

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Exposure to a road traffic accident, an assault, or another discrete traumatic stressor (i.e. any event that involved the threat of death, severe injury, or threat to bodily integrity, or witnessing such an event);
2. Age 3-8 years
3. Target Gender: Male & Female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
8 years

Sex
All

Total final enrolment
37

Key exclusion criteria
1. Intellectual disability
2. Another primary psychiatric diagnosis
3. PTSD following another previous trauma
4. Unconscious for >15 minutes following the traumatic event
5. Not being fluent in English
6. Ongoing exposure to threat
7. History of organic brain damage
8. Risk of self-harm

Date of first enrolment
10/07/2013

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Cognition and Brain Sciences Unit
Cambridge
United Kingdom
CB2 7EF

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0211-24045

Results and Publications

Individual participant data (IPD) sharing plan
The datasets and statistical acode generated during the current study will be available from the MRC Cognition and Brain Sciences Unit Data Repository, which can be acccessed at http://www.mrc-cbu.cam.ac.uk/publications/opendata/ .

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	17/06/2021	Yes	No
Protocol article	protocol	25/03/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes