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ASPECTS: Acute Stress Programme for Children and Teenagers

Submission date	Recruitment status	[X] Prospectively registered
05/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/03/2018	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Post-traumatic stress disorder (PTSD) is an anxiety disorder which can affect people following incidents such as road traffic accidents, assaults and natural disasters. This study is looking at a treatment for PTSD in children and young people who have recently experienced trauma. It is already known that the talking therapy Cognitive Behavioural Therapy (CBT) can help children and young people who have had PTSD for some time (chronic) but it is not known if it helps them in the acute (recent) stage. It is felt to be important to help children and young people in the early stages as the condition could become chronic and affect their development. The main aim of this study is to test the effectiveness of CBT as an early intervention for PTSD in children and young people. The researchers will also look at the course and prevalence of PTSD in the first 2 months after the traumatic event. Finally possible biological and psychological factors that may be associated with PTSD will be investigated.

Who can participate?
60 children and young people aged 8-17 who have experienced a road traffic accident, an assault or other single traumatic event and have a diagnosis of PTSD.

What does the study involve?
In the main study, participants are randomly allocated into two groups to either receive a course of up to 10 sessions of CBT or to be put on the waiting list. This allows the researchers to compare the differences between those who receive CBT and those that don't (those on the waiting list who are still experiencing PTSD after 10 weeks will be offered CBT). Participants are recruited 2-4 weeks after the traumatic event and re-assessed after 2 months. Participants from the CBT group are also assessed after 6 and 12 months to see if any benefits are maintained. For the other parts of the study, two more groups of 60 children of similar age and gender are recruited. One group will have experienced a traumatic event but without developing significant PTSD symptoms and the other group will not have experienced trauma. Participants undergo a series of psychological and physical tests.

What are the possible benefits and risks of participating?
The study will provide important information about the development of PTSD in children and young people, what factors effect recovery and whether CBT is an appropriate early treatment. There were no major risks of participating.

Where is the study run from?
MRC Cognition and Brain Sciences Unit (UK)

When is the study starting and how long is it expected to run for?
May 2010 to August 2013

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Cognitive behavioural therapy (CBT) as an early intervention for post-traumatic stress disorder (PTSD) in youth: preliminary efficacy and mechanisms of action

Acronym
ASPECTS

Study objectives

Is cognitive behavioural therapy (CBT) an efficacious early intervention for post-traumatic stress disorder (PTSD) in children and adolescents? This question will be addressed using a randomised controlled trial, where CBT is compared to a wait-list control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 1 Research Ethics Committee, 29/04/2010, ref: 10/H0304/11

Primary study design
Interventional

Study design
Single-centre single-blind randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-traumatic stress disorder (PTSD)

Interventions
Participants will enter the trial at 2 - 3 months after a traumatic event. They will either be allocated to active treatment or a wait list.

The experimental intervention will be a course of cognitive behavioural therapy (CBT). This will last for up to 10 sessions, and be delivered over a 10 week period. This treatment would be based largely on the treatment package devised for a previous trial of CBT for chronic PTSD in children and adolescents. Each session will last 60 - 90 minutes.

The control intervention will be a 10 week wait list group, with the same pre- and post-intervention assessments as the experimental intervention.

Post-treatment assessments will be conducted by doctoral-level psychologists blind to treatment allocation. Participants who still have PTSD at the end of the wait list period will be offered the CBT treatment.

Total duration of treatment for CBT will be 10 - 15 hours, over 10 weekly sessions; follow ups will take place at 6 months and 12 months post-treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. PTSD status, as assessed using the Children's PTSD Inventory (CPTSDI)
2. Child PTSD Symptom Scale (CPSS)

All of the primary and secondary outcome measures will be completed at the pre- and post-treatment assessments; all primary and secondary measures will be completed at the 6- and 12-month follow ups, with the exception of the Clinician's Global Assessment Scale.

Key secondary outcome(s)
1. Mood and Feelings Questionnaire (MFQ)
2. Spence Childrens Anxiety Scale (SCAS)
3. Childrens Global Assessment Scale (CGAS)

All of the primary and secondary outcome measures will be completed at the pre- and post-treatment assessments; all primary and secondary measures will be completed at the 6- and 12-month follow ups, with the exception of the Clinician's Global Assessment Scale.

Completion date
01/08/2013

Eligibility

Key inclusion criteria
1. Exposure to a road traffic accident, an assault, or another discrete traumatic stressor (i.e. any event that involve the threat of death, severe injury, or threat to bodily integrity, or witnessing such an event)
2. Aged 8 - 17 years, either sex
3. Meeting Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) diagnostic criteria for PTSD, or the alternative algorthim for children and young people proposed by Scheeringa and colleagues (Scheeringa, Wright, Hunt, & Zeanah, 2006), assessed by a structured interview
4. The index trauma occurred 2 - 3 months prior to trial entry

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 Years

Upper age limit
17 Years

Sex
All

Key exclusion criteria
1. Intellectual disability (i.e. mental retardation)
2. Another primary psychiatric diagnosis

3. PTSD following another previous trauma
4. Unconscious for greater than 15 minutes following the traumatic event
5. Not being fluent in English
6. Ongoing exposure to threat
7. History of organic brain damage
8. Significant risk of self-harm

Date of first enrolment
21/02/2011

Date of final enrolment
01/08/2013

Locations

Countries of recruitment
United Kingdom

England

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

Study participating centre
30 patient identification centres and research sites
United Kingdom
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) - Clinician Scientist Fellowship awarded to Dr Richard Meiser-Stedman (ref: G0802821)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

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
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2017		Yes	No