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A pilot randomised trial to determine the efficacy of early cognitive behaviour therapy (CBT) versus delayed treatment for children with significant post-traumatic reactions.

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
18/09/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0038183431

Study information

Scientific Title
A pilot randomised trial to determine the efficacy of early cognitive behaviour therapy (CBT) versus delayed treatment for children with significant post-traumatic reactions.

Study objectives
What is the efficacy of early, brief trauma-focused CBT for the treatment of significant acute posttraumatic reactions in child road traffic accident (RTA) victims?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Mental and Behavioural Disorders: Post-traumatic disorder

Interventions
1. Immediate course of psychotherapeutic sessions
2. Delayed course of psychotherapeutic sessions

Initial assessments for subjective distress, and diagnostic symptoms of PTSD. Children with high scores entered into study. Diary completed daily by child for 3 weeks, followed by assessments for PTSD, anxiety and depression. Those with significant enduring posttraumatic symptoms as determined by the CIES or the CPSS randomised into either the immediate or delayed treatment arms of the study.

Change in the severity of posttraumatic symptoms, determined by MANOVA. Changes in associated anxiety and depression. CIES, CPSS. Treatment effect size for changes in PTST symptoms analysed using Cohen's D statistic.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Child PTSD Symptom Scale (CPSS)
2. Children's Impact of Events Scale (CIES)
3. Children's Revised Manifest Anxiety Scale (MAS)
4. Birleson Depression Inventory (BDI)
5. 10 point cognitive change scale

Secondary outcome measures
Not provided at time of registration

Overall study start date
27/04/2006

Completion date
31/05/2007

Eligibility

Key inclusion criteria
Children aged 7 to 18 who attend the A&E departments at the Royal United Hospital Bath, and Frenchay Hospital Bristol, following an RTA.

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
18 Years

Sex
Not Specified

Target number of participants
20

Key exclusion criteria
1. Experienced life threatening physical injuries (Triage rating 1)
2. Were unconscious for 15 minutes or more
3. Suffer significant learning difficulties
4. Live outside 30 mile radius of RUH in Bath (so cannot attend treatment sessions)

Date of first enrolment
27/04/2006

Date of final enrolment
31/05/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Child & Family Therapy
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Avon and Wiltshire Mental Health Partnership NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2008		Yes	No