

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

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/09/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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. Birlson 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?
<a href="#">Results article</a>	results	01/07/2008		Yes	No