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Treating children with post-traumatic stress disorder (PTSD) following an accidental injury: a multicentre randomised controlled trial

Submission date	Recruitment status	[_] Prospectively registered
05/08/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/08/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/02/2011	Mental and Behavioural Disorders	[_] Record updated in last year

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
N/A

Study information

Scientific Title
Comparison of cognitive-behavioural treatments for children with post-traumatic stress disorder (PTSD) following an accidental injury: a multicentre randomised controlled trial

Study objectives
This study will evaluate the efficacy of a cognitive behavioural, trauma-focused intervention for children and adolescents aged between 7 and 16 years of age who experience post-traumatic stress disorder (PTSD) following an accidental injury.

Specifically, this study is a multicentre randomised controlled trial (RCT) in which participants will be randomly assigned to either a waitlist (WL) condition or one of two active treatment conditions, child-focused cognitive behavioural therapy (CBT) (CF) or family-focused CBT (FF). Participants allocated to the WL condition will be randomly allocated to either the CF or FF condition following the completion of the waiting period (10 weeks).

This study aims to compare the efficacy of the two active treatments and examine which is associated with greater reductions in psychosocial outcome measures over time. It is hypothesised that:
1. Following treatment, compared to participants in the WL condition, participants in both the active treatment conditions will demonstrate:
1.1. Significantly greater reductions in child trauma, anxiety and depressive symptoms
1.2. Significantly higher ratings on a health-related quality of life measure; and
1.3. Significantly reduced ratings of functional impairment
2. Compared to participants in the CF CBT treatment condition, participants in the FF CBT treatment condition will demonstrate:
2.1. Significantly greater reductions in child trauma, anxiety and depressive symptoms
2.2. Significantly higher ratings on a health-related quality of life measure
2.3. Significantly reduced ratings of functional impairment
2.4. Significantly greater reductions in parental anxiety, trauma and depressive symptoms
2.5. Significantly increased parental perception of their own ability to support their child
3. These treatment gains (and differences) will be maintained over long-term follow-up

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Queensland Human Research Ethics Committee approved on the 11th December 2008 (ref: 2008002119)
2. Royal Children's Hospital Children's Health Service District Ethics Committee approved on the 28th April 2009 (ref: HREC/09/QRCH/41)
3. Mater Health Services Human Research Ethics Committee approved on the 19th May 2009 (ref: 1305C)
4. CYWHS Human Research Ethics Committee approved on the 17th June 2009 (ref: REC2149/2/2112)

Study design
Multicentre randomised controlled trial

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 below to request an information sheet

Health condition(s) or problem(s) studied
Post-traumatic stress disorder/post-traumatic stress symptoms

Interventions
Participants are randomly allocated to one of three conditions:
1. Family-focused CBT condition: Participants allocated to this condition receive a 10-week intervention, comprised of 4 weekly parent sessions and 6 weekly child sessions, run consecutively. Participants in this condition will complete a 'post-intervention' assessment immediately following the completion of the intervention (at 10-weeks post-randomisation) and will also complete follow-up assessments at 6 and 12 months following the completion of the intervention. The total duration of treatment and follow-up for this condition is 62 weeks.
2. Child-focused CBT condition: Participants allocated to this condition receive a 6-week treatment program (child program only). To remain consistent and enable comparisons with the family-focused CBT condition and waitlist control condition, participants will also complete their 'post-intervention' assessment at 10 weeks following randomisation. Participants in the child-focused condition will also complete follow-up assessments at 6 and 12 months following the completion of the intervention. The total duration of treatment and follow-up for this condition is 62 weeks.
3. Waitlist control condition: Participants allocated to this condition receive no therapy or contact during the 'intervention phase'. Participants in this condition will complete a 'post-intervention' assessment at 10 weeks post-randomisation. Participants in the waitlist condition will then be randomly allocated to child-focused or family-focused CBT and will commence active treatment immediately. Participants will then complete a 'post-treatment' assessment 10 weeks following randomisation, and follow-up assessments at 6 and 12 months following the completion of the active intervention. The total duration of treatment and follow-up for this condition is 72 weeks.

Details of the intervention programs are below:

Child Program:
This intervention ("Me and the accident: a story with a good ending") consists of 6 sessions. This program takes a strengths-based, resilience-building approach and is highly visual. The intervention aims to:
1. Provide psychoeducation about the role of thoughts, behaviours (avoidance) and physical reactions in anxiety (and in PTSD in particular)
2. Emphasize the importance of the young person's story of his/her accident and their

perceptions of current danger or threat
3. Assist children/adolescents in identifying the 'hot spot' thoughts (i.e., particularly emotive thoughts or images) in their story
4. Provide young people with the skills to challenge their hot spot thoughts and to manage their "intruder thoughts" (i.e., any intrusive thoughts or images experienced)
5. Plan for the future (relapse prevention)

Parent Program:
This program ("My child and the accident: a story with a good ending") consists of 4 sessions and aims to:
1. Provide psychoeducation about PTSD, as well as a rationale for the child program
2. Focus on danger perceptions and the way these change after a traumatic incident (with an emphasis on factors such as the possible communication of threat from parent to child and reinforcement of perceptions of danger)
3. Focus on how changes in parenting practices after a traumatic incident effects a family member and encourage parents to think about their own parenting behaviours and whether these are likely to be helpful or not
4. Support parents to develop the skills to effectively parent a child experiencing PTSD

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Assessment of post-traumatic stress symptoms. Diagnostic status (of PTSD), symptom severity and associated disability/impairment will be assessed using the Clinician Administered PTSD Scale for Children (CAPS-CA). The CAPS will be administered pre-randomisation, post-intervention and at 6 and 12 month follow-up.

Secondary outcome measures
Measures administered during hospital admission:
1. Children's injury severity, assessed using the Injury Severity Score and Abbreviated Injury Scale

Measures administered at screening stage (1 - 2 weeks post-hospital admission):
2. Children's trauma symptoms/risk indicators, assessed using the Child Trauma Screening Questionnaire (CTSQ); also measured at pre-randomisation, 4-weeks post-randomisation, post-intervention, 6 and 12 months follow-up

Measures administered at pre-randomisation, 4-weeks post-randomisation, post-intervention, 6 and 12 months follow-up:
3. Children's PTSD symptoms, measured through the self-report Child PTSD Symptom Scale (CPSS)
4. Children's anxiety symptoms, measured using the Spence Child Anxiety Scale (SCAS)
5. Children's depression symptoms, measured through the Child Depression Inventory (CDI)
6. Children's quality of life, measured through the Pediatric Quality of Life Inventory, Child and Parent Versions (PedsQL)
7. Children's internalising and externalising symptoms, measured by the Child Behavior Checklist (CBCL)
8. Intensity of children's pain, measured through the Faces Pain Scale - Revised (FPS-R)

9. Parent's PTSD symptoms, assessed through the self-report Post-traumatic Stress Diagnostic Scale
10. Parental psychopathology, assessed using the Depression Anxiety and Stress Scale (DASS)
11. Parental state and trait anxiety, measured by the State Trait Anxiety Inventory (STAI)

In addition, treatment satisfaction will be measured through a Program Satisfaction Questionnaire, completed by parents and children following the intervention. Global distress and improvement will be assessed at 4-weeks post-randomisation, post-intervention, and at 6 and 12 months follow-up using a Global Assessment of Impairment/Improvement Scale.

Overall study start date
01/09/2009

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Aged between 7 and 16 years, either sex
2. Admission to hospital for accidental trauma/injury
3. Admission to hospital for minimum 6 hours (overnight stay)
4. Endorsement of greater than or equal to 5 items on the Child Trauma Screening Questionnaire within two weeks of admission ('at-risk' of developing PTSD)
5. Elevated clinical symptoms as identified on the structured diagnostic interview, the Clinician-Administered PTSD Scale for Children and Adolescents (CAPS-CA), 4 - 6 weeks following hospital admission

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
140 (3 conditions with ~45 participants)

Key exclusion criteria
1. Parent's English insufficient for questionnaire completion
2. Developmental delay or mental retardation in the child
3. Moderate-severe head injury or post-traumatic amnesia following the accident

4. Severe depression or suicide risk in the child
5. Alcohol, substance abuse or psychosis in the caregiver
6. Under the care of the Department of Child Safety
7. Injury due to physical or sexual abuse

Date of first enrolment
01/09/2009

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Australia

Study participating centre
Centre of National Research on Disability and Rehabilitation Medicine
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Sponsor information

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Sponsor type
Research organisation

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Funder(s)

Funder type
Research council

Funder Name
National Health and Medical Research Council (NHMRC) (Australia) (ref: 569660)

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

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?
Protocol article	protocol	16/11/2010		Yes	No