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Prevention of post-traumatic stress disorder in children and adolescents

Submission date	Recruitment status	[ ] Prospectively registered
22/01/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/01/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/01/2007	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

Study objectives
Risk of chronic Post-Traumatic Stress Disorder (PTSD) after Acute Stress Disorder (ASD) diminishes with an early intervention (Cognitive Behavioural Therapy [CBT]) that attempts to modify cognitive appraisals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medical Ethics Commission academic hospital of Maastricht /Maastricht University (Medisch Ethische Commissie azM/UM) on the 11th OCtober 2006 (ref: 06-3-045).

Study design
Randomised, crossover, single blind multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Post-Traumatic Stress Disorder (PTSD)

Interventions
Brief trauma-focused cognitive behavioral therapy intervention or control-condition (wait-list-controls).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Presence versus absence of PTSD
2. PTSD-symptom-severity, assessed with:
a. structured interview (Anxiety Disorders Interview Schedule for Children [ADIS-C])
b. self-completed questionnaires (Child Post-traumatic Stress Scale [CPSS])

Secondary outcome measures
Symptoms of anxiety and/or depression according to questionnaires (Revised Children's Anxiety and Depression Scale [RCADS]) and quality of life.

Overall study start date
01/12/2006

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Children (aged seven to 17)
2. Had contact with Victim Assistance experiencing a traumatic event less than two weeks ago
3. Meet the Diagnostic and Statistical Manual of mental disorders (DSM) criteria for Acute Stress Disorder

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
17 Years

Sex
Not Specified

Target number of participants
80

Key exclusion criteria
1. Brain injury
2. Psychotic or organic mental disorder
3. Current suicidal ideation
4. Intelligence Quotient (IQ) less than 80
5. Low proficiency in Dutch
6. No parent willing to participate in the study

Date of first enrolment
01/12/2006

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
University Maastricht
Maastricht
Netherlands
6200 MD

Sponsor information

Organisation
University Maastricht (UM) (The Netherlands)

Sponsor details
P.O. Box 616
Maastricht
Netherlands
6200 MD

Sponsor type
University/education

Website
http://www.unimaas.nl/default.asp?taal=en

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

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