ISRCTN57754429 https://doi.org/10.1186/ISRCTN57754429

The incidence of post-trauma psychopathology study (TRAUMA TIPS): efficacy of an innovative preventive multimedia intervention

Submission date	Recruitment status	[X] Prospectively registered
20/12/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/10/2014	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.traumatips.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR318

Study information

Scientific Title

Acronym
Trauma Tips-Prevention

Study objectives
Our primary hypothesis is whether a brief early multimedia intervention is effective in preventing symptoms of post-traumatic stress, anxiety and depression in injured trauma patients.

On 21/03/2012, the following changes were made to the trial record:
1. The anticipated start date was changed from 01/09/2006 to 01/09/2007.
2. The anticipated end date was changed from 01/09/2007 to 01/07/2010.
3. The target number of participants was changed from 180 to 300.
4. 'Netherlands Organisation for Health Research and Development (ZonMW) (Grant no. 62300038)' was added to the sources of funding field.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre randomised single-blinded active-controlled parallel-group 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
Depression, post-traumatic stress disorder (PTSD), anxiety

Interventions
Current interventions as of 21/03/2012:
The multimedia (MM) intervention group (n = 151) versus the the control/non-intervention group (n = 149).

The subjects' informed consent will be obtained 1 to 7 days after the critical incident. The MM intervention session, lasting a maximum of 30 minutes, is an internet-based programme containing interactive elements and visual and auditory materials. Its aim is to reduce acute psychological stress in trauma victims. The following core and elective modules will be included:
1. Information about procedures in trauma units
2. Information about commonly experienced reactions to accident injuries
3. An audio clip providing relaxation techniques
4. Tips for dealing with the initial period after the traumatic experience

Subjects will be assessed at pre-intervention (1 to 7 days after the trauma and immediately preceding the intervention) and at post-intervention (immediately following the intervention and at 1, 3, 6 and 12 months post-trauma).

Previous interventions:
The multimedia (MM) intervention group (n = 90) versus the the control/non-intervention group (n = 90).

The subjects informed consent will be obtained 1 to 7 days after the critical incident. The MM intervention session, lasting a maximum of 30 minutes, is an internet-based programme containing interactive elements and visual and auditory materials. Its aim is to reduce acute psychological stress in trauma victims. The following core and elective modules will be included:
1. Information about procedures in trauma units
2. Information about commonly experienced reactions to accident injuries
3. An audio clip providing relaxation techniques
4. Tips for dealing with the initial period after the traumatic experience

Subjects will be assessed at pre-intervention (1 to 7 days after the trauma and immediately preceding the intervention) and at post-intervention (immediately following the intervention and at 1 month and 6 months post-trauma).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
PTSD scores (Clinician-Administered PTSD Scale [CAPS] and the revised Impact of Event Scale [IES-R])

Secondary outcome measures
1. Other psychopathology (Mini International Neuropsychiatry Interview Plus [MINI-PLUS] clinical interview)
2. Anxiety and depression (Hospital Anxiety and Depression Score [HADS] questionnaire)
3. Quality of life (World Health Organization Quality of Life Assessment [WHOQOL])

Overall study start date
01/09/2007

Completion date
01/07/2010

Eligibility

Key inclusion criteria
1. Injured patients who entered the shockrooms of the Academic Medical Centre (AMC) or the Vrije University Medical Centre (VUMC) in Amsterdam, Netherlands
2. Aged 18 years and older
3. Proficiency in Dutch

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Mentally incapable of participating in trial (i.e., Glasgow Coma Scale score less than 13)
2. Physically incapable of participating in trial
3. Suicidality
4. Fulfilling diagnostic criteria for a bipolar disorder, depression with psychotic features, psychotic disorder or organic disorder according to Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM IV)

Date of first enrolment
01/09/2007

Date of final enrolment
01/07/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Meibergdreef 5
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
Academic Medical Centre
Department of Psychiatry
Center for Anxiety Disorders, Research Group Psychotrauma
Meibergdreef 5
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

Website
http://www.amcpsychiatrie.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (Netherlands)

Funder Name
Achmea Victim and Society Foundation (Achmea Stichting Slachtoffer en Samenleving) (SASS) (Netherlands)

Funder Name
Netherlands Organisation for Health Research and Development (ZonMW) (Grant no. 62300038)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2011		Yes	No
Protocol article	protocol	01/09/2011		Yes	No
Results article	results	13/08/2013		Yes	No