

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

Submission date 20/12/2005	Recruitment status No longer recruiting	☒ Prospectively registered
		☒ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 02/10/2014	Condition category Mental and Behavioural Disorders	☐ 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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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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])

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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	13/08/2013		Yes	No
Protocol article	protocol	01/03/2011		Yes	No
Protocol article	protocol	01/09/2011		Yes	No

Study website	Study website	11/11/2025	11/11/2025	No	Yes
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