The Incidence of Post trauma Psychopathology Study (TRAUMA TIPS): efficacy of an innovative preventive multimedia-intervention.

No registrations found.

Ethical review Positive opinion

Status Recruitment stopped

Health condition type -

Study type Interventional

Summary

ID

NL-OMON25077

Source

NTR

Brief title

Trauma Tips-Prevention

Health condition

Posttraumatic Stress Disorder (PTSD), Anxiety and Depression

Sponsors and support

Primary sponsor: Academic Medical Center

Department of Psychiatry,

Center for Psychological Trauma

Source(s) of monetary or material Support: Achmea Stichting Slachtoffer en

samenleving (SASS)

Academic Medical Center (AMC)

Intervention

Outcome measures

Primary outcome

PTSD scores (Clinician-Administered PTSD Scale CAPS, Blake et al., 1995 and the revised Impact of Event Scale IES-R, Weiss et al., 1997).

Secondary outcome

Other psychopathology (MINI-PLUS clinical interview); anxiety and depression (HADS questionnaire); quality of life (WHOQOL).

Study description

Background summary

Previous research has shown that individual, single-session intervention interviews (psychological debriefing) in the aftermath of a traumatic event are not effective in preventing posttraumatic stress disorder (PTSD). Little research has been done so far on alternatives to debriefing. In this study, we propose to test a brief multimedia intervention (MM intervention) and to test its efficacy in a randomised controlled trial (RCT). The trial will involve adults who have sustained injuries in accidents or crime, to be recruited at the Trauma Units of the Academic Medical Centre (AMC) and the VU University Medical Centre (VUMC), both in Amsterdam. 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: information about procedures in trauma units, information about commonly experienced reactions to accident injuries, an audio clip providing relaxation techniques, and 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 posttrauma). The primary outcome measures will be symptoms of acute distress and PTSD scores. Secondary measures will be anxiety and depression and quality of life. If efficacy is demonstrated, the intervention can be made available to patients at all Dutch trauma centres.

Key words:

Randomised controlled trial Stress disorders, posttraumatic

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Anxiety
Depression
Preventive health services
Emergency medicine
Internet
Multimedia

Study objective

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

Study design

N/A

Intervention

- 1. The multimedia (MM) intervention group (n = 90) and
- 2. The control / non-intervention group (n = 90).

Contacts

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Eligibility criteria

Inclusion criteria

- 1. Injured patients who entered the shockrooms of the Academic Medical Center (AMC) or the Medical Center of the Free University (VUMC) in Amsterdam, the Netherlands;
- 2. Age 18 years and older;
- 3. Proficiency in Dutch.

Exclusion criteria

- 1. Mentally uncapable of participating in trial (i.e. Glasgow Coma Scale score < 13);
- 2. Physically uncapable of participating in trial;
- 3. Suicidality;
- 4. Fulfilling diagnostic criteria for a biplar disorder, depression with psychotic features, psychotic disorder or organic disorder according to DSM IV.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Control: Active

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-09-2006

Enrollment: 180

Type: Actual

Ethics review

Positive opinion

Date: 09-09-2005

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

NTR-new NL280

NTR-old NTR318

Other : N/A

ISRCTN ISRCTN57754429

Study results

Summary results

Mouthaan, J., Sijbrandij, M., Reitsma, J.B., Luitse, J.S.K., Goslings, J.C., & Olff, M. (2011). Trauma TIPS: an internet-based intervention to prevent posttraumatic stress disorder in injured trauma patients. Journal of Cybertherapy and Rehabilitation, 4(3), 331-340. https://doi.org/10.2016/j.c./

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