

The acceptance of TraumaGameplay as an early intervention tool to prevent intrusive memories.

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To determine the acceptance and usability of the TraumaGameplay (TGP) app in individuals who have experienced a traumatic event within the first five days and the staff members of Slachtofferhulp Nederland (Department Amsterdam) who will deliver the...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON43944

Source

ToetsingOnline

Brief title

Acceptance of TraumaGameplay

Condition

- Anxiety disorders and symptoms

Synonym

Posttraumatic Stress Disorder (PTSD), traumarelated complaints

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: NWO;Creatieve Industrie,Vodafone (Mobiles for good geldprijs),Vodafone Mobile for Goods Award

Intervention

Keyword: Intrusions, Prevention, PTSD, Serious Gaming

Outcome measures

Primary outcome

- Credibility and Expectancy Questionnaire (CEQ; Borkovec & Nau, 2000).
- System Usability Scale (SUS; Brooke, 1996).
- A self-designed questionnaire containing five questions regarding the experience using TraumaGameplay

Secondary outcome

- Visual Analogue Scale (VAS) distress, vividness and emotionality of the memory of the event. In addition, distress, vividness and emotionality of intrusions, and the difficulty of retrieving the images will be measured using VASs (e.g. Engelhard et al., 2011; Engelhard et al., 2010). For a detailed description of the administration of these VASs please see 5.1 Investigational intervention (page 17) of the researchprotocol.
- Impact of Events Scale-Revised (IES-R; Weiss & Marmar, 1997).
- Experience of Intrusion Scale (Salters-Pedneault, Vine, Mills, Park, & Litz, 2009).

Study description

Background summary

Posttraumatic Stress Disorder (PTSD) is a serious psychiatric disorder that has a major impact on individual wellbeing. Currently there are effective treatments for people who have developed PTSD, however effective early interventions to prevent the onset of PTSD is still lacking. Recent studies

have shown that negative autobiographical memories become less vivid and emotional when during memory retrieval a dual task, that taxes working memory, is performed. In addition an analogue trauma study by Holmes et al., (2009) found that healthy participants, who played the computer game Tetris after watching an extremely aversive film, reported fewer flashbacks during the following week, compared to a control group that didn't play Tetris. These findings have been replicated several times; however no studies have yet explored the acceptability of a computer game as an early intervention for individuals who have just experienced a traumatic event.

Study objective

To determine the acceptance and usability of the TraumaGameplay (TGP) app in individuals who have experienced a traumatic event within the first five days and the staff members of Slachtofferhulp Nederland (Department Amsterdam) who will deliver the intervention.

Study design

A pilot feasibility study

Intervention

TGP is a computer game comparable to Tetris, designed for smartphones or tablets. TGP consists of a trauma selection screen, in which the participant can choose an icon that matches the traumatic event he or she just experienced (e.g. an icon of a car accident). This icon will be used as the background of the playing field to help the participant retrieve the traumatic event from memory. The participant first gets a practice trial to get used to the gameplay, followed by eight trials lasting 24 second with a 10 second break between each trial. During these 24 seconds of gameplay the participant has to form 2 x 2 squares by rotating and positioning blocks that fall from the top of the screen; while simultaneously retrieving the traumatic event from memory. The intervention will be provided in addition to care as usual by Slachtofferhulp Nederland (Department Amsterdam).

Study burden and risks

The burden of participation consists of completing baseline questionnaires (10 minutes) and performing the intervention (10 minutes). In addition, participants will be asked to complete a post-intervention assessment immediately after the intervention (5 minutes) and a follow up interview within 1 week after the traumatic event (45 minutes). There is minimal risk involved in participating in this study. Participants may experience an elevated level of distress while playing the TraumaGameplay app, or shortly thereafter. However the probability that these elevated distress result in actual complaints or symptoms of PTSD is

minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Slachtofferhulp (study1):

- 1) exposure to an event according to the stressor A1 criterion of the DSM 5 (American Psychiatric Association, 2013) such as an assault, robbery, accident, etc.
- 2) the event happened no longer than five days earlier.

Exclusion criteria

- 1) are severely injured (i.e., physically unable of undergoing the intervention)
- 2) present with symptoms of severe psychiatric symptoms (psychotic disorders, bipolar disorder, depression with psychotic features, or suicidality) that need imminent specialized treatment
- 3) victims of rape or sexual assault will be excluded
- 4) having insufficient Dutch language skills to complete the questionnaires in Dutch.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Will not start

Enrollment: 30

Type: Anticipated

Medical products/devices used

Generic name: TraumaGameplay (TGP) application

Registration: No

Ethics review

Approved WMO

Date: 30-03-2016

Application type: First submission

Review commission: METC Amsterdam UMC

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
CCMO	NL55236.029.15