Online EMDR and cognitive therapy for traffic accident survivors: A randomized controlled trial

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23650

Source
NTR

Brief title
TrafVic

Health condition

Post-traumatic stress disorder (PTSD), major depressive disorder (MDD)

Sponsors and support

Primary sponsor: Utrecht University; University of Groningen
Source(s) of monetary or material Support: Fonds Slachtofferhulp (Fund Victim Support)

Intervention

Outcome measures

Primary outcome

PTSD: PTSD Checklist for DSM-5 (PCL-5; Weathers, et.al., 2013)

Secondary outcome

Depression: Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001)
Rumination: Brooding subscale of the ruminative response scale (RRS; Treynor et al., 2003)
Self-efficacy: General self-efficacy scale (GSES; Schwarzer & Jerusalem, 1995)
Acceptability of treatment: Two open-ended qualitative questions (i.e., “which aspects of the treatment were you satisfied with?”, “which aspects of the treatment were you dissatisfied with?”)

Study description

Background summary

The primary aim of this study is to study the effectiveness of online EMDR+CT (vs. waitlist controls), in terms of reduction in PTSD and depression symptom-levels, for people who have been involved in a traffic accident. We expect that people allocated to a condition with online EMDR+CT will show lower PTSD and depression symptom-levels post-treatment than people allocated to a waitlist, while taking baseline symptom-levels into account.

Secondary aims are (i) to assess the effectiveness of online CT, (ii) to assess the effectiveness of online EMDR+CT compared to online CT, (iii) to examine rumination and self-efficacy as correlates of change, and (iv) to assess the acceptability of online treatment.

A two-arm (online EMDR+CT vs. waitlist followed by online CT) open label parallel randomized controlled trial will be conducted. Self-report measures will be completed by participants at pre-treatment and post-treatment.

Eligible for participation are people who have been involved in a traffic accident at least one month prior to participating and are currently experiencing clinically relevant levels of PTSD (as indicated by the PCL-5 questionnaire)

Study objective

We expect that people allocated to the EMDR+CT condition will show lower symptom-levels of PTSD and depression post-treatment compared with waitlist controls post-waiting (Hypothesis 1).

Additionally, we expect that people allocated to the waitlist followed by online CT will show lower PTSD and depression levels post-treatment compared to their own post-waiting symptom-levels (within-person; Hypothesis 2), that people allocated to the online EMDR+CT group will show lower symptom-levels of PTSD and depression post-treatment than those allocated to the online CT group post-treatment (Hypothesis 3), and that that a reduction in rumination and improvement in self-efficacy will be related to reductions in PTSD and depression symptom-levels post-treatment in both intervention condition (Hypothesis 4).

Study design

Online EMDR+CT condition: pre-treatment and 6 weeks post-allocation
Online CT: pre-treatment, 6 weeks and 12 weeks post-allocation

Intervention

This investigational treatment is an online EMDR+CT treatment targeted at people with clinically relevant levels of PTSD who have been involved in a traffic accident. The online CT consists of six weekly sessions.

Intervention: Six weeks of online EMDR combined with online cognitive therapy (CT). In week 1, participants will get an explanation of the online platform (Therapieland), psychoeducation about PTSD, a questionnaire on what they would like to achieve in treatment and an introductory meeting with their therapist. In week 2, participants will learn about different forms of exposure and will perform a writing assignment. Weeks 3-5 will consist of the online EMDR treatment. The first two EMDR sessions will last 75 minutes each and the third EMDR session will last 90 minutes to give therapist and participant the chance to discuss the therapy and form a conclusion. In week 6, therapy will be concluded by writing a letter to a loved one about the impact of the event and an evaluation of goals that were set in week 1. During the weeks with no EMDR the participant will have no contact with the therapist and will focus on the unguided therapy sessions in Therapieland that they can finish in their own time.

Control group: The control group will be allocated to a (no-treatment) waiting period, in weeks 1-6. After these six weeks, participants in the control group will get access to the online cognitive therapy (CT) module of Therapieland. Similar to online EMDR and online CT (the experimental intervention), the CT module is a six week intervention. It includes writing assignment focused on identifying and altering maladaptive cognitions and evidence-based writing assignments focused on processing memories associated with the accident (cf. Dawson et al., 2020). No EMDR is included in this CT module.

Contacts

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Eligibility criteria

Inclusion criteria

Have experienced at least 1 traffic accident at least one month prior to participating; Being ≥18 years of age; Reporting clinically relevant symptom-levels of post-traumatic stress disorder (PTSD) based on self-report questionnaires.

Exclusion criteria

Does not master the Dutch language; Does not have access to Internet; Cannot participate in an online intervention due to medical complaints (e.g., neck complaints due to the accident).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2021
Enrollment:	64
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	02-08-2021
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	NL9641
Other	METC UMCU : 21-271/D

Study results

Summary results

N/A