Online EMDR and cognitive therapy as a treatment of posttraumatic stress and depressive symptoms in traffic accident survivors.

Published: 10-06-2021
Last updated: 05-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON50943

Source
ToetsingOnline

Brief title
Traffic accident survivors and online EMDR

Condition

- Anxiety disorders and symptoms

Synonym
Posttraumatic stress disorder; trauma related disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: Fonds Slachtofferhulp

Intervention

Keyword: EMDR, Online, PTSD, Treatment

Outcome measures

Primary outcome

Primary outcomes are symptom-levels of PTSD and depression.

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

Depression: Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001)

Secondary outcome

Secondary outcomes are rumination, self-efficacy, and the acceptibility of online treatment.

Rumination: Ruminative Response Scale (RRS; Treynor et al., 2003)

Self-efficacy: General Self-efficacy Scale (GSES; Schwarzer et al., 1995)

The acceptability of online treatment will be measured using 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

Eye movement desensitization and reprocessing (EMDR) combined with cognitive therapy (CT) is a treatment of choice for post-traumatic stress disorder (PTSD). In the current Covid-19 pandemic, many therapies have necessarily switched to an online format. Promisingly, studies investigating online

cognitive therapy (CT) indicate the positive effects of this treatment for PTSD and depression. However, to data only one (uncontrolled) study has been conducted to assess the effects of online EMDR. This means that the scientific basis for online EMDR for PTSD is currently lacking. As online EMDR is already being used by many therapists within the Netherlands, it is important to investigate what the effects of online EMDR treatment for PTSD are. Therefore, we aim to investigate whether online EMDR is an effective therapy that should be used in clinical practice.

Study objective

The primary aim of this study is to study the effectiveness of online CT+EMDR (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.

Study design

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.

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 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. In weeks 7-12 participants will have no treatment.
Control group: The control group will consist of a waiting list in weeks 1-6. After the six weeks are over, participants will get access to the online cognitive module of Therapieland. This module will be the same as the

online EMDR+CT group, expect for weeks 9-11. In these three weeks (where the online EMDR+CT group receives EMDR treatment), online EMDR will be replaced with imaginal exposure including writing assignments, which is a science-based treatment (Dawson et al., 2020).

Study burden and risks

Answering the survey questions could evoke painful thoughts or feelings related to the traffic accident. The treatment could lead to a temporary increase in PTSD symptoms. However, there are no indications based on prior research that EMDR or CT results in an unacceptable risk of exacerbation of complaints.

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

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 PTSD based on self-report questionnaires.

Exclusion criteria

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

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

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

Ethics review

Approved WMO Date:	10-06-2021
Application type:	First submission
Review commission:	METC NedMec

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	NL77219.041.21