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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23650

Bron
NTR

Verkorte titel
TrafVic

Aandoening

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

Ondersteuning

Primaire sponsor: Utrecht University; University of Groningen
Overige ondersteuning: Fonds Slachtofferhulp (Fund Victim Support)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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)

Doel van het onderzoek

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).

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2021
Aantal proefpersonen:	64
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	02-08-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9641
Ander register	METC UMCU : 21-271/D

Resultaten

Samenvatting resultaten
N/A