Investigating a digital device to increase the efficiency of trauma-focused psychotherapy in PTSD patients: a pilot randomized controlled trial of the EMD app.

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

Summary

ID

NL-OMON47137

Source
ToetsingOnline

Brief title
Addition of the EMD app in PTSD treatment

Condition

- Anxiety disorders and symptoms

Synonym
posttraumatic stress disorder, PTSD

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Kansen voor West / Europees Fonds voor Regionale Ontwikkeling (EFRO)

Intervention

Keyword: App, Digital Device, Posttraumatic stress disorder, Treatment efficiency

Outcome measures

Primary outcome

The primary outcome parameter is the difference in PTSD symptom severity

response pattern during the five sessions between the EMDR + EMD app group as

compared to the EMDR alone group.

Secondary outcome

Secondary outcomes include depressive symptoms, general anxiety symptoms,

acceptability, usability and client satisfaction.

Study description

Background summary

Posttraumatic stress disorder (PTSD) is a mental health problem with a high prevalence in the general population; 8% of the population is diagnosed with this disorder during their lives. Trauma-focused psychotherapies such as Cognitive Behavioural Therapy (CBT) and Eye Movement Desensitization and Reprocessing therapy (EMDR) are the first line treatments for PTSD, but 30% of patients do not benefit sufficiently from these interventions. There is a need to increase the efficiency and efficacy of treatments for PTSD. Mobile applications can facilitate application of therapeutic techniques at home in a way that is easily accessible and low in costs.

Study objective

The primary objective of the current study is to investigate a potential increase in efficiency of standard trauma treatment for outpatients with PTSD

by adding a digital device that closely follows the principles of manualized EMDR treatment, the EMD app (EMD stands for Eye Movement Desensitization). Secondly, we aim to assess the acceptability and usability of the EMD app from the perspective of the patients who are treated for their PTSD. Good feasibility (i.e. adequate system acceptability and usability) and a positive preliminary effect will justify a larger study investigating the efficiency gains of the application in the future.

Study design

This is a two arm pilot randomized controlled trial with a pre-post design, in which patients will be randomized to receive EMDR treatment with addition of the EMD app (five weeks unlimited access to the EMD app) or EMDR treatment alone (no access to the EMD app). Measurements will take place at baseline and at each of the five weekly EMDR sessions. A post-measurement takes place in the sixth week; after five EMDR sessions.

Intervention

The EMD app is a digital application that can be used on smartphone, laptop and computer at home as an additive therapeutic intervention to EMDR treatment. The application closely follows the main steps of the EMDR treatment, which is one of the most effective interventions for PTSD. It includes focusing on a repetitive intrusive image together with the associated cognition and emotion, followed by repeatedly performing a task that taxes working memory, monitoring of the distress evoked by the image, and introduction of a more positive cognition in relation to the image.

Study burden and risks

Because all participating patients receive regular manualized treatment for their PTSD by a licensed psychologist or psychotherapist, participation in this study entails a negligible additional risk. If patients do not experience a drop in distress related to an image during the use of the app, the app has a built-in feature to advise contacting the therapist. During the development of the application, the EMD app was tested among employees of Arq Psychotrauma Expert Group. This pilot study indicated preliminary positive results for the usability, acceptability and efficacy of the application.

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

- 18 * 65 years of age or older
- Referred to a mental health care organisation for PTSD following one or more traumatic experiences
- Meet the DSM-5 diagnostic criteria for PTSD as confirmed by the CAPS-5
- Are in possession of a device such as a laptop, tablet, mobile phone or computer
- Have sufficient command of the Dutch language, both verbally and in writing
- Provide signed informed consent

Exclusion criteria

- Having current high risk for suicide according to the M.I.N.I. Interview for psychiatric disorders, section C
- Having serious psychiatric co-morbidity i.e. bipolar affective disorder, psychotic disorder, substance dependence that would interfere with EMDR treatment as assessed by the therapist in the intake.
- Being unable to comprehend the spoken and written Dutch language.
- Not having access to a computer, laptop, tablet or smartphone with an internet connection.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2016
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Digital application
Registration:	No

Ethics review

Approved WMO Date:	12-11-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-04-2018
Application type:	Amendment

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

ID: 23716
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL53877.018.15
OMON	NL-OMON23716

Study results

Date completed: 30-06-2020

Actual enrolment: 57

Summary results
Trial is onging in other countries