

Addition of the EMD app in PTSD treatment

No registrations found.

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

Summary

ID

NL-OMON23716

Source

Nationaal Trial Register

Brief title

EMD-APP for PTSD

Health condition

Post traumatic stress disorder

Post traumatische stress stoornis

Sponsors and support

Primary sponsor: Department of Psychiatry, Academic Medical Center at the University of Amsterdam

Source(s) of monetary or material Support: Kansen voor West/ Europees Fonds voor Regionale Ontwikkeling
Vereniging EMDR Nederland
Arq Psychotrauma Expert Groep

Intervention

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 group that receives EMDR alone and will be measured with the PCL-5 Questionnaire.

Secondary outcome

Secondary outcomes include depressive symptoms (HADS), general anxiety symptoms (HADS), quality of life (SF-12), acceptability (CSQ-8), usability (SUS) and client satisfaction.

Study description

Background summary

Posttraumatic stress disorder (PTSD) is a mental health problem with a high prevalence in the general population. Still 30% of patients do not benefit sufficiently from existing interventions. There is a need to increase the efficiency and efficacy of treatments for PTSD. 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.

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.

We will recruit N = 60 adult outpatients with a current PTSD diagnosis due to a work-related traumatic incident who are referred by their company doctor to the Institute for Psychotrauma (IVP), part of Arq Psychotrauma Expert Group.

The EMD app is a digital application that can be used on smartphone, laptop and computer at home as an additive therapeutic intervention to an outpatient EMDR treatment. The application closely follows the main steps of the EMDR treatment, which is one of the most effective interventions for PTSD.

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 outcomes include depressive symptoms, general anxiety symptoms, acceptability, usability and client satisfaction.

Update:

After recruiting 33 patients, we updated in March 2019 the EMD app 1.0 and started providing our patients since then with the new 2.0 version. The 2.0 version is identical to the 1.0 version but entails instead of one, it includes three digital games with the intend to tax working memory in patients according to the EMDR protocol. In addition, the EMD-app 2.0 was made accessible as a mobile app via the IOS and Android store as compared to being a

web-app only.

The stop date was updated due to recruitment challenges and is the 30-06-2020.

Study objective

The hypothesis is that by addition of the EMD- app the regular treatment effect of EMDR will be reached within fewer treatment sessions, because patients will actively apply therapeutic techniques at home, similar to the techniques that are provided in their treatment sessions.

Study design

The primary outcome is assessed at seven time points:

1. Before treatment (baseline)
2. A measurement at the start of the first five EMDR-sessions
3. Posttreatment after five sessions

Secondary outcomes are assessed pre- and post-treatment.

Intervention

The EMD-app is a digital application that can be used on smartphone, laptop and computer at home as an additive intervention to an EMDR treatment. The application closely follows the main steps of the EMDR treatment.

The user of the EMD-APP will receive the instruction to keep in mind the most disturbing image from a traumatic recollection. The intervention consist of a simple “game” in which a participant must match abstract figures as quickly als possible. This serves as a distracting stimulus to tax the working memory sufficiently.

In the intervention group patients receive an EMDR treatment with addition of the EMD app. They have to use the EMD-APP in between of the first six EMDR-sessions of their treatment. Patients in the control group receive an EMDR-treatment as usual.

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Eligibility criteria

Inclusion criteria

- 18 – 65 years of age
- Referred to the Institute for Psychotrauma (IVP), part of Arq Psychotrauma Expert Group, for PTSD following one or more work-related traumatic experiences.
- Meet the DSM-5 diagnostic criteria for PTSD as confirmed by the CAPS-5
- 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 section C
- Having serious psychiatric co-morbidity i.e. bipolar affective disorder, psychotic illness, 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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	23-02-2016
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	26-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47137
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5643
NTR-old	NTR5758
CCMO	NL53877.018.15
OMON	NL-OMON47137

Study results