EMDR as an innovative strategy in the treatment of OCD

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

Summary

ID

NL-OMON44536

Source
ToetsingOnline

Brief title
EMDR for OCD

Condition

- Anxiety disorders and symptoms

Synonym
Compulsive Disorder, Obsessive-Compulsive Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Altrecht GGZ (Den Dolder)
Source(s) of monetary or material Support: EMDR Research Foundation

Intervention

Keyword: EMDR, Exposure & Response Prevention, OCD

Outcome measures

Primary outcome

- Yale-Brown Obsessive Compulsive Scale (Y-BOCS; Goodman et al., 1989): severity OCD symptoms

De Y-BOCS has been validated in many different languages; the findings regarding the factor structure, reliability, and validity are positive and robust. The Y-BOCS has been validated in Dutch by van Oppen et al. (1995).

Secondary outcome

- Structured Clinical Interview for mental Disorders (SCID-I; First et al., 1997): classification of Axis-I disorders, a.o. OCD.
- Obsessive Compulsive Inventory-Revised (OCI-R; Foa et al., 2002): type of OCD
- Obsessive Beliefs Questionnaire (OBQ-44; OCCWG, 2003): dysfunctional core beliefs in OCD
- Beck Depression Inventory (BDI-II; Beck et al., 1996): severity of depressive symptoms
- World Health Organization Quality of Life short version (WHOQOL-BREF; WHOQOL Group,2004)
- 2 VASs (willingness to engage in ERP, and inclination to drop-out)

The OCI-R, de OBQ-44, BDI-II en WHOQOL-BREF are validated in many languages as well, a.o. the Dutch language. Findings are stable across languages: the

psychometric properties are good to excellent (Dutch version OCI-R:

Cordova-Middelbrink, Dek, & Engelbarts, 2007; Dutch version OBQ-44: Anholt, van

Oppen, Cath, Emmelkamp, Smit, & van Balkom, 2010; Dutch version BDI-II: van der

Does, 2002; Dutch version WHOQOL-BREF: Trompenaars, Masthoff, van Heck,

Hodiamont en de Vries, 2005).

Study description

Background summary

A widely accepted first-line treatment for obsessive-compulsive disorder (OCD) is exposure and response prevention (ERP). However, approximately half of the patients do not respond optimally to this treatment, and about 25% of OCD patients refuse the treatment or drop-out prematurely. Hence, the development of innovative strategies for OCD is of paramount importance. Recent studies suggest that overall treatment resistance is likely associated with the intrusive images (e.g., causing illness and death) that 90% of the OCD patients experience. Eye Movement Desensitization and Reprocessing (EMDR) has established efficacy in reducing the impact of traumatic images in various disorders.

Study objective

The aim is to critically evaluate the additive effect of EMDR to ERP on treatment acceptability, drop-out, and outcome; a) does EMDR lead to a decrease in OCD related memory representations (or in other words; does it lead to a decrease in the amount of obsessions)? ;b) are patients more inclined to be subjected to ERP after EMDR and less inclined to drop-out then before they received EMDR? and c) does the combinated use of EMDR and ERP to an additional observable effect by reducing drop-out and a higher decrease in OCD symptoms?

Study design

An experimental multiple baseline case series design is used (Kazdin, 2011), consisting of 4 phases, i.e., baseline, exploration, treatment, and return-to-baseline phase. Different baseline lengths are determined before the start of the study (i.c., 3, 4, 5, 6, and 7 weeks). After inclusion each patient is allocated a) alternately to one of both therapists, and hereafter b) randomly to one out of 5 baseline lengths (2 patients for each baseline length, baseline lengths equally divided between both therapists). Since the Altrecht

Academic Anxiety Centre is a highly specialised treatment centre, to which only severe and chronic patients are referred, it is expected that complaints (YBOCS) at baseline will be stable. At the end of the baseline phase the patient is asked to rate the two VASs on willingness to engage in ERP, and inclination to drop out of ERP. After the baseline phase, the exploration phase (4 weeks) starts. During this phase no active interventions are used, thus serving as an additional control phase. This is followed by the active treatment phase, starting with 6 sessions EMDR. At the end of the last EMDR session the patient is asked again to rate both VASs on ERP. Hereafter 15 sessions ERP are conducted (or more if needed). After treatment there is a *return-to-baseline* phase of 6 weeks, in which the patient receives no treatment.

Although RCTs are generally considered the *golden standard* for testing therapy effectiveness, there are limitations with respect to feasibility, costs, and external validity (e.g., Hawkins et al., 2007). Therefore, as a first step often an open trial is used in order to explore the effect of an intervention. However, this design offers no solid base for conclusions. A powerful alternative is a multiple baseline case series design (Onghena, 2005). Advantages are that a) patients serve as their own controls, and b) variation in baseline lengths offers the possibility to differentiate between time effects and experimental effects of the treatment. By adding an exploration phase, it is also possible to control for the effect of attention, and the power of the design is increased (see Arntz, Sofi, & van Breukelen, 2013). Moreover, multiple baseline case series fit in with daily practice more closely than RCTs, and offer the opportunity to continue treatment (i.c., ERP) until adequate reduction of complaints is reached (Kazdin, 2011). There is also an ethical advantage, whilst in comparison to RCTs, less patients have to be included.
Multiple baseline case series are less suited to directly compare the effect of two different treatments; for that purpose between-subjects designs are needed. However, it is explicitly not the aim of our study to determine the relative effect of EMDR and ERP. Our goal is to examine the additive effect of EMDR; hence a carry-over effect of EMDR on ERP is expected. Moreover, it was decided not to use a cross-over design (alternating order of EMDR and ERP), since it is expected that EMDR especially has a favourable additive effect when preceding ERP (by more willingness to engage in ERP, and less inclination to drop-out). Finally, if the expected effects are not found, this provides a strong argument that EMDR has no benefits in OCD. However, when the expected effects do appear, EMDR is considered a promising treatment component in this specific patient group, making a formal RCT a logical further step.

Intervention

6 x weekly session of Eye Movement Desensitization and Reprocessing (EMDR)
15 x weekly session of Exposure & Responspreventie (ERP)

ERP is the standard intervention; next to this patients receive 2 sessions idiosyncratic case-conceptualisation (45 minutes each) in which targets are selected for EMDR and the treatment rationale is explained, followed by 6 sessions (90 mintues each active EMDR treatment.

Study burden and risks

There are no risks involved by participation in this study.

Most secondary outcome measures are part of a standard measurement procedure at the Altrecht Academic Anxiety Centre, i.e., part of *Routine Outcome Monitoring* (ROM). Whether a patient is enrolled in the present study or not, all patients have to complete ROM measurements during their treatment. The burden for patients who will participate in the present study is:

a) - at two times (before and at the end of EMDR treatment) they have to endorse two Visual Analogue Scales (placing a cross on a line) concerning their inclination to drop out during ERP, and their willingness to fully engage in ERP (2 min per time);
- each week they have to endorse the YBOCS, a short questionnaire into the severity of OCD symptoms (5 min per week). During the baseline and return-to-baseline phases the YBOCS is send to the patient, so he/she can endorse the questionnaire at home; during the exploration and active treatment phase, the patient endorses the questionnaire at location (AAA), just before a treatment appointment.

b) 2 sessions idiosyncratic case-conceptualisation (selection of targets to be processed with EMDR) and explanation of the rational of EDMR treatment (2x45 minutes)

b) 6 sessions (6x90 minutes) active EMDR treatment.

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

a) an OCD diagnosis, as established by the Structured Interview for DSM-5 disorders (SCID), and b) mild to severe OCD symptoms (total score YBOCS > 15)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: a) already received ERP or EMDR in the last twelve months, b) suffering from psychotic disorders, substance abuse/addiction, or a severe depression (score on Beck Depression Inventory-II >30), c) Insufficient knowledge of the Dutch language or not being able to read, d) Mental retardation (IQ<80). The use of antidepressants is permitted, provided that dosages are kept constant during the study, and usage has started at least 6 months before entering the trial. The use of benzodiazepines is not permitted.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-12-2017
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	28-09-2017
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	NL62220.041.17