PERSONALIZED EXPOSURE AND ESM FEEDBACK VERSUS EXPOSURE AS USUAL FOR OCD

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

Summary

ID

NL-OMON55600

Source
ToetsingOnline

Brief title
Doorbreek Dwang Digitaal

Condition

- Anxiety disorders and symptoms

Synonym
obsessive-compulsive disorder, OCD

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia (Den Haag)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ehealth, experience sampling, Exposure, Obsessive-compulsive disorder

Outcome measures

Primary outcome

The main study parameter is a difference in treatment outcome as measured with

the Yale Brown Obsessive-Compulsive Scale (YBOCS) and the World Health

Organization Quality of Life (WHOQOL-bref)

Secondary outcome

The 16-item self-report Quick Inventory of Depressive Symptomatology (QIDS)

The Positive and Negative Affect Schedule (PANAS)

The NEO Five Factor Inventory (NEO-FFI)

The State-Trait Anxiety Inventory (STAI)

General Self-Efficacy Scale (GSES)

Treatment Credibility Questionnaire (TCQ)

Technology Acceptance Model (TAM)

Experience sampling data

Log data NiceDay

The Prodromal Questionnaire (PQ-16)

The Trauma Screening Questionnaire (TSQ)

Screener for Substance Abuse

Study description

Background summary

This study aims to compare personalized exposure and ESM feedback sessions with exposure as usual in patients with obsessive-compulsive disorder. We will do this by applying experience sam-pling methodology (ESM), using the smartphone application *NiceDay*, which collects both objective and subjective data in real-time and real-place. Exposure and response prevention (ERP) will be pro-vided in a personalized way, in the patient*s own environment where and when support is needed. Personalized feedback based on ESM data will be used to identify triggers and protective factors for symptom severity and to optimize the effect of ERP.

Study objective

The primary goal of the project is to investigate the effectiveness of providing personalized mental health care to patients with OCD, compared to exposure and response prevention (ERP) in the tradi-tional context of a therapist*s room. We will do so by personalizing existing evidence based treatment (ERP) by using a smartphone app (NiceDay). We will use NiceDay as a tool to personalize exposure exercises, moving therapy out of the therapist room and into real time and world increasing the eco-logical validity of interventions. A second goal is to explore if our treatment approach increases pa-tients* self-directedness, (perceived) autonomy, motivation for and active participation in the thera-peutic process and to investigate whether this is a mediating factor in treatment effect.
Another goal of this study is to identify different subgroups of patients on a network level in order to create more insight in the heterogenic group of OCD patients. Furthermore, we are interested in how feasible the use of a smartphone app, network models and personalized feedback is in perception of both patients and therapists.

Study design

The design of the study will be a 20 sessions (on a weekly basis) 2 group (ERP, ERP with Niceday and ESM feedback) randomized controlled clinical trial with repeated measurements at baseline (T0), 5 weeks (T1), 10 weeks (T2), 15 weeks (T3), post-treatment (T4), 6 weeks follow-up (T5), 3 months follow-up (T6) and a year follow-up (T7).

Intervention

One group will receive exposure with response prevention as usual, the other group will receive exposure with response prevention with smartphone application NiceDay.

Study burden and risks

There are no risks associated with participation in the study. The only burden

could be the five as-sessments consisting of questionnaires and interviews and the daily collection of ESM data through participant*s smartphone.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria: A OCD diagnosis according to DSM 5 criteria, with further psychometric profiling using non-DSM based (multidimensional) rating scales.

Exclusion criteria

Severe comorbidity in the psychiatric field (psychosis, addiction/intoxication), insufficient fluency in the Dutch language, medication use that has not been stable for 3 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2020
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	16-12-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-12-2020

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	18-03-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 22344
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68816.058.19
OMON	NL-OMON22344