Doorbreek Dwang Digitaal

No registrations found.

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

Summary

ID

NL-OMON22344

Source
NTR

Brief title
Het 3D - Onderzoek

Health condition

Obsessive-compulsive disorder

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

difference in treatment outcome as measured with the Yale-Brown Obsessive Compulsive Scale (Y-BOCS)

Secondary outcome

World Health Organization Quality of Life – Bref (WHOQOL-Bref)
The 16-item self-report Quick Inventory of Depressive Symptomatology (QIDS)

The Acceptance and Action Questionnaire II (AAQ-II)
The Self-Efficacy Questionnaire for OCD (SEQ-OCD)

Study description

Background summary

Rationale: This study aims to compare personalized exposure and ESM feedback sessions with exposure
as usual in patients with obsessive-compulsive disorder. Personalized exposure will be provided
according to individual needs face-to-face as well as screen-to-screen in ecological valid situation
by means of the app NiceDay. This app will also be used as a data collection tool during therapy.
By means of experience sampling methodology (ESM) objective and subjective data in real-time and
real-place will be systematically collected. 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.

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
traditional context of a therapist’s room. Evidence based treatment (ERP) will be personalized by using
a smartphone app (NiceDay) as a tool to increase ecological validity of exercises, by conducting them
into patients ‘real time and world'. A second goal is to assess if there is a difference in relapse rates
and patterns between patients receiving personalized ERP compared to ERP as usual. A third 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. With these networks we aim to determine predictors
for treatment success and relapse. A fourth goal is to explore if our treatment approach increases patients’
self-efficacy and active participation in the therapeutic process and to investigate whether this
influences treatment effect. Finally, 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 as
usual versus personalized ERP) randomized controlled clinical trial with repeated measurements at
baseline (T0), 5 weeks of treatment (T1), 10 weeks of treatment (T2), 15 weeks of treatment (T3),
posttest at 20 weeks (T4), 6 weeks follow-up (T5), 3 months follow-up (T6), 6 months follow-up (T7)
and a year follow-up (T8).

Study population: The study will be conducted in 160 patients with an OCD diagnosed according to
DSM 5 criteria.

Intervention (if applicable): One group will receive exposure with response prevention as usual, the
other group will receive personalized exposure with response prevention with smartphone application
NiceDay and personalized feedback sessions based on experience sampling data.

Main study parameters/endpoints: The main study parameter is a difference in treatment outcome
as measured with the Y-BOCS.

Study objective

We expect to find a difference in treatment effect with a small to medium effect size in favour of the experimental condition

Study design

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Intervention

Exposure as usual
Personalized Exposure

Contacts

Public
PsyQ

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria:
An OCD diagnosis according to DSM 5 criteria. Furthermore, they should not have received any
treatment for OCD in the past 3 months, medication has to be stable for at least three months and patients
have to be willing to refrain from following other treatment for OCD and keep possible medication
stabile during the experimental part of the study. When entering the naturalistic follow-up phase
the restrictions will be released.

Exclusion criteria

Since the focus of the research project is related to personalized care, taking into account the heterogeneity of OCD symptoms and individual, social and contextual differences between patients,
we will be economical with exclusion criteria. Therefore, our exclusion criteria will only relate to our obligation
to offer appropriate care and to guarantee patient safety. So, only patients who suffer from severe
comorbidity in the psychiatric field (psychosis, addiction/intoxication) will be excluded from participation
in this study. Furthermore, since the treatment and questionnaires will be in Dutch insufficient
fluency in the Dutch language is also a criterion for exclusion.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-12-2019
Enrollment:	160
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-12-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55600
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8254
CCMO	NL68816.058.19
OMON	NL-OMON55600

Study results