Transdiagnostic processes in (comorbid) anxiety disorder(s), post-traumatic stress disorder, obsessive-compulsive disorder and depression (TAPOD)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON49963

Source
ToetsingOnline

Brief title
TAPOD

Condition

- Psychiatric disorders NEC

Synonym
affective disorders, stress-related disorders

Research involving
Human

Sponsors and support

Primary sponsor: ProPersona (Nijmegen)

Source(s) of monetary or material Support: Pro Persona. De aanstelling van betrokken onderzoekers worden door Pro Persona gefinancierd.

Intervention

Keyword: anxiety-disorders, depression, stress-related-disorders, transdiagnostic

Outcome measures

Primary outcome

The main study parameters at all timepoints across all groups are: the severity of anxiety and depressive symptoms (assessed with the BAI and IDS-SR), RNT and avoidance (assessed with the RRS, PSWQ, MRNT; BFT, CBAS, BEAQ and Manikin task), cognitive control (assessed with the ATQ-short and IST).

Secondary outcome

The secondary study outcome differ per group, see below.

Across all patient groups: Intolerance of uncertainty, perceived criticism and general clinical outcomes (assessed with the IUS, PC and OQ, respectively).

Anxiety group only: Autobiographical specificity and selectivity (assessed with the AMT and AMT-F in anxiety disorders and stress-related disorders), autobiographical memory function (assessed with the TALE), problem-solving ability (assessed with the MEPS), disorder specific symptom measures for SAD (assessed with the LSAS), panic disorder (assessed with the PDSS-SR) and agoraphobia (assessed with the Mobility Inventory).

Depression group only: Anhedonia (assessed with the DARS-NL and SHAPS-NL),

autobiographical specificity and selectivity (assessed with the SRET in depressive disorders), physical activity (as clinical outcome; assessed with the IPAQ).

PTSD and OCD groups only: Autobiographical specificity and selectivity (assessed with the AMT and AMT-F), autobiographical memory function (assessed with the TALE), problem-solving ability (assessed with the MEPS), disorder specific symptom measures for PTSD and OCD (assessed with the PSS-SR and Y-BOCS respectively).

Study description

Background summary

Anxiety, post-traumatic stress disorder (PTSD) and obsessive-compulsive disorder are all found to be highly comorbid with depression(37-48%). This comorbidity has been linked to more severe symptoms accompanying each diagnosis, poorer treatment outcomes, and early treatment drop-out. Despite the impact of comorbidity, most research focuses on processes in mental disorders without comorbidity. In order to gain more knowledge about comorbidity in the development of symptoms and treatment outcomes, it is important to investigate the role of transdiagnostic processes within anxiety, OCD, PTSD and/or comorbid depressive complaints. Transdiagnostic processes are processes implicated in a wide range of psychopathological disorders, and hence are observed across disorders. Relevant transdiagnostic cognitive processes related to anxiety, OCD, PTSD and depression are repetitive negative thinking (RNT), avoidance, cognitive control, and autobiographical memory bias. These transdiagnostic processes contribute to the development, maintenance and exacerbation of anxiety and depression.

Study objective

This project aims to 1) investigate transdiagnostic processes in patients with anxiety disorders, PTSD, OCD and depressive disorders with and without comorbidity, 2) relate these processes to severity of symptoms, treatment progress, and relapse. This can help understand why treatment works or does not

work for patients that have these disorders in the presence of absence of comorbidity. In addition, it aids in the development of new interventions and personalised treatments in specialized mental healthc

Study design

This is a naturalistic, observational study with a longitudinal design. This design
is suitable to observe changes in cognitive processes over the course of treatment and to
predict treatment outcome and relapse using data of intermediate changes assessed during different time points.

Assessments will be done before start of treatment (Timepoint 1, baseline, experimental assessment), and then every three months. That is, after 3 months (Timepoint 2, online assessment), 6 months (Timepoint 3, experimental assessment), 9 months (Timepoint 4, online assessment), 12 months (Timepoints 5, online assessment), and 24 months (Timepoint 6, follow-up, online assessment).

The second experimental assessment (Timepoint 3) is planned after 6 months as most of the treatment programs take between 15-25 sessions. Relevant treatment progress directly after treatment, may thus be best observed after 6 months.

Study burden and risks

There is no risk involved in the assessments using questionnaires, experimental tasks and the heart-rate registration via the sport watch.. Nevertheless, performance on (repeated) experimental tasks and completing questionnaires during assessment might impose some burden on participants. According to the NFU brochure *Kwaliteitsborging mensgebonden onderzoek 2.0*, the overall risk classification of this study is *negligible risk*.

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

Current (primary) Axis I diagnosis of anxiety (GAD, Social Phobia, Panic Disorder, Agoraphobia), PTSD or OCD and/or depression (MDD, Persistent Depressive Disorder) diagnosis (assessed using the Mini-international Neuropsychiatric Interview)
From age 18 onwards
Fluent in Dutch
Able to give Informed Consent

Exclusion criteria

Insufficient comprehension of the Dutch language
Physical, cognitive, or intellectual impairments interfering with participation, such as deafness, blindness, or sensorimotor handicaps
Diagnosis of bipolar disorder, schizophrenia, schizophreniform disorder, schizoaffective illness
Current psychosis
Drug or alcohol addiction in the past 6 months

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-12-2021
Enrollment:	574
Type:	Actual

Ethics review

Approved WMO

Date:	18-05-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL72055.091.20