Psychiatric assessment Revisited: Social, Psychophysiological and Environmental Characterization of a Transdiagnostic cohort (PRoSPECTs) feasibility study

Published: 12-10-2021
Last updated: 05-04-2024

The objective of the current study is to assess feasibility and acceptance of the pre-treatment assessments (PRoSPECTs feasibility study).

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

Summary

ID

NL-OMON49907

Source
ToetsingOnline

Brief title
PRoSPECTs feasibility study

Condition

- Psychiatric disorders NEC

Synonym
Mental disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Assessment, Feasibility, Mental disorders, Transdiagnostic

Outcome measures

Primary outcome

Acceptability of the assessments, and feasibility of the recruitment and

assessments.

Secondary outcome

-

Study description

Background summary

Unlike most branches of medicine, psychiatric diagnoses are based on characteristic clusters of mostly subjectively experienced signs and symptoms that are not necessarily connected to a specific etiology and / or pathophysiology. Relatedly, most diagnostic classifications limitedly predict treatment response and outcome. Given the enormous burden associated with mental disorders and overall modest effects of treatment, other ways to improve treatment outcome are needed. We propose to take a *pragmatic*, yet evidence-based approach to improve clinical decision making, by developing and applying precision medicine. Adhering to new and relevant insights into the developmental, dimensional, dynamic and complex nature of mental disorders, we propose that the inclusion of markers of underlying biological, psychological and social processes, as well as clinical and treatment characteristics are important to improve tailored treatment and prediction of outcomes. In order to maximize the (ecological) validity of the assessments, methodological innovation to address individual change and context is needed. Finally, given that many diagnostic categories share substantial overlap in symptom presentation, pathophysiology, risk factors and response to treatment, transdiagnostic prognostic assessments are needed to uncover new and relevant subgroups. In order to examine whether a novel, transdiagnostic standardized assessment of the above-mentioned domains is helpful to identify clinically relevant subgroups and develop a framework for precision psychiatry in academic mental healthcare, a developmental research approach needs to be taken. This means starting out with feasibility studies for the assessments, then starting up a clinical cohort study to link these pre-treatment factors to treatment

outcomes and develop and validate prognostic models based within the mental health care setting. Finally, these models, if promising, can be transformed into easy-to-use decision tools, which will be evaluated and compared against regular diagnostic classifications to determine whether clinical utility can be increased. We aim to pursue all these steps with the Psychiatric assessment Revisited: Social, Psychophysiological and Environmental Characterization of a Transdiagnostic cohort (PRoSPECTs) study, within the University Center of Psychiatry (UCP).

Study objective

The objective of the current study is to assess feasibility and acceptance of the pre-treatment assessments (PRoSPECTs feasibility study).

Study design

This study consists of two subsequent phases, in which a heterogeneous patient group of the UCP will be administered the pre-treatment assessments. Phase 1, which is mainly focused on acceptance of patients, entails qualitative interviews with patients about the assessment. Phase 2, entails, next to qualitative assessments of acceptance, quantitative assessments of feasibility.

Study burden and risks

The health risks attached to participation will be negligible. In terms of risk, venipuncture, which is part of the assessments, is associated with negligible and known risks (e.g. skin irritation and bruising), with negligible to mild burden. Other assessments, such as a short physical assessment, can make participants feel uncomfortable. This constitutes a negligible to mild burden. The assessments cost time. Patients will be assessed and interviewed at baseline and two weeks thereafter, with a total assessment time at the UCP of about 3 hours. In addition, patients will fill out questionnaires at home, which takes about 30 minutes. Finally, during two weeks, patients will fill out several questions on their smartphone five times a day (3 minutes per assessment) and wear an actigraphy device around their wrist. Benefits might include an increased insight in their own momentary affect patterns as personal feedback on the daily life assessments is part of the study. As severe mental health problems may interfere with decision-making, concentration, attention and energy, we will take this into account by taking at least 20 minutes to welcome the participants with a beverage and provide answers to any of their questions or concerns about the study. In addition, more cognitively demanding tasks will be alternated with more easy ones, and brief breaks will be inserted. Participants can object to any or part of the assessments during study participation.

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

- All patients >= 18 years
- Patient is to be evaluated for diagnosis and possible treatment at the University Center of Psychiatry

Exclusion criteria

- Insufficiënt proficiency of the Dutch language
- Inability to understand or comply with study requirements, as judged by the investigator(s) or treating clinician

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-05-2022
Enrollment:	42
Type:	Actual

Medical products/devices used

Generic name:	Actigraph (MotionWatch)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-10-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL78322.042.21