Personalized Treatment Management and Prognosis in Psychiatry: A feasibility Study

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Page 9 research protocol:Objective:The aim of this project is to apply motor-cognitive-mental functions together in psychiatric diagnosis for a better treatment, and prognosis (feasible and practicable and personalized). We will examine and quantify...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON42559

Source
ToetsingOnline

Brief title
Personalized Treatment and Prognosis in Psychiatry: feasibility Study

Condition

- Movement disorders (incl parkinsonism)
- Psychiatric disorders NEC

Synonym
Mental Disorder

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Centraal (Amersfoort)
Source(s) of monetary or material Support: Nog geen bericht fonds en directie

ontvangen

Intervention

Keyword: cognition, mental, motor, personalised, treatment

Outcome measures

Primary outcome

Page 9 research protocol:

Main study parameters/endpoints:

The study endpoints are a significant change of affect, aberrant salience,

stress, emotional instability, and/or cognitive function * during the study *

in association with patients* (a) treatment needs, and (b) 6-months treatment

response.

Secondary outcome

na

Study description

Background summary

Page 8 of research protocol:
Rationale:
The main function of diagnosis in medicine is to provide accurate information to predict treatment needs (management) and treatment response (prognosis). However, in psychiatry the predictive value of (DSM/ICD) *mental* signs and symptoms is limited. Interestingly, alterations in motor and cognitive function represent more accurate predictors, likely because they are indicators of neurodevelopmental liability, and may dramatically enhance diagnostic usefulness. The critical question is: is it feasible and practicable to add areas of motor and cognitive function to standard diagnostic function in mental health care?

Keywords: motor, cognition, mental, treatment, personalised

Study objective

Page 9 research protocol:
Objective:
The aim of this project is to apply motor-cognitive-mental functions together in psychiatric diagnosis for a better treatment, and prognosis (feasible and practicable and personalized).
We will examine and quantify the diagnostic value of motor-cognitive-mental functions in predicting (a) treatment needs, and (b) 6-months treatment response. It is hypothesized that the diagnostic value of motor-cognitive-mental functions will yield early predictive parameters of treatment needs and treatment response, complementing the standardised criteria in DSM/ICD.

Study design

Page 9 research protocol:
Study design:
Novel ambulatory assessment methodology, i.e. in the flow of daily life, will be used to collect intensive time-sampling data of mutually impacting motor and cognitive in addition to mental alterations. I will use novel Motor Sensor Devices (MSD) in combination with Experience Sampling Methodology (ESM) (together: MSD-ESM). MSD-ESM makes it possible to collect synchronised momentary measures of motor, cognitive, and mental alterations. Patients will collect their own data in the flow of daily life over 3 periods of 2 days: at baseline, and at 3 and 6 months post-baseline.

Study burden and risks

Page 9 research protocol:
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The risk associated with the study is minimal. Subjects will be asked to invest a total of 9 days, divided over three 3-days periods. The risks of using the device for 2 days are low, while the results vastly improve psychiatric diagnosis by making it more personalized and by making both diagnosis and treatment more representative of patients needs. A possible risk is that patients will pay more attention to negative parameters, like negative affect and stress. A possible benefit for patients is that they may become aware of factors which are related to successful treatment response. While some patients may find the repetitive tests tiresome, in general, patients experience their collaboration in their own diagnosis as a positive endeavour. This figure will be the same for all subjects as the study consists of a single group.

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

Page 15 of research protocol:
* Minimum age of 18 years, recent-onset affective/psychotic psychopathology, and sufficient command of the Dutch language.
* Is mentally competent (wilsbekwaam) according the algorithm from the Royal Dutch Medical Association (KNMG) , i.e. the patient is able to make choices, understands medical information, can apply this to his/her own situation, and whether he/she is able to logically consider the choice. (Mental incompetence is a legally defined status * there is no straightforward relation between mental incompetence and the underlying diagnosis).

Exclusion criteria

Page 16 of research protocol:
* A history of neurological disorder impacting motor/cognitive/mental function
* GAF-score below 45

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	45
Type:	Anticipated

Ethics review

Approved WMO

Date:	04-05-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL53733.068.15