Integrating biology and behaviour for precision stratification of mental disorders

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON53630

Source
ToetsingOnline

Brief title
MENTALPRECISION

Condition

- Anxiety disorders and symptoms

Synonym
mental disorders, psychiatric disorders

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: European Research Council

Intervention

Keyword: Behaviour, Cross-diagnosis, Neuroimaging, Smartphone monitoring

Outcome measures

Primary outcome

- Behavioural phenotypes derived from fitting a machine learning models (e.g. hidden Markov models) to timeseries of smartphone sensor data provided by the BeHapp platform.

- Parameters from multi-modal neuroimaging data from healthy individuals and individuals with mental disorders (e.g. measures of cortical thickness derived from structural MRI, functional connection strength derived from resting state fMRI).

- cross-diagnostic symptom scores across different functional domains (latent factor scores derived from a factor analysis).

Secondary outcome

- Subject-level deviation maps derived from normative models of neuroimaging-based measures and behavioural phenotypes derived from smartphone measures (e.g. subject level Z-statistic images)

- Measures of subject-level overlap across these measures

Study description

Background summary

In many areas of medicine -for example oncology- quantitative markers of biology have transformed diagnosis and treatment allocation, allowing for targeted and personalized interventions in the spirit of *precision medicine* ultimately leading to better outcomes for patients and a better understanding

of disease entities. This is not the case in psychiatry, where disorders are still diagnosed on the basis of symptoms and biomarkers to assist treatment allocation remain to be developed. Finding markers to predict and stratify mental disorders is a formidable goal that requires understanding their impact across multiple levels from neurobiology to behaviour. Advances in neuroimaging provide unprecedented ability to measure neurobiology non-invasively across increasingly large cohorts. Simultaneously, the near ubiquity of smartphone technology in modern life makes it possible to measure behaviour quantitatively, unobtrusively and in real-world situations using digital phenotyping. However, the potential of these techniques for improving clinical decision-making is not being realized due to a lack of analysis tools to chart variation across individuals, to integrate complimentary information from different data modalities and to predict trajectories of functioning at the level of the individual.

Study objective

The primary objectives of this study are to: (i) derive quantitative measures of behaviour on the basis of smartphone monitoring in a healthy cohort and a cross-diagnostic cohort of patients with mental disorders (e.g. depression, anxiety and substance use disorders); (ii) establish the validity of these as measures of mental state by performing quantitative comparisons of individuals with mood disorders against healthy controls (i.e. in a case-control sense and via continuous associations with symptom levels) and using these measures to predict subjective mood scores acquired on a moment-to-moment basis using ecological momentary assessment; (iii) combine these measures with multi-modal neuroimaging data to predict measures of mental health across the spectrum of functioning. For this we will use normative models (*brain growth charts*) to bind different samples into a common reference space. Throughout this project behaviour will be conceptualised and quantified in terms of functional domains (e.g. negative valence, arousal/inhibition) approximately corresponding to those outlined in the Research Domain Criteria framework.

Study design

Observational cross-sectional study

Study burden and risks

Burden: All subjects will visit the study centre for an intake visit, where they will install the necessary software on their smartphone and be instructed on the use of the ecological momentary assessments (approximately 1 hour). Participants in the clinical group will also visit the study centre a second time, during which a standardized neuroimaging protocol will be acquired (total 1.5 hours). The use of patients in this study is necessary because the goal is to develop quantitative and ecological measures of behaviour that can be used

to predict functioning in mental disorders.
Risks: Minimal risk
Benefits: While there will be no direct benefit to the participants themselves, the study may contribute knowledge that may be helpful in the future for patients with the same mental disorders

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

Healthy cohort:
- Volunteer aged 16-80, who has participated in prior studies at the Donders Centre for Cognitive Neuroimaging and for whom neuroimaging data are available (see protocol for details)
- Has provided consent to be re-contacted for future research

- Possesses and uses an Android smartphone (required for the BeHapp software)

Patient cohort:
- Volunteer who has participated in the MIND-Set 2 study. This means the subject is:
-- Adult (age >=16) in- and outpatient at the Department of Psychiatry of the Radboudumc
-- Referred for a diagnostic and/or treatment question relating to either stress-related (mood, anxiety), neurodevelopmental (ASD, ADHD, personality) and/or impulse-regulation disorders.
These criteria are assessed by the clinician during the intake interview, and will be confirmed through detailed diagnostic interviews.
- Has provided consent to be contacted about participation in other studies.
- Possesses and uses an Android smartphone (required for the BeHapp software)

Exclusion criteria

- Cannot speak, read and/or understand Dutch (VMBO level) and English (working profiiency)
- Prior history of significant neurological illnesses
- Pregnancy
- Standard contra-indication for MRI:
-- unsafe metal or devices in the body (Cardiac Pacemaker, cochlear implant, aneurism clip)
-- previous brain surgery
-- moderate to severe claustrophobia

Additional exclusion criteria for healthy controls:
- Current disease that affects the brain
- Prior history of significant psychiatric illness
- Neurological disorders of the central nervous system
- Fifteen or more units of alcohol per week
- Recreational drug use of once or more per week
- Benzodiazepine use of once or more per week
- Malignancies
- Rare, chronic somatic disorders

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-06-2023
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-03-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-10-2024
Application type:	Amendment
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	NL82527.091.22