Remote Assessment of Disease and Relapse in Major Depressive Disorder

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Observational non invasive

Summary

ID

NL-OMON48543

Source
ToetsingOnline

Brief title
RADAR-MDD

Condition

- Mood disorders and disturbances NEC

Synonym
depression, Major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Institute of Psychiatry, Psychology & Neuroscience/South London and Maudsley NHS Foundation Trust, King's College London
Source(s) of monetary or material Support: Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 115902. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

Intervention

Keyword: depression, remote assessment, smartphone, wearables

Outcome measures

Primary outcome

Main endpoint the presence of a new or continuing major depressive episode

(IDS-SR & CIDI-SF).

Secondary outcome

self-esteem (RSES), anxiety (GAD7) , quality of life (WSAS), and illness

perception (BIPQ), MDD remission (IDS-SR & CIDI-SF).

Study description

Background summary

The last decade has seen an explosion in the capability of monitoring individuals via sensors in smartphones or wearable devices. The development of remote measurement technologies (RMT) is an innovation which could, in the foreseeable future, be used to predict and avert negative clinical outcomes, as well as providing predictive information indicative of future deterioration. RMT has been hailed as a paradigm shift in the way in which clinical services can be delivered, but will require healthcare adaptation for its delivery. The aim of RADAR-MDD is to evaluate the utillity of remote technologies (smartphone apps and Fitbit) to assist in the early identification of relapse or deterioration.

Study objective

RADAR-MDD is a clinical study aiming to assess the utility of multiparametric RMT in clinical populations with MDD.
Specifically, the aims of this study are to: 1) Determine the usability, feasibility and acceptability of, and adherence to, RMT to provide real-time objective multidimensional indications of clinical state in individuals with MDD. 2) Improve and refine clinical outcome measurement using RMT as a means of identification of current clinical state. 3) Determine whether multi-parametric RMT collected in populations with recurrent MDD can provide information

predictive of depressive relapse and other critical outcomes.

Study design

observational non-randomised, non-interventional study in which data is collected through a smartphone app and fitness tracker and where participants fill out questionnaires.

Study burden and risks

Risks in this study are minimal as measurements are not invasive. There is a risk that the used study technologies are hacked, but this risk is no greater than with any smartphone or fitness tracker. The encryption and data de-identification processes used will minimize any risk in the unlikely event of hacking. There are no immediate benefits for the participants. As this is an observational study, the burden is limited to time needed to fill out questionnaires and online tests.

Contacts

Public
Institute of Psychiatry, Psychology & Neuroscience/South London and Maudsley NHS Foundation Trust, King's College London

De Crespigny Park 16
London SE5 8AF
GB

Scientific
Institute of Psychiatry, Psychology & Neuroscience/South London and Maudsley NHS Foundation Trust, King's College London

De Crespigny Park 16
London SE5 8AF
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Aged 18 or over
* Meet DSM-5 diagnostic criteria for diagnosis of non-psychotic MDD within the past 2 years
* Recurrent MDD (a lifetime history of at least 2 episodes of depression
* Willing and able to complete self-reported assessments via smartphone.
* Able to give informed consent for participation.
* Fluent in English, Spanish, Catalan or Dutch language
* Existing ownership of Android smartphone or willingness to use an Android smartphone as their only smartphone.

Exclusion criteria

* Lifetime history of bipolar disorder, schizophrenia, MDD with psychotic features, schizoaffective disorders.
* Dementia
* History of moderate to severe drug or alcohol abuse within 6 months
* History of major medical disease which might impact upon the patient*s ability to participate in normal daily activities for more than 2 weeks (e.g. due to likely hospitalisations or other periods of indisposition).
* Pregnancy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2019
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	10-09-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-01-2021

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL63557.029.17