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A pilot study on a sensor-based Social Information Monitoring for Patients with Bipolar Affective Disorder (SIMBA) via smart phones

Submission date
04/04/2013

Recruitment status
No longer recruiting

Registration date
07/05/2013

Overall study status
Completed

Last Edited
08/01/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
In Germany, bipolar disorder is becoming one of the most often diagnosed psychiatric disorders. This disease is characterized by extreme and uncontrollable mood and activity swings. Patients often do not recognize their mood changes in a timely manner and lose their insight into illness when entering a manic phase. Besides the suffering of people affected by a bipolar disorder and the disruptive impact on their social environment, the disease also has high socioeconomic costs. For an early prediction of impending phase changes in bipolar disorder, information from the social environment of the person concerned may be helpful. Sensors in modern smart phones provide the opportunity to collect these information in real-time and could therefore deliver a comprehensive picture of the users current habits and behaviours as well as spontaneous deviations from these patterns. As part of a 12 month initial study, we want to examine if data measured by sensors in smart phones will enable us to detect and evaluate indicators of phases and phase transitions in bipolar disorder. We will study both bipolar patients and healthy individuals.

Who can participate?
Women and men aged 18 years or more with bipolar affective disorders (bipolar I and bipolar II) from a psychiatric outpatient clinic and healthy individuals without psychiatric diagnoses.

What does the study involve?
We want to test a new experimental method for the sensor-based detection and evaluation of phase-specific symptoms in bipolar disorders by using a smartphone application (app). This "Social Information Monitoring for Patients with Bipolar Affective Disorder", SIMBA for short, should enable us to determine differences in communication and movement behaviour between people affected by the disease and healthy people, in order to create rest-activity profiles of patients with bipolar disorder for an earlier prediction of manic and depressive phase changes. All participants received a smart phone (Sony Ericsson Xperia Neo V) used as measuring instrument in the study.

What are the possible benefits and risks of participating?
Equipment und usage costs are paid form research funds of the study centre so there are no costs for the participants. Participants will also receive an expense allowance of 300 Euro after the 12 month study. The payment is dependent on returning the smart phones. We do not expect that the measuring technique will have a negative impact on the health of participants. Patients will be closely monitored by their treating medical specialist or psychotherapist during the complete study performance.

Where is the study run from?
The study is carried out by the Leuphana University Lueneburg (Germany), EU-funded project Innovation-Incubator, competence tandem Integrated Care/Online Therapy.

When is study starting and how long is it expected to run for?
The study will start in April 2013 and will run for 12 months followed by analyses.

Who is funding the study?
The study is funded by the federal state of Lower Saxony (Germany), the European Regional Development Fund.

Who is the main contact?
Dr. Joern Moock, supervisory project coordinator
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Study website
http://www.leuphana.de/inkubator/gesundheit/vernetzte-versorgung/projekte/onlinetherapie.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DRKS00004872

Study information

Scientific Title
"SIMBA - Social Information Monitoring for Patients with Bipolar Affective Disorder: A feasibility study on a sensor-based application for smart phones to predict phase transitions in bipolar disorder

Acronym
SIMBA

Study objectives
SIMBA is useful in creating rest-and-activity-profiles for patients with bipolar affective disorder in order to improve the prognosis of phase transitions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee on ethical issues in research at Leuphana University Lueneburg, 03/04/13

Study design
Exploratory study / feasibility study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
F31.- (Bipolar I and bipolar II disorder)

Interventions
Clinical interviews with the patients are conducted prior to enrolment in the study and after the end of the 12-months period of observation. As primary outcome we continuously measure data

concerning movement and communication behavior via sensors in smart phones during the whole survey period. In addition, we measure patient-reported outcomes by automated daily to weekly self-reports of the study participants on the smart phones (e.g. mood, level of energy, quality of life, sleep quality/quantity, substance use). External medical assessment and the patients' self-assessment of manic and depressive symptoms are conducted every eight to 12 weeks in order to validate sensor data. There are at present no plans for follow-up.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Data concerning movement and communication behavior measured by sensors in smart phones, collected and transmitted by SIMBA.

Secondary outcome measures
Patient-reported outcomes (depressive and manic symptoms measured by the ADMS, quality of life measured by the SF-12, sleep quality/quantity and substance use) and external medical assessment (YMRS D, HRSD).

Overall study start date
22/04/2013

Completion date
22/04/2014

Eligibility

Key inclusion criteria
1. The target group consists of patients (both genders) of the psychiatric outpatient clinic with a principal diagnosis of bipolar I or bipolar II disorder (F31.-) aged 18 years or more.
2. The control group consists of healthy individuals without psychiatric diagnoses
3. Sufficient speech intelligibility

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Current inpatient care
2. Risk of suicide
3. Diagnosis of schizophrenia
4. Diagnosis of mental disability
5. Abuse of alcohol and/or drugs six months prior to the study
6. Current alcohol and/or drug withdrawal
7. Missing written consent

Date of first enrolment
22/04/2013

Date of final enrolment
22/04/2014

Locations

Countries of recruitment
Germany

Study participating centre
Leuphana University Lueneburg/Innovation-Incubator
Lueneburg
Germany
D-21335

Sponsor information

Organisation
Investment & Development Bank of Lower Saxony Nbank (Germany)

Sponsor details
European Regional Development Fund (Europäischer Fonds für Regionale Entwicklung Land Niedersachsen)
Günther-Wagner-Allee 12-16
Hannover
Germany
D-30177

Sponsor type
Government

Website
http://www.efre.niedersachsen.de

ROR
https://ror.org/03h3mye18

Funder(s)

Funder type
Government

Funder Name
Federal state of Lower Saxony (Germany) - The European Regional Development Fund, within the framework of the Innovation-Incubator at Leuphana University Lueneburg

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/01/2016		Yes	No