

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

<b>Submission date</b> 04/04/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/05/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/01/2016	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 and usage costs are paid from 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  
joern.moock@inkubator.leuphana.de

## Contact information

### Type(s)

Scientific

### Contact name

Prof Dr. med. Dipl.-Psych. Wulf Rössler

### Contact details

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Not Specified

**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(s)**

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

**Key secondary outcome(s)**

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).

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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)

**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

**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?
<a href="#">Results article</a>	results	06/01/2016		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes