

# TRANS-ID recovery: Monitoring mood during psychological treatment

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To examine whether there is a systematic presence of EWS and change in daily life experiences preceding transitions towards improvement of depressive symptoms within single individuals who receive psychological treatment

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

## Summary

### ID

NL-OMON47087

### Source

ToetsingOnline

### Brief title

TRANS-ID recovery

### Condition

- Mood disorders and disturbances NEC

### Synonym

Depressive symptoms, feeling down, mood transitions

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** European Research Council

## Intervention

**Keyword:** Depression, Diary study, Mechanisms of change, Recovery, Transitions

## Outcome measures

### Primary outcome

The main study parameter is a within-person critical transition towards improvement of depressive symptoms.

### Secondary outcome

Secondary study parameters include daily experiences (affect, behavior, cognitive factors, context), heart rate variability, and physical activity over the flow of daily life.

## Study description

### Background summary

A better understanding of the mechanisms at play in the process of recovery from depression is needed to optimize the effectiveness of current treatments for depression and to prevent depressive relapse. We propose that the change process towards improvement of depressive symptoms may behave like a complex dynamical system, in which sudden symptom gains can occur (i.e., sudden transitions towards no/mild symptoms) that are preceded by early warning signals (EWS) and change in daily life experiences that mark the first steps towards symptom improvement. Only if we find that certain daily life experiences or EWS temporally and systematically increase just before the jump towards improvement within single individuals, then we know which changes in daily life experiences and the hypothesized EWS can signal, what we can call, \*readiness for change\*.

### Study objective

To examine whether there is a systematic presence of EWS and change in daily life experiences preceding transitions towards improvement of depressive symptoms within single individuals who receive psychological treatment

## Study design

The study concerns an observational study in which a repeated single-subject intensive time-series design is adopted.

## Study burden and risks

There are no risks involved in study participation. The burden associated with participation consists of: baseline assessments (max 2 hours), a baseline interview (max 2 hours), filling in diary questions on a smartphone (2 minutes, 5 times a day for 4 months), conducting Heart Rate Variability (HRV) measurements (5 minutes, 2 times a day for 4 months), wearing an accelerometer on their wrist (4 months), carrying an extra smartphone for the HRV measurements (only for those participants without an iOS smartphone), completing a weekly depressive symptom scale once a week (5 minutes a week for 6 months), an evaluation interview (1,5 hour), and completing a monthly depressive symptom scale once a month (5 minutes a month for 6 months).

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- age  $\geq 18$
- presence of depressive symptoms (Inventory of Depressive Symptomatology score  $\geq 14$ )
- being bound to receive a psychological treatment for depressive symptoms
- capable of following the study procedures
- willing to and capable of giving informed consent

### Exclusion criteria

- presence of a current manic episode or current psychotic symptoms
- chronic depressive symptoms ( $> 2$  year)
- reported primary diagnosis of a personality disorder
- insufficient Dutch language skills to understand the diary questions
- inability to work with a smartphone

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 08-06-2017

Enrollment: 45

Type: Actual

## Ethics review

Approved WMO

Date: 12-12-2016

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 20-04-2017

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 19-03-2018

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## 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**

CCMO

**ID**

NL58848.042.16