

# TRAILS TRANS-ID: Tracking transitions across diagnostic boundaries of psychopathology, a daily diary study in the TRAILS clinical cohort

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON45395

### Source

ToetsingOnline

### Brief title

TRAILS TRANS-ID

### Condition

- Other condition
- Psychiatric and behavioural symptoms NEC

### Synonym

(mental) health and functioning

### Health condition

lichamelijke gezondheidsproblemen, bijv. pijnklachten

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** NWO, Europese Unie

## Intervention

**Keyword:** Mental health, Transdiagnostic, Transitions, Young adults

## Outcome measures

### Primary outcome

The main study parameter is within-person change in levels of psychiatric symptoms. EWS and network parameters of each individual will be used to predict their course.

### Secondary outcome

Not applicable

## Study description

### Background summary

The period of young adulthood is a critical time for changes in psychiatric complaints. Pathways of symptom enhancement or symptom improvement may differ largely between individuals, and involve dynamic processes spanning multiple psychopathological domains. To improve our understanding of these changes, we are in need of transdiagnostic, personalized models to capture the within-person dynamics of symptoms over time for each individual. We propose to use two novel approaches to improve prediction of future courses of symptoms: i) identifying early warning signals (EWS) that anticipate transitions and ii) mapping the underlying dynamic structure of psychopathology using network analysis.

### Study objective

The aim of this project is to map the full process of change within individuals

in a fine-grained and detailed way across a wide range of psychopathological symptoms. Using (i) early warning signals and (ii) networks, we hope to reveal underlying mechanisms of change and improve personalized prediction of future course of psychopathology.

Additionally, secondary objectives are a) to examine whether there are symptom-specific patterns of EWS that differentiate the direction of the type of psychopathology that an individual is most likely to make a transition to, b) to evaluate whether comorbidity is indeed accompanied by network connections between symptoms across these disorders, as is predicted by the network theory, c) to identify empirically-driven subgroups of individuals with similar symptom network characteristics, and d) to investigate whether EWS and symptom specific patterns of transition, and individual differences in network characteristics can be understood from early patterns of psychopathology and environmental circumstances since age 11

## **Study design**

Participants will report their day-to-day symptoms, some context variables and daily functioning (maximum 5 minutes per day) for six consecutive months on their smartphone. Symptomatology and functioning will be assessed directly before and after the ambulatory assessment period, and during follow-up about 12 months after the ambulatory assessment has ended.

## **Study burden and risks**

There are no risks involved in participating in the study. The burden associated with participation consists of: (i) an interview before (baseline; ca. 2 hours) and after (expected duration ca. 60 min) the ambulatory assessment period, (ii) filling in a questionnaire using a smartphone every evening for six months (maximum of 5 minutes per day), and (iii) an one follow-up interview of ca. 30-60 minutes. Benefits are a financial compensation up to 200 euros and the opportunity for participants to get insight in their personal, daily symptoms over time. Participants, who appreciate this will be guided through their study assessments, including descriptive graphs of their completed questions directly at the end of the ambulatory assessment period. To be clear, participants will not receive any personal models of prediction or other personalized analyses based on their data. They will only be able to see an overview of the crude data of their daily responses.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Participation in TRAILS-CC

Age \* 18

Read and speak Dutch fluently

Capable of following the study procedures

Willing to and capable of giving written informed consent

### Exclusion criteria

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): 06-11-2017

Enrollment: 150

Type: Actual

## Ethics review

Approved WMO

Date: 29-09-2017

Application type: First submission

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	ID
CCMO	NL60724.042.17