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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	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

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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