TRANS-ID tapering : Transitions In Depressive symptoms during tapering of antidepressants

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To search for personalized early warning signals of critical transitions in depressive symptoms within single individuals with a history of depression who wish to taper their antidepressant medication.

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

Summary

ID

NL-OMON45304

Source
ToetsingOnline

Brief title
TRANS-ID tapering

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: complex dynamic systems, depression, diary study, transitions

Outcome measures

Primary outcome

The main study parameter is a within-person critical transition towards higher

levels of depressive symptoms.

Secondary outcome

Secundary study parameters are daily affect, behavior, context, Heart Rate

Variability, and physical activity.

Study description

Background summary

There is a need for a more accurate assessment of personalized risk of transitions towards higher levels of depressive symptoms. It has been suggested that depression may behave like a complex dynamical system, in which sudden transitions can occur between alternative stable states (i.e., no/mild symptoms versus severe symptoms). Transitions in a complex dynamical system may be anticipated by early warning signals (EWS). If transitions in depressive symptoms indeed behave according to complex dynamical system principles, this would mean that there is an alternative route to getting precise and person-specific information on vulnerability, likelihood, and timing of transitions to new episodes of depressive symptoms.

Study objective

To search for personalized early warning signals of critical transitions in depressive symptoms within single individuals with a history of depression who wish to taper their antidepressant medication.

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: an introductory interview before the diary assessments (1,5 hour), filling in diary questions (2 minutes) on a smartphone 5 times a day (thus in total: 10 minutes per day) for a period of 4 months, conducting Heart Rate Variability (HRV) measurements for 5 minutes 2 times a day, wearing an accelerometer on their body for a period of 4 months, completing a weekly depressive symptom scale once a week (5 minutes a week) for a period of 6 months, and an evaluation interview at the end of the study (1,5 hour).

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- age >= 18
- fulfil the criteria of a past depressive episode according to DSM-IV criteria
- having made a shared decision with a mental health care provider (general practitioner, psychiatrist or a mental health care provider that is supervised by a general practitioner or psychiatrist) to taper the current dose of antidepressant medication
- having made a tapering scheme or plan with a mental health care provider

Exclusion criteria

- current depressive episode according to the DSM-IV criteria
- presence of bipolar disorder or a psychotic disorder
- reported diagnosis of a personality disorder
- start of any other antidepressant treatment
- inability to work with a smartphone
- not giving informed consent on checking the tapering scheme or plan with the mental health care provider

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):	04-07-2017
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	30-11-2016
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)

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	NL58469.042.16