Development and validation of measures for assessing ultra-high risk criteria for emerging personality disorders

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Personality disorders and disturbances in behaviour
Study type	Observational non invasive

Summary

ID

NL-OMON56497

Source
ToetsingOnline

Brief title
assessment of UHR criteria PD

Condition

- Personality disorders and disturbances in behaviour

Synonym
Personality disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Early_detection, Personality_disorders, Prognostic_test, Risk_assessment

Outcome measures

Primary outcome

De primaire uitkomstmaten zijn de scores op elk van de instrumenten voor UHR-criteria. We verwachten op alle criteria hogere gemiddeldes in de risicosteekproef dan in de samenlevingssteekproef.

The primary outcome is the score on each of the instruments meant to assess the UHR-criteria. We predict higher mean scores in the risk sample then in the cohort sample for all criteria.

Secondary outcome

not applicable

Study description

Background summary

For optimal indication for indicated prevention, it is necessary to predict the onset of a mental disorder. This is especially true for severe and potentially chronic (mental) disorders, such as personality disorders. Recent models of personality disorders imply the existence of four ultra high risk criteria for the development of personality disorders. In this study we aim to develop and validate assessment tools for these four UHR-criteria.

Study objective

This study examines a the role of four key ultra-high-risk criteria for personality disorders: interpersonal trauma, personality functioning, quality of social support system and subclinical features of borderline personality disorder. For two of these four UHR-criteria, there a not yet validated assessment tools. In this study we aim to develop and validate those tools in a

risk sample.

Study design

In across-sectional design the instrument to assess UHR-criteria are developed and validated in a risk and cohort sample.

Study burden and risks

Interviews and questionnaires are conducted. The baseline measurement takes a little over 1,5 hours with the child/adolescent and 75 minutes with a parent.
The risks are minimal. Development of a reliable and valid instrument requires extensive assessment of the identified UHR criteria.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adults (18-64 years)

Children (2-11 years)

Inclusion criteria

The clinical sample consists of children and adolescents (and their parents) enrolled in MST-CAN, a treatment programme for families where there is objectified maltreatment. The control sample is a community sample. Participants are both children/adolescents and their parent(s). Children must be between 10 and 15 years old.

Exclusion criteria

Inability to participate in interviews or questionnaires due to insufficient command of language, intelligence or for other reasons

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-03-2024
Enrollment:	114
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	13-02-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL84463.028.23