Development and validation of a psychological measure and derived short screener to estimate the risk to develop personality disorders based upon the taxation of ultra-high risk domains

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

Summary

ID

NL-OMON57150

Source
ToetsingOnline

Brief title
Preventive Detection Personality Disorders (PDPD)

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: Stichting tot Steun VCVGZ

Intervention

Keyword: Early_detection, Personality_Disorders, Prevention, Prognostic_test

Outcome measures

Primary outcome

At baseline, the various instruments belonging to the four appraisals are administered: interpersonal trauma (JTV), personality functioning (STiP-5.1 KV + PV, LoPF-Q), social support system (QSS-A) and onset characteristics of PD, both symptom-based (SCID-5-P, BPFSC) and trait-based (DIPSI-BPS traits). We also conduct baseline measurement of psychosocial functioning (KidScreen, SMA, Social Support, school functioning and Promis Peer). Here we choose a multi-method and multi-informant approach, as reflected in a set of instruments with both self-reporting and reporting by others. In follow-up, the same instruments will be administered, with the exception of the trauma questionnaire. However, a modified survey of recent life events will be added. A detailed description of all instruments is attached.

The primary predictable outcome is the presence or absence of a personality disorder after 36 months.

Secondary outcome

See above

Study description

Background summary

Optimal indication for indicated prevention requires that the onset of a mental disorder can be be predicted and is especially relevant for conditions with progressive social breakdown. This study investigates the prognostic value of a multi-factorial risk test for personality disorders, based on the evaluation of four ultra-high-risk criteria: interpersonal trauma, current personality functioning, quality of social support system and subclinical features of borderline personality pathology.

Study objective

The prognostic accuracy of combining these four criteria to predict the later development of personality disorders (with/without psychosocial breakdown) is investigated in a longitudinal study. From this, a selection of items with the strongest prognostic value will be derived (screener).

Study design

This study uses a prospective, longitudinal design in which four pre-identified UHR criteria for PS are assessed at baseline in young adolescents (11-14 years) from both a risk and a cohort sample. These adolescents are then followed up for 3 years, with follow-up measurements at 1, 2 and 3 years assessing which adolescents are developing or have developed a PS and which adolescents with PD are (or are beginning to) socially disengaged, as well as which adolescents are resuming a normative developmental trajectory (multifinality). The prognostic accuracy of the baseline test based on four UHR criteria for developing a personality disorder (with/without social dropout) is investigated.

Study burden and risks

There are four measurement moments for both parents and children. At each measurement moment there are interviews and questionnaires. For children, the workload is estimated at 90 minutes per assessment, for parents at 60 minutes at the first assessment and 45 minutes at follow-up assessments. Interviews and questionnaires deal with personality and psychological symptoms. The

instruments have all been used before for studies in these target groups.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

For this study, children (and their parent) between 11 and 14 years will be recruited from risk samples and cohort samples.The risk samples will be recruited in the Netherlands (within the Viersprong and a number of foster care services) on the one hand, and within Flemish General Paediatrics (AP) and Child and Adolescent Psychiatry services on the other. Within de Viersprong, we recruit in two treatment programmes: MST-CAN (children with documented intrafamilial experiences of abuse or severe neglect) and MBT-early (children

with incipient features of Borderline PD). From existing research collaborations between Ghent University and a number of Flemish AP and KJP services, additional young teenagers with incipient characteristics of Borderline PD will be recruited. A third risk sample will be recruited in collaboration with the foster care services Vigere and Sterkhuis. The first and third high-risk samples are recruited because, by definition, there are interpersonal traumatic experiences in childhood, which is seen as a major risk factor for the development of personality problems. The second risk sample is recruited because, by definition, there are (incipient) characteristics of BPD, which is a demonstrated risk factor for the development of PD in late adolescence and young adulthood as well as for social, community and health problems. The cohort sample is a 'convenience' sample that we will include mainly to recruit children with a presumed low-risk on the various risk factors. These participants will be recruited through schools. Through quota sampling, predetermined quotas for age and socio-economic status will be set to ensure representativeness of the sample. Participants in each sample will always be the children/young people and one of the (foster) parents or other caregiver who assumes a close parenting role.

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)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-12-2024
Enrollment:	200

Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	29-11-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-01-2025
Application type:	Amendment
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	NL87456.028.24