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Guideline-Informed Treatment-Personality Disorders Youth: exploring the feasibility of early intervention treatment for emerging personality disorder in adolescents

Submission date
15/04/2022

Recruitment status
No longer recruiting

Registration date
25/04/2022

Overall study status
Completed

Last Edited
12/12/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A personality disorder is a type of mental disorder in which you have a rigid and unhealthy pattern of thinking, functioning and behaving. Given the longstanding consequences of personality disorders (PD), the focus in the field has recently switched to prevention and early intervention. Although there is increasing evidence for the benefits of some specialist psychotherapeutic approaches, their widespread dissemination is hampered by high training demands. The primary aim of GIT-PD Youth is to prevent personality pathology from having a major impact on the development of adolescents by designing a pathway for early detection and generalist intervention based on the common factors of these evidence-based treatments. In the long term, the ultimate goal may be to help close the treatment gap for adolescents with emerging PDs by offering an alternative and accessible frontline PD-oriented treatment.
The aim of this study is to assess the feasibility of the GIT-PD Youth intervention and of a multicentre research design. More specifically, the researchers will assess the feasibility of the intervention itself by studying its acceptability by young persons and families in terms of treatment retention and client satisfaction, and by estimating potential treatment benefits following the intervention.

Who can participate?
Adolescents (aged 12–18 years) who meet the threshold for personality disorders, meaning they display moderate or more severe impairments in personality functioning

What does the study involve?
The researchers will study the feasibility of the intervention as well as the study design. The results will inform the design of a larger-scale randomized study.

What are the potential benefits and risks of participating?
The implemented treatment framework uses the assumed effective principles of existing evidence-based treatments to improve care as usual. Therefore, an improvement in regular care

may be assumed. There is a small burden of completing the questionnaires, although only 30 minutes are estimated to be needed.

Where is the study run from?
This study is a collaboration between different settings and the Tilburg University with the main location at de Viersprong (Netherlands)

When is the study starting and how long is it expected to run for?
January 2022 to January 2025

Who is funding the study?
De Viersprong (Netherlands)

Who is the main contact?
Joost Hutsebaut
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ABR 81304

Study information

Scientific Title
Guideline-Informed Treatment-Personality Disorders Youth: exploring the feasibility of a generic early intervention program for emerging personality disorder in adolescents

Acronym
GIT-PD Youth

Study objectives
Several aspects of the feasibility of the intervention as well as the study design will be examined following these research questions for which the following benchmarks were formulated:

1. How acceptable is a generic early intervention approach for emerging PD in terms of treatment retention and client satisfaction?

Benchmark: Based upon previous studies among PD adolescents (Jorgensen et al., 2020), the researchers consider the intervention to be acceptable when less than 35% of participants drop out of treatment and when the average client satisfaction score on the client thermometer is 7 /10.

2. How many referred adolescents in each unit who are eligible for the study also agree to participate in the study?

Benchmark: Based on the number of drop-outs observed in Beck et al. (2020), Schuppert et al. (2012) and Chanen et al. (2008), the researchers consider that if at least 50% of the eligible participants are willing to participate in the study, they may consider enrolment in the study as feasible for young persons.

3. How many included participants complete the full study protocol in each setting?

Benchmark: Based upon the drop-out rate observed in Griffiths et al. (2019) and Schuppert et al. (2012) the researchers consider that if at least 70% of the enrolled participants also has completed all measures, they can consider the design as feasible.

4. How suitable are the selected primary and secondary outcome measures to assess change and demonstrate the potential superiority of GIT-PD Youth in a follow-up study?

Benchmark: the researchers expect an effect size of d = 0.70 for assessing within-subjects change between baseline and end-of-treatment to be necessary to demonstrate suitability of the selected primary outcome. They assume that observed change may inform on the one hand on the potential benefits of the intervention but could on the other hand also inform about each measure's sensitivity to change. This may in turn inform a power analysis for further research on the effect of GIT-PD Youth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/06/2022, Medical Ethical Review Committee Brabant (METC Brabant, Postbus 9015, 5000 LC Tilburg, Netherlands; +31 013 2218006; info@metcbrabant.nl), ref: NL81304.028.22

Study design
Feasibility study with a one-group pretest-posttest design

Primary study design
Interventional

Secondary study design
Feasibility study with a a one-group pretest-posttest design

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Early intervention for emerging personality disorders in youth (12-18 years)

Interventions
GIT-PD Youth provides a treatment framework to improve care as usual by applying a set of principles derived from existing evidence based treatments. It's a principle-driven, common factors approach with specific attention to relational dynamics and crisis management. Treatment is highly structured and the clinical process is phased with specific treatment goals to be identified, resulting in a modular treatment approach. The intervention will use a personalized approach with varying duration and intensity. However, the researchers estimate that on average the intervention will be 26 weeks and have weekly sessions of 45-60 minutes.

Intervention Type
Behavioural

Primary outcome measure
Severity of PD symptoms is measured using the Personality Inventory for DSM-5 Brief Form score (PID-5-BF) at baseline and end of treatment (on average after 26 weeks)

Secondary outcome measures
1. Symptoms of anxiety are measured using the Generalized Anxiety Disorder- 7 score (GAD-7) at baseline and end of treatment (on average after 26 weeks)
2. Symptoms of depression are measured using the Patient Health Questionnaire-9 score (PHQ-9) at baseline and end of treatment (on average after 26 weeks)
3. Symptoms of borderline personality disorder are measured using the McLean Screening Instrument for Borderline Personality Disorder score (MSI-BPD) at baseline and end of treatment (on average after 26 weeks)
4. Emotion dysregulation is measured using the Difficulties in Emotion Regulation Scale-18 score (DERS-18) at baseline and end of treatment (on average after 26 weeks)
5. Severity of suicidal ideation is measured using the Columbia Suicide Severity Rating Scale score (CSSRS) at baseline and end of treatment (on average after 26 weeks)
6. Health-related quality of life is measured using the Kidscreen-10 score at baseline and end of

treatment (on average after 26 weeks)
7. Level of personality functioning as measured by the Level of Personality Functioning Scale-Brief Form 2.0 score (LPFS-BF 2.0) at baseline and end of treatment (on average after 26 weeks)

Overall study start date
01/01/2022

Completion date
01/01/2025

Eligibility

Key inclusion criteria
1. Adolescents with emerging symptoms of personality pathology
2. Aged 12 to 18 years
3. Meet the threshold for personality disorders according to the alternative model for personality disorders in DSM-5, meaning they should display moderate or more severe impairments in personality functioning (score ≥2) as assessed through the Semi-structured Interview for Personality Functioning DSM-5 (STiP-5.1)

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
75

Key exclusion criteria
1. Insufficient mastery of the Dutch language
2. Severe risk of suicide requiring immediate intervention and cognitive impairment (IQ <75). The WAIS-IV will be administered when intellectual impairment is suspected
3. Meet the DSM-5 criteria for (severe) psychotic disorders, autism spectrum disorder and (severe) substance abuse

Date of first enrolment
01/06/2022

Date of final enrolment
01/09/2024

Locations

Countries of recruitment
Netherlands

Study participating centre
De Viersprong
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Sponsor information

Organisation
De Viersprong

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Sponsor type
Hospital/treatment centre

Website
https://www.deviersprong.nl

ROR
https://ror.org/048jnwk41

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
De Viersprong

Results and Publications

Publication and dissemination plan
This study is part of a formation to become a clinical psychologist which requires submission of a study paper in an internationally peer-reviewed journal before the end of the formation.

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Paulien Jansen (pa.jansen@dimence.nl). Type of data: SPSS, questionnaire data, routine outcome monitoring. Data will be available after the end of the study (31/10/2024) and will be available for 15 years. Participants have signed informed consent, data are anonymous.

IPD sharing plan summary
Available on request