The (cost-)effectiveness of MBT-early

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1) We expect MBT-early to be superior to CBT in reducing the severity of BPD symptoms from baseline to end of treatment (primary outcome). 2a) We expect MBT-early to be non-inferior to CBT in reducing symptoms of anxiety and depression from...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27931

Bron
NTR

Verkorte titel
EARLY

Aandoening

(Symptoms of) borderline personality disorder
Depressive disorders
Anxiety disorders

Ondersteuning

Primaire sponsor: De Viersprong, specialist in persoonlijkheid, gedrag en gezin
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The severity of BPD symptoms

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND: Although clinical guidelines prioritize the treatment of depression and anxiety in young persons, there is accumulating evidence that the presence of features of borderline personality disorder (BPD) is associated with limited effectiveness of these standard treatments. These findings stress the need for interventions that address earlystage BPD in young people with presenting symptoms of anxiety and depressive disorders.
OBJECTIVE: The aim of this study is to investigate the (cost-)effectiveness of an early intervention program for BPD (MBT-early), compared with a standard protocolized treatment for symptom (i.e. depressive and/or anxiety) disorders, cognitive-behavioural therapy (CBT), in adolescents with depressive/anxiety disorders in combination with emerging BPD symptoms.
HYPOTHESIS: We hypothesize that MBT-early will be superior to standard protocolized CBT in reducing symptoms of BPD from baseline to end of treatment (primary outcome). We also expect MBT-early to be superior in terms of improving personality, social, and academic functioning from baseline to end of treatment and 12, 18 and 24 months, while MBT early is expected to be non-inferior in reducing symptoms of depression and anxiety (secondary outcomes). We also expect that MBT-early is cost-effective compared to standard protocolized CBT at 2-year follow-up (secondary outcome).
DESIGN: Multi-site superiority randomized controlled trial
POPULATION: Adolescents (12–18 years) with depressive/anxiety disorder(s) as assessed with the Structured Clinical Interview for DSM-5 Syndrome Disorders (SCID-5-S) and earlystage BPD, defined as having 3–6 BPD symptoms as assessed with the Structured Clinical Interview for DSM-5 Personality Disorders (SCID-5-PD).
INTERVENTIONS: CBT is a protocolized, time-limited intervention, which may be accompanied by interventions for parents. MBT-early is a protocolized, time-limited intervention for early-stage BPD that focuses on improving personality impairments.
RESEARCH SETTINGS: This study will be conducted in Mentaal Beter, GGz Breburg and De Viersprong, mental health care centres for young people with (emerging) mental health problems.
MEASURES: Primary outcome is the severity of BPD symptoms; secondary outcomes are level of personality, social and academic functioning, severity of depressive/anxiety symptoms and cost-effectiveness.
TIMEPOINTS: Baseline measurements will be taken before randomization and follow-up measurements will be conducted at end of treatment and at 12, 18 and 24 months after start of treatment.
INSTRUMENTS: Instruments are administered at every timepoint unless mentioned otherwise.

Adolescents:
- SCID-5 (only at screening)
- Demographic variables (only at baseline)
- LPFS-BF 2.0
- PHQ-9
- GAD-7

- BSI
- WHODAS 2.0 12 items
- KIDSCREEN-10
- EQ-5D-NL
- NRI-BSV
- School attendance
- RFQ
- BPDSI-IV-ado (only at baseline, end of treatment and 24-month follow-up)
- C-SSRS (only at baseline, end of treatment and 24-month follow-up)

Parents:
- CBCL
- TiC-P Kinderen
- Questions about extra time investment treatment (not at baseline)

SAMPLE SIZE: In accordance with power analysis, two groups of 59 adolescents (118 in total) need to be randomized; anticipating a dropout of 10% before completion of baseline measures and before randomization, two groups of 66 adolescents (132 in total) will to be recruited.
DATA ANALYSIS: Multilevel modelling based on intention-to-treat principles, including all adolescents with complete baseline measures and randomized to either MBT-early or standard protocolized CBT.

Doel van het onderzoek

1) We expect MBT-early to be superior to CBT in reducing the severity of BPD symptoms from baseline to end of treatment (primary outcome).
2a) We expect MBT-early to be non-inferior to CBT in reducing symptoms of anxiety and depression from baseline to end of treatment.
2b) We expect MBT-early to be superior to CBT in improving personality, social, and academic functioning from baseline to end of treatment.
3a) We expect MBT-early to be superior to CBT in reducing the severity of BPD symptoms from baseline to 12-, 18- and 24-month follow-up.
3b) We expect MBT-early to be non-inferior to CBT in reducing symptoms of anxiety and depression from baseline to 12-, 18- and 24-month follow-up.
3c) We expect MBT-early to be superior to CBT in improving personality, social, and academic functioning from baseline to 12-, 18- and 24-month follow-up.
4) We expect that MBT-early is cost-effective compared to standard protocolized CBT at 2 years after start treatment in terms of cost per QALY.

Onderzoeksopzet

Baseline measurements will be taken before randomization and follow-up measurements will be conducted at end of treatment and at 12, 18 and 24 months after start of treatment

Onderzoeksproduct en/of interventie

1) MBT-early is an early intervention program for adolescents with emerging BPD, which focuses on improving mentalizing. The capacity to mentalize is thought to underpin healthy personality functioning and may therefore be a primary target to improve personality functioning in young people.
2) Standard protocolized CBT refers to the psychotherapeutic intervention that adolescents with presenting symptoms of depressive and anxiety disorders would receive according to the Dutch treatment guidelines (GGZ Standaarden) as a first-choice psychological treatment for these symptom disorders.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible for this study, adolescents must meet all the following criteria: a) age between 12 and 18 years, b) either depressive (major depressive disorder or persistent depressive disorder) and/or anxiety disorder(s) as assessed by the Structured Clinical Interview for DSM-5 Syndrome Disorders (SCID-5-S; Arntz, Kamphuis, & Derks, 2018), c) 3 to 6 traits of borderline personality disorder using the Structured Clinical Interview for DSM-5 Personality Disorders (SCID-5-PD; Arntz, Kamphuis, & Derks, 2017).

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

Adolescents meeting any of the following criteria will be excluded from participation in this study: a) presence of a primary diagnosis that requires other specialist treatment (e.g. autism spectrum disorder, chronic psychotic disorder, severe eating disorder of sever substance abuse disorder), b) IQ < 75, or c) severe disability with regard to functioning in school, at home and in the peer group representative for later stage BPD.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-06-2021
Aantal proefpersonen:	118
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-06-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9569
Ander register	METC Erasmus MC : MEC-2020-0995

Resultaten