

The effectiveness of Mentalization-Based Treatment-early (MBT-early) in adolescents with emerging borderline-personality disorder: a single case experimental design

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To study the effectiveness and exploratively the presumed working mechanisms of the new MBT-early intervention. Given that MBT-early specifically targets young people with early characteristics of borderline personality disorder, we expect to find...

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

Summary

ID

NL-OMON55944

Source

ToetsingOnline

Brief title

MBT-early: a single case experimental design

Condition

- Personality disorders and disturbances in behaviour

Synonym

Borderline personality disorder

Research involving

Human

Sponsors and support

Primary sponsor: De Viersprong

Source(s) of monetary or material Support: De Viersprong

Intervention

Keyword: Borderline personality disorder, Early intervention, MBT-early, Prevention

Outcome measures

Primary outcome

Primary outcome of the study are (1) the level of personality functioning as assessed by the Level of Personality Functioning Scale-Brief form, version 2.0 (LPFS-BF-2.0, 12 items) and (2) depressive symptoms as assessed by the Patient Health Questionnaire-2 (PHQ-2, 2 items).

The questionnaire for the current study comprises in total 23 items. See appendix *E1 Vragenlijst SCED - V1 - 20230913* for the questionnaire.

Secondary outcome

Secondary outcomes are (1) mentalizing capacities as assessed by the Reflective Function Questionnaire for Youth-5 (RFQY-5); and (2) epistemic trust, as assessed by 4 selected items from the Questionnaire Epistemic Trust (QET).

The composite questionnaire for the current study comprises in total 23 items. See appendix *E1 Vragenlijst SCED - V1 - 20230913* for the questionnaire.

Other

o At the first assessment, adolescents will complete six questions concerning

demographic variables such as their living situation, nationality, level of education, and current school situation. Demographic variables will be used to describe the population of participants.

o Patients*, parents* and therapists* perspectives on the effectiveness and working mechanisms of MBT-early

Study description

Background summary

Borderline personality disorder (BPD) is characterized by problems in emotion regulation, identity disturbances, and impaired interpersonal functioning. Because BPD may determine health and quality of life in long term, it is important to focus on early detection and early intervention to prevent worsening. In this study, the effectiveness of a new intervention, MBT-early, is investigated in adolescents with borderline personality problems through a single case experimental design (SCED).

Existing studies into the efficacy of psychotherapeutic interventions for young people with a (subclinical) borderline personality disorder (BPD) show mixed results. An obvious explanation therefore lies in the heterogeneity of the samples studied, where the same intervention is investigated by young people with some characteristics of borderline personality problems in an early stage as by young people with significant borderline personality problems at a later stage. However, there is evidence that interventions should be targeted specifically at the stage of progression of the disorder ('staged care'). Interventions may be more effective when they correspond to the stage of disease progression.

MBT-early is an intervention intended for young people in an early stage of BPD. The intervention not only addresses the characteristics of BPD, it is more generally aimed at improving personality functioning so that there is no developmental stagnation and chronic consequences can be avoided. The expected working mechanisms of MBT-early's are twofold. MBT-early tries to strengthen the young person's mentalizing capacity. Mentalizing ability appears to play a role in the development of borderline personality disorder and improving mentalizing is a working mechanism of behind a MBT treatment. However, more recent theories have identified another working mechanism of MBT treatment, which is to increase epistemic trust (the openness to learn from others).

Research questions:

1. What is the effectiveness of MBT-early in youth with early stage BPD?
 - o What effect does MBT-early have on the improvement of personality functioning?
 - o What effect does early MBT have on the degree of depressed mood?
2. What are the possible working mechanisms of MBT-early?
 - o Does the youth's mentalizing ability influence the improvement of personality functioning?
 - o Does epistemic trust affect the improvement of personality functioning?
 - o What are the patients', parents* and therapists* perspectives on treatment trajectories as illustrated by the quantitative data?
 - o What are the experiences of patients, parents and therapists regarding helping and hindering factors over the course of the MBT-early treatment?

Study objective

To study the effectiveness and exploratively the presumed working mechanisms of the new MBT-early intervention. Given that MBT-early specifically targets young people with early characteristics of borderline personality disorder, we expect to find improvements in level of personality functioning and reductions of depressive symptoms (which is often the reason for seeking treatment).

Study design

Single Case Experimental Design (SCED).

Characteristic of a SCED design is that the 'state' of a participant is monitored at different times by means of frequent repeated measurements, so that the course of change as a result of the intervention can be monitored. An ABC design is used with three phases (A, B and C). Phase A is a baseline period prior to treatment in which there is no active intervention, in which 6 weekly assessments will be conducted. Phase B is the intensive intervention phase in which weekly treatment sessions take place over a period of 16 weeks. Assessment takes place as an integrated part at the beginning of treatment sessions. Phase C entails the booster phase, in which 4 low-frequency treatment sessions take place, spread over a duration of 6 months. In phase C assessment will also take place at the outset of the booster therapy sessions (4 assessments).

Semi-structured interviews are performed with patients, parents and therapists about their experiences with MBT-early. Interviews focus on the perspectives of patients, parents and therapist on the course of the treatment (based on the collected SCED data). The interviews have a maximum duration of 60 minutes. Topics include reflecting on moments in the treatment trajectory where improvement was observed in the questionnaires, interpreting these improvements, and exploring potential explanations for stagnation. Additionally, broader treatment experiences will be examined, including satisfaction, factors that facilitated or hindered progress, and insights

gained by the patients.

Intervention

MBT-early is an early intervention program for BPD that has been developed as an adaptation of MBT, an empirically supported treatment for BPD. MBT-early builds upon the theory and methods of MBT but integrates the principles of early intervention approaches such as Helping Young People Early (HYPE). MBT-early is a time-limited intervention that has been designed for early-stage BPD and focuses on improving personality functioning. MBT-early is a two-phase treatment that integrates interventions at the individual, family, and context level.

Study burden and risks

Participation is entirely voluntary. Informed consent takes place after the screening of the regular intake procedure. After giving information and receiving the information letter, the young person has one week to consider participation. The young person (and parents if the young person is not yet 16 years old) gives permission to participate. The difference from the standard procedure of MBT-early is the addition of a baseline period of 6 weeks with 6 repeated measures (taken by telephone) and a slight adjustment of the original ROM (23 instead of 16 items). The additional time investment for completing 23 versus 16 items is negligible. The standard waiting time is about 3-6 weeks, so the baseline period required for the additional measurements are minimized. The structural baseline period of 6 weeks is a (slight) deviation from the regular route and may result in a limited delay (0-3 weeks) in starting regular treatment. This six-week baseline period is necessary for a valid SCED design with sufficient measurements in the first phase. We minimize the expected delay to a minimal level because the preparation for the treatment process (attuning with youth professionals, planning appointments, signing an arrangement), which normally also takes a number of weeks, does start already. After these six weeks the face-to-face treatment can start immediately. The questions of the additionally included items do not differ in terms of content from the regular lists and there are no additional critical items with regard to the regular package. We therefore do not expect any increased risks or additional burden from this.

The interviews will involve a maximum time commitment of 60 minutes. No increased risks or additional burden are expected as a result of the questions posed during the interviews.

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)

Inclusion criteria

- a) age between 12 and 18 years,
- b) Three to six traits of borderline personality disorder as assessed by the Structured Clinical Interview for DSM-5 Syndrome Disorders
- c) Mild to moderate disability with regard to functioning in school, at home and in the peer group.

Exclusion criteria

- a) presence of a primary diagnosis that requires other specialist treatment (e.g. autism spectrum disorder, chronic psychotic disorder, severe eating disorder or severe substance abuse disorder),
- b) More than one comorbid classification,

- c) IQ < 75,
d) Severe disability with regard to functioning in school, at home and in the peer group representative for later stage BPD.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 27-03-2024

Enrollment: 8

Type: Actual

Ethics review

Approved WMO

Date: 24-11-2023

Application type: First submission

Review commission: METC Brabant (Tilburg)

Approved WMO

Date: 14-10-2024

Application type: Amendment

Review commission: METC Brabant (Tilburg)

Approved WMO

Date: 23-01-2025

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	NL85140.028.23