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Published in:
European Child & Adolescent Psychiatry

DOI:
10.1007/s00787-020-01551-2

Publication date:
2021

Document version:
Accepted manuscript

Citation for pulished version (APA):
Jørgensen, M. S., Storebø, O. J., Bo, S., Poulsen, S., Gondan, M., Beck, E., Chanen, A. M., Bateman, A., Pedersen, J., & Simonsen, E. (2021). Mentalization-based treatment in groups for adolescents with Borderline Personality Disorder: 3- and 12-month follow-up of a randomized controlled trial. *European Child & Adolescent Psychiatry*, *30*(5), 699-710. https://doi.org/10.1007/s00787-020-01551-2

Mentalization-based Treatment in Groups for Adolescents with Borderline Personality Disorder: 3 and 12-months Follow-up of a Randomized Controlled Trial

Mie Sedoc Jørgensen[1, 2, 3], Ole Jakob Storebø[1, 2, 4], Sune Bo[1, 2], Stig Poulsen[5], Matthias Gondan[5], Emma Beck[1, 2, 5], Andrew M. Chanen[6], Anthony Bateman[7], Jesper Pedersen[2] & Erik Simonsen[1, 3]

1: Psychiatric Research Unit, Region Zealand, Denmark
2: Child and Adolescent Psychiatric Department, Region Zealand, Denmark
3: Department of Clinical Medicine, Faculty of Health and Medical Sciences, University of Copenhagen, Denmark
4: Department of Psychology, University of Southern Denmark
5: Department of Psychology, University of Copenhagen, Denmark
6: Orygen, Melbourne, Australia, and Centre for Youth Mental Health, University of Melbourne, Melbourne, Australia
7: Research Department of Clinical, Education and Health Psychology, University College London, London, UK

Correspondence address: Mie Sedoc Jørgensen, Child and Adolescent Psychiatric Department, Region Zealand, Smedegade 16, 4000 Roskilde, Denmark, mipjo@regionsjaelland.dk. ORCID ID: https://orcid.org/0000-0003-3320-1231

Mie Sedoc Jørgensen, MSc, Child and Adolescent Psychiatric Department, Region Zealand, Smedegade 16, 4000 Roskilde, Denmark, mipjo@regionsjaelland.dk

Ole Jakob Storebø, PhD, Psychiatric Research Unit, Region Zealand, Fælledvej 6, 4200 Slagelse. ojst@regionsjaelland.dk

Sune Bo, PhD, Child and Adolescent Psychiatric Department, Region Zealand, Smedegade 16, 4000 Roskilde, Denmark, subh@regionsjaelland.dk

Stig Poulsen, PhD, Department of Psychology, University of Copenhagen, 2A Øster Farimagsgade, 1353 Copenhagen K, Denmark, stig.poulsen@psy.ku.dk

Matthias Gondan, Dr. rer. nat. habil., Department of Psychology, University of Copenhagen, 2A Øster Farimagsgade, 1353 Copenhagen K, Denmark, matthias.gondan@psy.ku.dk

Emma Beck, PhD, Department of Psychology, University of Copenhagen, 2A Øster Farimagsgade, 1353 Copenhagen K, Denmark, ebk@psy.ku.

Andrew M. Chanen, MBBS (Hons), B.Med.Sci (Hons), MPM, PhD, FRANZCP, Orygen, Melbourne, Australia, and Centre for Youth Mental Health, The University of Melbourne, Melbourne, Australia, andrew.chanen@orygen.org.au

Anthony Bateman, PhD, Research Department of Clinical, Education and Health Psychology, University College London, UK. anthony.bateman@ucl.ac.uk

Jesper Pedersen, PhD, Child and Adolescent Psychiatric Department, Region Zealand, Smedegade 16, 4000 Roskilde, Denmark, jpee@regionsjaelland.dk

Erik Simonsen, PhD, Psychiatric Research Unit, Region Zealand, Fælledvej 6, 4200 Slagelse, Denmark, es@regionsjaelland.dk

Statistical expert: Matthias Gondan

Funding: TrygFonden (grant number 115638), Department of Child and Adolescent Psychiatry Region Zealand, Psychiatric Research Unit Region Zealand, the Health Scientific Research Fund of Region Zealand, and Department of Health and Medical Sciences, University of Copenhagen.

The authors declare no conflicts of interest.

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. The trial is also approved by the Regional Ethics Committee of Zealand (no: SJ-371), and is registered at the Danish Data Protection Agency (no: REG-55-2014)

Word count (text only, excluding abstract, references, tables/figures, appendices/supplementary material) = 5607

Abstract

Background: Mentalization-based treatment in groups (MBT-G) has never been tested in adolescents with Borderline Personality Disorder (BPD) in a randomized controlled trial. The current study aimed to test the long-term effectiveness of MBT-G in an adolescent sample with BPD or BPD features (≥ 4 DSM-5 BPD criteria).

Methods: 111 patients with BPD (n = 106) or BPD features (n = 5) were randomized to either 1) a 1-year modified MBT-G program comprising three MBT introductory sessions, five individual case formulation sessions, 37 weekly MBT group sessions, and six MBT-Parent sessions, or 2) Treatment as usual (TAU), defined as at least 12 individual monthly treatment sessions with follow-up assessments at three and twelve months post treatment. The primary outcome was the score on the Borderline Personality Features Scale for Children (BPFS-C), and secondary outcomes included clinician-rated BPD symptoms and global level of functioning as well as self-reported self-harm, depression, externalizing and internalizing symptoms, and caregiver reports.

Results: There were no statistically significant differences between MBT-G and TAU on the primary outcome measure or any of the secondary outcomes. Both groups showed improvement on the majority of clinical and social outcomes at both follow-up points, although remission rates were modest with just 35% in MBT-G and 39% in TAU two years after inclusion into the study.

Conclusions: MBT-G was not superior to TAU in improving borderline features in adolescents. Although improvement was observed equally in both interventions over time, the patients continued to exhibit prominent BPD features, general psychopathology and decreased functioning in the follow-up period, which points to a need for more research and better understanding of effective components in early intervention programs.

The ClinicalTrials.gov identifier is NCT02068326

Keywords: Mentalization-Based Treatment; Mentalizing; Adolescence; Borderline Personality Disorder; Group Psychotherapy; Follow-up

Introduction

Borderline Personality Disorder (BPD) is a severe mental disorder associated with high rates of suicide, severe functional impairment, extensive comorbid mental state disorders, intensive use of treatment, and high costs to society (Leichsenring et al., 2011). Clinically significant BPD usually manifests during adolescence or young adulthood, and it has now been established that the phenomenology, structure, stability, validity, and morbidity of BPD in adolescence is similar to that seen in adult populations (Chanen, 2015). BPD is prevalent among adolescents with around 11-22% in outpatient settings (Chanen et al., 2004; 2017), and 19-53% in inpatient settings (Becker et al., 2002; Sharp et al., 2012; Ha et al., 2014).

Remission of acute BPD symptoms, such as self-harm, suicidal threats or acts and impulsivity are more common than previously recognized (Zanarini et al., 2005; Gunderson et al., 2011). In spite of this, many individuals with remitted borderline symptomatology continue to display prominent psychiatric symptoms, high rates of comorbid disorders, and severe social dysfunctioning (Zanarini et al., 2005; 2007; 2012; Gunderson et al., 2011). Hence, there has been an increasing interest in treating adolescents that show early signs of BPD, since these symptoms seem to be relatively stable throughout childhood and adolescence (Stepp et al., 2010; Chanen & McCutcheon, 2013). A Clinical Staging Model, with associated health management, has been proposed to outline BPD in stages proportionate to the presenting clinical picture, that is from risk factors and precursor signs at a subthreshold level to threshold and more severe stages of BPD. For each stage matched interventions or health management are proposed (Chanen et al., 2016; Hutsebaut et al., 2019). The aim of early intervention is to target BPD in its early stages, where BPD features are still flexible and malleable, in order to prevent the poor psychosocial outcomes seen in adult BPD samples (Chanen & McCutcheon, 2013). Due to previous reluctance to diagnose BPD in youth, only a few randomized controlled trials (RCTs) have been conducted among adolescents with BPD features, and of these,

154 only five included follow-up assessments. Without follow-up assessments it is difficult to determine
155 the long term efficacy of such psychotherapeutic interventions.

156 Mehlum et al. (2014) compared Dialectical Behavior Therapy for Adolescents (DBT-A) to
157 enhanced usual care for self-harming adolescents. At end of treatment (EOT), DBT-A showed
158 superiority in reducing self-harm, suicidal ideation, and depressive symptoms. However, only the
159 reduction in self-harm persisted one and three years post treatment (Mehlum et al., 2016; 2019), and
160 no difference was encountered for BPD symptomatology. McCauley et al. (2018) compared DBT-A
161 to individual and group supportive therapy and found significant advantages for DBT-A on all
162 outcomes (suicide attempts, non-suicidal self-injury, and self-harm) at EOT. However, the superiority
163 of DBT-A decreased six months after EOT, with no statistically significant group-differences. Three
164 other RCTs have been conducted, one on Integrative Borderline Personality Disorder-oriented
165 Adolescent Family Therapy (Santisteban et al., 2015), one on Emotion Regulation Training
166 (Schuppert et al., 2012), and one on Helping Young People Early plus Cognitive Analytic Therapy
167 (CAT, Chanen et al., 2008). None of these trials found any significant differences between the
168 experimental intervention and the control interventions (i.e. individual drug counseling, treatment as
169 usual (TAU) and manualized good clinical care) at EOT or in the follow-up period, but the latter
170 found that the CAT group improved more rapidly.

171 Mentalization-based treatment (MBT) was developed by Anthony Bateman and Peter Fonagy,
172 and has shown promising results in the reduction of BPD pathology in their two trials (Bateman &
173 Fonagy, 1999; 2009). Mentalizing refers to the capacity of "making sense of each other and
174 ourselves, implicitly and explicitly in terms of subjective states and mental processes" (Bateman &
175 Fonagy, 2004, p. 36), and this capacity is theorized to be acquired gradually over the first few years
176 of life in the context of safe and secure child-caregiver relationships. Only four RCTs with MBT for
177 BPD for adults included follow-up assessments (Bateman & Fonagy, 2001; 2008; Jørgensen et al.;

2014; Robinson et al., 2016, Laurenssen et al., 2018). Bateman and Fonagy (1999) conducted follow-up assessments after 18 months and after eight years. In both follow-up periods, participants in MBT showed continued clinical and statistical superiority over TAU on suicidality, diagnostic status, service use, use of medication, global function above 60 on the Global Assessment of Functioning (i.e. mild symptoms or less), and vocational status (Bateman & Fonagy, 2001; 2008). In another trial by Jørgensen et al. (2013; 2014) no superiority of MBT over TAU was detected on any outcomes at EOT and at follow-up after 18 months. Robinson et al. (2016) compared a specifically designed MBT for eating disorders with specialist supportive clinical management (SSCM) for participants with eating disorders and symptoms of BPD. Treatment duration was 12 months, and the participants attended follow-up assessments two times after EOT, namely after six and 24 months. There was, however, extensive drop-out from the research assessments, and the authors were only able to collect data from 10 participants (29%) in MBT at both time follow-up time points, and 5 and 9 participants (15 and 27%) in SSCM (Robinson et al., 2016). The high drop-out rate hinders any conclusions about long-term effectiveness of MBT. Finally, Laurenssen et al. (2018) compared day hospital MBT to specialist TAU for BPD. The treatment duration was 18 months, and the participants attended follow-up assessments six, twelve and eighteen months after EOT. The authors found no significant differences between the interventions on any outcome in the follow-up period (Laurenssen et al., 2018).

To our knowledge, only one trial has tested MBT for adolescents (MBT-A) for adolescents with BPD or BPD features (Rossouw & Fonagy, 2012). In this trial, the MBT-A program consisted of individual sessions (weekly) and family sessions (monthly). This trial showed superiority of MBT-A over TAU in reducing self-harm, depression, and borderline features. However, the results of this trial should be interpreted with caution due to a high drop-out rate, lack of published protocol, and

possible allegiance bias. Furthermore, since there was no follow-up study, we have no knowledge of the long-term effectiveness of MBT for adolescents with BPD features.

We conducted an RCT comparing a one-year modified MBT group therapy (MBT-G) program with TAU for adolescents with BPD or BPD features. At EOT, no superiority of either treatment was found on any of the outcome measures (primary as well as secondary measures) (Beck et al., 2020). Since no follow-up studies after an RCT have been done on any MBT intervention for adolescents with BPD, this study will provide novel information on the long-term effectiveness of this treatment.

Methods

Design

Participants and procedures

This study was a three- and twelve months follow-up study of the original sample who had participated in an RCT of MBT-G compared with TAU for adolescents with BPD or subthreshold BPD. The design, sample, procedures and outcomes have previously been described (Beck et al., 2016; 2020). The adolescents were recruited from four child and adolescent psychiatric outpatient clinics in Region Zealand, Denmark. The sample consisted of 111 adolescents (mean age at baseline for MBT-G = 15.7, *SD* = 1.1, and TAU = 15.9, *SD* = 1.0) who were mainly female (110 girls, one boy). To be included, they had to meet a minimum of four DSM-5 BPD criteria, score above clinical cut-off of 66 on the Borderline Personality Features Scale for Children (BPFS-C), be 14-17 years, and caregivers had to give informed consent and also participate in MBT-Parent sessions. Participants were excluded if they had a diagnosis of pervasive developmental disorder, learning disability (IQ < 75), anorexia nervosa, current psychosis, diagnosis of schizophrenia or schizotypal personality disorder, antisocial personality disorder, if any other mental disorder than BPD was considered the primary diagnosis, current (past two months) substance dependence (but not substance abuse), and

current psychiatric inpatient treatment. Five patients were diagnosed with schizophrenia or a psychotic disorder during the treatment phase of the trial, and an additional three during the follow-up period.

A sample size calculation was conducted prior to the trial (Beck et al., 2016). With 90% power, a significance level of 5% two-tailed and an expected intra-class correlation of 0.03 warranting an increased sample size of 24%, we needed to recruit 90 patients. To address drop-out, we recruited a surplus of 20% patients. This yielded a total of 112 patients to be randomized in a 1:1 ratio (Beck et al., 2016). Participants were randomly assigned to receive either treatment by use of a computerized block randomization with a varying block size, concealed from the investigators. Randomization was stratified according to clinic affiliation and self-reported BPD severity (high ≥ 86 BPFS-C score). In both arms, the treatment was delivered for one year.

Interventions

MBT-G and TAU were delivered at four child and adolescent psychiatric outpatient clinics in Region Zealand, Denmark. Patients received pharmacological treatment if needed according to a protocol developed for the current study and based on national and international recommendations for adolescents and BPD (available on request).

MBT-G consisted of three MBT-Introduction sessions, 37 MBT-Group sessions, and six MBT-Parents sessions. All components lasted 90 minutes. As part of the MBT-G program, five individual case formulations sessions were delivered. MBT was delivered by trained and supervised clinical psychologists and psychiatrists who had completed a two-day introduction to MBT-theory and basic principles and a five-day training program led by Professor Sigmund Karterud, Oslo University Hospital, Norway, who has authored the original MBT-G manuals in collaboration with Anthony Bateman (Karterud, 2012; Karterud & Bateman, 2011). To ensure adherence to the manual, therapists

were supervised by national specialists in MBT for 1-2 hours monthly. For a more thorough description of the treatment program please see Beck et al. (2020).

TAU consisted of at least 12 individual supportive sessions, comprising at least one monthly session. Therapists in TAU were psychologists, psychiatrists, nurses or social workers not trained in or practicing MBT. TAU was non-manualized and thus varying in content, duration and caregiver involvement. TAU sessions were not videotaped. Therapists were provided supervision according to the regular supervision at the clinics.

Assessments

Participants were assessed at baseline (before randomization), three times during the treatment phase (week 10, 20, and 30), at EOT, and three- and twelve months post treatment (for details, please see the CONSORT flow diagram in Figure 1). As results from baseline and end of treatment have been published previously, only key results from EOT will be presented here. Assessments at follow-up were by means of clinical interviews and self-report. Clinical interviews were made by two independent psychologists not trained in MBT.

Insert Figure 1 around here

Measures

Outcomes

The primary outcome was the 24-item BPFS-C (Crick, Close & Woods, 2005). A difference of 12 points on the BPFS-C was chosen as the setting for minimum clinical relevance corresponding to three items changing from worst to best (Beck et al., 2020). Secondary outcomes are described below.

Depression was measured with the 20-item Beck's Depression Inventory for Youth (BDI-Y, Thastum et al., 2009; Beck et al., 2012). *Self-harm* was measured with the 18-item self-harm scale from the Risk-Taking and Self-harm Inventory for Adolescents (RTSHI-A, Vrouva et al., 2010). *Externalizing and internalizing symptoms* were assessed with the 112-item Youth Self-Report (YSR, Achenbach, 1991). Caretakers filled out corresponding versions of the BPFS-C, Borderline Personality Features Scale-Parent (BPFS-P, Sharp et al., 2011) and the YSR, the 112-item Child Behavior Checklist (CBCL, Achenbach, 1991). The interview-based assessments included the Zanarini Rating Scale for Borderline Personality Disorder (ZAN-BPD, Zanarini & Frankenburg, 2001), and the Children's Global Assessment Scale (CGAS, Shaffer et al., 1983) that measures global level of functioning. The CGAS was based on information from the clinician-administered interviews as well as medical records from the preceding month (possible information on treatment allocation was removed). We collected medical data on hospitalizations, emergency room visits and medication from patients' medical accounts.

To minimize potential detection bias we made sure that 1) outcome assessors were blind to treatment allocation and all information from previous interviews, 2) the first author made all of the practical arrangements for follow-up interviews, and collected treatment history data, 3) the assessors did not communicate with therapists, and 4) participants were asked not to reveal treatment allocation during the assessments. After each follow-up assessment, assessors were asked to guess treatment allocation of the patient in question. Assessors responses were correct for 58% of the cases at three months follow-up (Cohen's $\kappa = 0.16$), and 56% at twelve months follow-up ($\kappa = 0.12$) thus indicating that blinding was successful. Interviews were audiotaped and inter-rater reliability (IRR) for CGAS and ZAN-BPD was assessed for 10 random cases. IRR was found to be excellent at both time points (ZAN-BPD at three months follow-up: $\kappa = .99$, and $\kappa = .96$ at twelve months follow-up; CGAS at three months follow-up: $\kappa = .98$, and $\kappa = .97$ at twelve months follow-up).

Statistical analysis

The statistical analysis plan was written before unblinding and has previously been described (Beck et al., 2020). To summarize, the primary outcome was the total BPFS-C score treated as a continuous, normally distributed variable. To test the main research question whether the primary outcome differed between the two treatment arms, we used a two-sided multilevel model for comparison with significance level of 5%. Outcome analyses were adjusted for *Therapy* as the main effect, baseline BPFS-C as a continuous covariate, and *Therapy Group* (MBT-G) and *Therapist* (TAU) as random intercepts, which is recommended in partially nested designs (Flight et al., 2016). Baseline severity was used as a baseline covariate in the statistical analysis consistent with the EMA guideline (CMPH, 2015). Site was used as a stratification variable, but did not enter the primary analysis as a covariate. The random factor *Therapist* was nested in *Site*, and therefore we decided not to include Site as a covariate to avoid numerical problems in model fitting. In a sensitivity analysis, *Therapist* was taken out and *Site* was included instead.

Datasets were combined using Rubin's rules (Rubin, 1987), and treatment effects were evaluated using intention-to-treat, taking into account all the available data at the two follow-up time points and multiple imputation of missing data. Missing responses on individual items were filled in by mean imputation. All drop-outs and missing data on entire scales were replaced using multiple imputation (Hayes, 2009) including all previous time points (baseline, week 10, week 20, week 30, end of treatment, and three months follow-up for the twelve months follow-up time point), as well as the covariates of the primary statistical analysis, and therapy arm. No suicides occurred thus no worst case imputation was applied.

In the main analysis, a mixed model for partially clustered designs was used to allow different intra-class correlations for patients treated in groups (MBT-G) and patients treated individually by

the same therapist in TAU (Baldwin, 2011). In the imputation model, a simpler approach with one overall intra-class correlation was used. Since number of attended sessions systematically differs between the two interventions, this was not included in the imputation model. To avoid overfitting, we only included the repeated measurements of the primary outcome variable into the imputation model, and the random therapist effects were assumed to be equal in the two treatment arms in the imputation procedure. Missing data were not imputed for secondary outcomes.

Differences between the groups on primary and secondary outcomes are presented as covariate-adjusted differences in group means with a two-sided 95% confidence interval.

Results

Treatment attendance and adherence

Information regarding treatment attendance and retention as well as adherence to the manual has previously been described in-depth (Beck et al., 2020). To briefly summarize, participants in MBT-G attended an average of 17.7 (*SD* = 11.3, range 0-25) sessions, and participants in TAU attended an average of 10.1 (*SD* = 4.7, range 2-24) sessions. 31 (56%) of the participants in MBT-G dropped out of treatment compared to 14 (25%) in TAU. The MBT-G group consisted of a maximum of eight participants (Beck et al., 2016). Due to the high drop-out rate in MBT-G, however, the mean number of participants in each of the five groups was 4.6, 4.3, 2.6, 2.6, and 3 (Beck et al., 2020).

Adherence to MBT was measured using the Adherence and Competence Scale for Mentalization-based Group Therapy (Folmo et al., 2017; Karterud, 2013). On a scale from 1–7 with 4 defined as "good enough" adherence, the overall adherence score was rated at 5.47 (*SD* = 0.80) and the overall quality rating was 5.53 (*SD* = 1.10) (Beck et al., 2020).

Primary outcome: Borderline features

At three months follow-up, the primary outcome was available for 93 out of 111 participants (18 missing), comprising 43/55 in MBT-G, and 50/56 in TAU. The average BPFS-C score was 70.3 (*SD* = 16.5, range 35 – 99) for MBT-G, and 69.6 (*SD* = 13.7, range 32 – 104) for TAU. The results of the covariate-adjusted group difference, accounting for the multilevel structure of the data, and with missing data imputed from assessments at baseline, week 10, week 20, week 30, and at EOT showed a difference of 0.6 on the BPFS-C in favor of TAU (95% CI = −7.3 to 6.2, p = .87). Comparable to EOT, the highest score in the confidence interval is below the minimal clinical relevant difference of 12 units on the BPFS-C, thus there is no indication for superiority of either treatment. Deterioration (i.e. a higher BPFS-C score at follow-up than baseline) was observed among 11 participants (20 %) in MBT-G, and 12 (21 %) in TAU. Remission (i.e. a BPFS-C score lower than clinical cut-off < 66) had occurred among 16 participants (29 %) in MBT-G, and 21 (38 %) in TAU.

At twelve months follow-up, the primary outcome was available for 97 participants (14 missing), comprising 46/55 in MBT-G, and 51/56 in TAU. The average BPFS-C score was 68.6 (*SD* = 15.0, range 32 – 100) for MBT-G, and 67.7 (*SD* = 14.8, range 33 – 100) for TAU. The results of the covariate-adjusted group difference, accounting for the multilevel structure of the data, and with missing data imputed from assessments at baseline, week 10, week 20, week 30, at EOT and at three months follow-up showed a difference of 1.6 on the BPFS-C in favor of TAU (95% CI = −7.7 to 4.6, p = .62). Comparable to end of treatment and three months follow-up, the highest score in the confidence interval is below the minimal clinically relevant difference of 12, which again points to no superiority of either treatment. Deterioration was observed among 8 participants (15 %) in MBT-G, and 12 (21 %) in TAU. Remission had occurred among 19 participants (35 %) in MBT-G, and 22 (39 %) in TAU.

Two sensitivity analyses were performed. One in which the eight patients whose BPD diagnosis was changed to a psychotic disorder during the course of the trial were excluded. These results

showed no difference on the BPFS-C at either three months follow-up (1.0 BPFS-C units, CI: −5.9 to 7.8, p = .79) or twelve months follow-up (−1.0 BPFS-C units, CI: −7.1 to 5.1, p = .76). Another sensitivity with a per-protocol subset of the data, excluding all patients who did not complete treatment (N = 66) likewise showed no significant difference on the BPFS-C at three months follow up (−5.7 BPFS-C units, CI: −13.6 to 2.3, p = .16) nor at twelve months follow-up (−3.6 BPFS-C units, CI: −11.7 to 4.5, p = .38).

Secondary outcomes

The results of the secondary outcomes at the two follow-up points are presented in Tables 1 and 2. Consistent with the findings at EOT, no statistically significant difference were observed on any secondary outcome except a higher rate of hospitalizations and emergency rooms visits among participants in the MBT-G arm. However, these results are explained by the skewed occurrence of hospitalizations and emergency room visits among the patients later diagnosed with psychotic disorders. When we excluded the eight patients diagnosed with a psychotic disorder, the results became insignificant at both follow-up time points for hospitalizations (p = 1.0, and .37), and emergency room visits (p = .40, and .94, for three months and twelve months follow-up, respectively).

Group mean levels for depression (BDI-Y) were in the "moderately elevated" range at both follow-up time points. Level of global functioning (CGAS) remained in the category "moderate degree of interference in functioning in most social areas or severe impairment of functioning in one area" in both groups at both follow-up time points. Group mean levels for internalizing and externalizing symptoms (YSR) were below "the borderline clinical range" (below the 93rd percentile) at both follow-up time points. Self-harm (RTSHI-A) was in the clinical range in both groups at both follow-up time points with no pre-post change, which could be related to the limited ability to detect change on the RTSHI-A (i.e. questions are phrased "*have you ever...*", Vrouva et al., 2010). At both

follow-up time points, the total level of BPD symptoms on the ZAN-BPD had decreased and was close to that seen among non-BPD patients in Zanarini et al.'s results on the discriminant validity of the ZAN-BPD (a score of 5.2, *SD* = 3.5, Zanarini et al., 2003). Use of psychoactive drugs in both treatment arms are summarized in Table 3. At both follow-up time points, we found no significant difference in the use of any psychoactive drugs or use of polypharmacy (defined as three drugs or more).

Insert Table 1 around here.

Insert Table 2 around here.

Insert Table 3 around here.

Discussion

Findings from the three and twelve-month follow-up time points show no superiority of MBT-G over TAU across all outcomes. For the total sample, we found that BPD features (BPFS-C) had decreased to just above clinical cut-off for BPD. The clinician-rated BPD features (ZAN-BPD) supported this finding, with BPD symptoms at a level just above that seen in a non-BPD sample (Zanarini et al., 2003). It is difficult to determine whether this decrease in BPD pathology is an expression of effectiveness of treatment or merely natural remission of the disorder or regression to the mean. However, when inspecting the secondary outcomes, the general pattern shows that psychopathology decreased, and more importantly, that interpersonal difficulties as measured with the ZAN-BPD and global functioning (CGAS) both improved. Level of global functioning moved from "major impairment" at baseline (Beck et al., 2020) to "moderate degree of interference*"* at EOT and in the follow-up period with only one point from a level of "variable functioning with sporadic difficulties or symptoms*"* at twelve months follow-up. The latter finding is important because acute symptoms

of BPD generally decline from adolescence into adulthood, but interpersonal difficulties and poor functioning generally remain stable (Newton-Howes et al., 2015). Thus, it is important to emphasize that even though there were no significant differences between the two treatment arms, this does not equate to ineffectiveness of the treatments delivered. Taken together, the decrease in BPD pathology and general psychopathology in addition to an increase in psychosocial functioning could point to some effectiveness of both interventions, but we cannot disregard the possibility that the observed reductions occurred because of natural remission or regression towards the mean.

Despite the abovementioned improvements, our sample still scored above clinical cut-off for BPD, displayed symptoms of mental state disorders, and their level of functioning was still impaired two years after inclusion. Based on our findings, MBT-G (as delivered in the M-GAB trial) was not more effective than TAU while at the same time being associated with significantly more drop-out and also less cost-effective to implement than TAU. Both treatments were ineffective in producing results that were clinically relevant and remission rates were modest. This points to the need for more effective treatments.

One explanation for not finding superiority of MBT-G might be that the treatment program was insufficient in treating the severe levels of psychopathology encountered in our sample of adolescents with BPD. If we compare our sample with adolescent BPD samples from previous RCTs, the level of functioning in our sample was considerably lower and, furthermore, more participants fulfilled diagnostic criteria for BPD. Ninety-six percent of our sample had BPD with a mean of 7.3 (*SD* = 1.46) BPD criteria (Beck et al., 2020). To compare, only 21% in Mehlum et al.'s trial (2014), 41% in Chanen et al.'s trial (2008), 53% in McCauley et al.'s trial (2018), and 73% in Rossouw and Fonagy's trial (2012) and Schuppert et al.'s trial (2012) had BPD. Number of BPD criteria is important to consider since severity of personality disorder criteria is associated with higher levels of social and occupational dysfunctioning, co-occurring mental state disorders, and mental health service use

(Winograd et al., 2008; Thompson et al., 2019). At baseline, our sample reported a mean level of global functioning of 35.2 (TAU) and 35.7 (MBT-G) on the CGAS (i.e. "major impairment in functioning in several areas and unable to function in one of these areas", Beck et al., 2020). In Mehlum et al.'s trial (2014) the baseline CGAS score was 55.3 and 57.9 (i.e. "variable functioning with sporadic difficulties or symptoms"), and in Chanen et al.'s trial (2008), the baseline scores on the Social and Occupational Functioning Assessment Scale (that has an identical range of scores as the CGAS but focuses on social and occupational functioning) were 60.27 and 61.16 which translates to "moderate difficulty in social, occupational, or school functioning".

The MBT-G program was designed as an early intervention for BPD, and the group format was chosen to test whether this could be a cost-effective treatment for BPD in its early stages (the rationale for including BPD and BPD features) compared to multicomponent MBT (combined individual and group therapy). MBT-G was thus of a lower dosage and intensity than previous MBT trials on adult BPD samples. Although at an early stage of BPD (given their age), our sample, however, proved to be acutely unwell with major impairment in functioning. According to the Clinical Staging model proposed by Chanen et al. (2016), and later elaborated on by Hutsebaut et al. (2019), proposed interventions for patients with BPD consist of *early intervention* (i.e. case management, active engagement of families or caregivers with psychoeducation and time-limited family intervention, general psychiatric care, capacity for outreach care in the community and specific and targeted pharmacotherapy) *in combination with* specialized psychotherapy programs for young people such as MBT-A, CAT or DBT-A. Both of our treatments matched that of lower stages BPD (simpler and more benign), and did not sufficiently include other important aspects of early intervention, namely outreach care and active engagement of families (Chanen et al., 2016). TAU was based on supportive sessions ("case management") without a specialized BPD intervention, whereas MBT-G was based on a specialized BPD intervention but without case management. Given that our sample consisted of

almost exclusively full threshold BPD, in a phase where they were acutely unwell with considerable comorbid mental state disorders and low levels of functioning, our interventions perhaps did not match their treatment needs. Instead of matching treatment according to the clinical stage of BPD, we solely used participants' chronological age. Both interventions were thus possibly insufficient in treating severe BPD pathology.

If we compare the drop-out rate in MBT-G (56%) to that in MBT-A (50%), the drop-out rates are somewhat similar (Rossouw & Fonagy, 2012). The attrition rates in MBT are thus considerably higher than other large scale trials for adolescents with BPD pathology, e.g., 27% in CAT (Chanen et al., 2008), 17% in ERT (Schuppert et al., 2012), and 23 and 26% in DBT-A (McCauley et al., 2018; Mehlum et al., 2014). The higher tendency towards drop-out in MBT could point to: 1) MBT is less acceptable to the participants, or 2) the format is less acceptable to the participants. Compared with other large scale trials for adolescents with BPD or BPD features (i.e., CAT, ERT and DBT-A), the duration of treatment is six months or less, whereas the treatment duration in MBT-A and MBT-G both consisted of one year treatment with weekly individual or group therapy. Additionally, the distribution of participants that met diagnostic criteria for BPD were higher in MBT-G (96%) and MBT-A (73%) compared with the majority of other trials on early intervention for BPD, as mentioned earlier. Despite comparable attrition rates in MBT-G and MBT-A, MBT-A found superior outcomes over TAU, whereas MBT-G did not. This finding raises important questions regarding the content and format of our MBT-G program. For one, individual sessions were omitted specifically to test a group-based intervention for adolescents with BPD or BPD features, despite previous findings that individual psychotherapy often counteract the strong tendency towards drop-out among adult participants with BPD (Linehan et al., 2015). Individuals with BPD are generally sensitive to interpersonal triggers, and it is possible that MBT-G in our study led to more drop-out due to an overstimulation of attachment systems in the group setting (Bateman & Fonagy, 2016). To

summarize, the reasons for the high drop-out rate in MBT-G could be multifactorial and raises important research questions for future trials on early intervention programs for adolescents with BPD or BPD features.

Kvarstein et al. (2019) found that MBT and psychodynamic group-based treatment had similar outcomes among patients with less severe BPD, but that MBT (consisting of 12 introductory psychoeducational sessions and a combination of weekly individual and group therapy) may be particularly beneficial for severely disordered BPD patients. The somewhat comparable attrition rates in MBT-G and MBT-A in combination with the higher level of BPD pathology in these trials, indicate that combined individual and group therapy sessions might be preferred to hinder drop-out. Due to the possible mismatch between the design of our study and the high level of psychopathology we found in our sample, the question of whether MBT-G could be beneficial for BPD in a less severe phase or earlier stage BPD, remains unanswered. The fact that our sample still report BPD features above clinical cut-off two years after baseline, points to a need of effective treatments for this debilitating disorder in order to reduce BPD pathology and increase functioning.

There are several strengths of the initial trial of which several have been mentioned previously (Beck et al., 2020). Regarding the follow-up study presented here, it is the first follow-up study on MBT for adolescents with BPD, and the first RCT of MBT for adolescents with BPD not conducted by the developers of MBT. Although many participants dropped out of treatment prematurely, the compliance to assessments was high and we were able to collect data on the primary outcome from 87 % of the original sample at the twelve months follow-up. We followed our published protocol with the exception of the mediational outcomes, which were left out of the analyses due to a lack of superior effectiveness of MBT-G, thus no mediational analyses were employed. To deter publication bias it is important to report negative findings like these.

There are, however, also limitations regarding the assessments and implementation of the trial as well as the generalizability of the results that are important to consider when interpreting the findings. First and foremost, it is important to take into consideration that follow-up studies like this are uncontrolled and thus participants may engage in differential psychotherapeutic or pharmacological treatments that can give an uncontrolled effect.

Concerning the assessments, the limited validity of detecting change on the RTSHI-A is a major limitation to our results because we cannot conclude on either treatment's effectiveness in reducing self-harm. Dealing with self-harm is of clinical importance, and, therefore, specifically addressed in the MBT-G manual that the therapists were trained in (Karterud, 2012). According to this manual, "patients at risk of self-mutilation or other kinds of gross self-destructive behavior (or violence against others) should be provided with a crisis plan" (Karterud, 2012, p. 17). Accordingly, the M-GAB protocol specifically mentions the use of an updated crisis plan with the therapist's contact details (Beck et al., 2016). Furthermore, we found major impairment in functioning in our sample but, in retrospect, the CGAS was perhaps not a good measure of functioning because it conflates symptoms and functioning. Lastly, we found that eight participants were diagnosed with a psychotic disorder in the duration of the trial and the follow-up period (six of which were in MBT-G), and this could also have influenced the results. Two blinded psychiatrists relistened to baseline recordings from MINI-KID and identified three participants that should have been excluded from the trial according to our exclusion criteria "current psychosis, diagnosis of schizophrenia or schizotypal personality disorder" (Beck et al., 2020). The remaining five participants most likely developed psychotic symptoms after inclusion into this study, as is common in this age group.

Concerning the implementation of the trial, all therapists in MBT-G and TAU were employed in the child and adolescent psychiatry. We have no knowledge on possible differences in years of experience between MBT-G and TAU therapists, but MBT-G was implemented prior to the trial, and

in comparison to TAU, relatively new to the organization as well as the therapists, and this could have influenced the results. Bales et al. (2017), for example, found that the effectiveness of MBT was reduced by almost half in a time characterized by organizational reorganization. Furthermore, seven TAU therapists and five MBT-G therapists were replaced in the duration of the trial. Given the group format in MBT-G, more participants in MBT-G experienced a therapist replacement (33%) compared to participants in TAU (12.5%) (Beck et al., 2020). Individuals with BPD are generally sensitive to feelings of rejection and abandonment, and, therefore, this higher rate of therapist replacement in MBT-G could have influenced the outcome of treatment as well as participant drop-out

Concerning generalizability, our trial does not allow for conclusions regarding the effectiveness of MBT, since the MBT-G program was based on a shortened version of the MBT program (Beck et al., 2020). Moreover, our sample consisted almost exclusively of females (except for one male) and, consequently, results cannot be generalized across genders.

Acknowledgements

The authors wish to thank all the participants and their families for participating in this study. We thank the staff at the child and adolescent psychiatry in Region Zealand, and their managers for their support. We are grateful to the therapists and supervisors. We thank the members of the steering committee and a special acknowledgement of Michael Maagensen for assisting in the development of the medical protocol. Thank you to our research assistants Louise Lejbach and Christian Fjellerad Andersen, and also to Karterud for his supervision of therapists and advice on the design of the MBT group program. Thank you to Trygfonden, Department of Child and Adolescent Psychiatry, Psychiatric Research Unit and the Health Scientific Research Fund of Region Zealand, and Department of Health and Medical Sciences at University of Copenhagen for funding this study.

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746 Figure 1. CONSORT flow diagram of the M-GAB trial

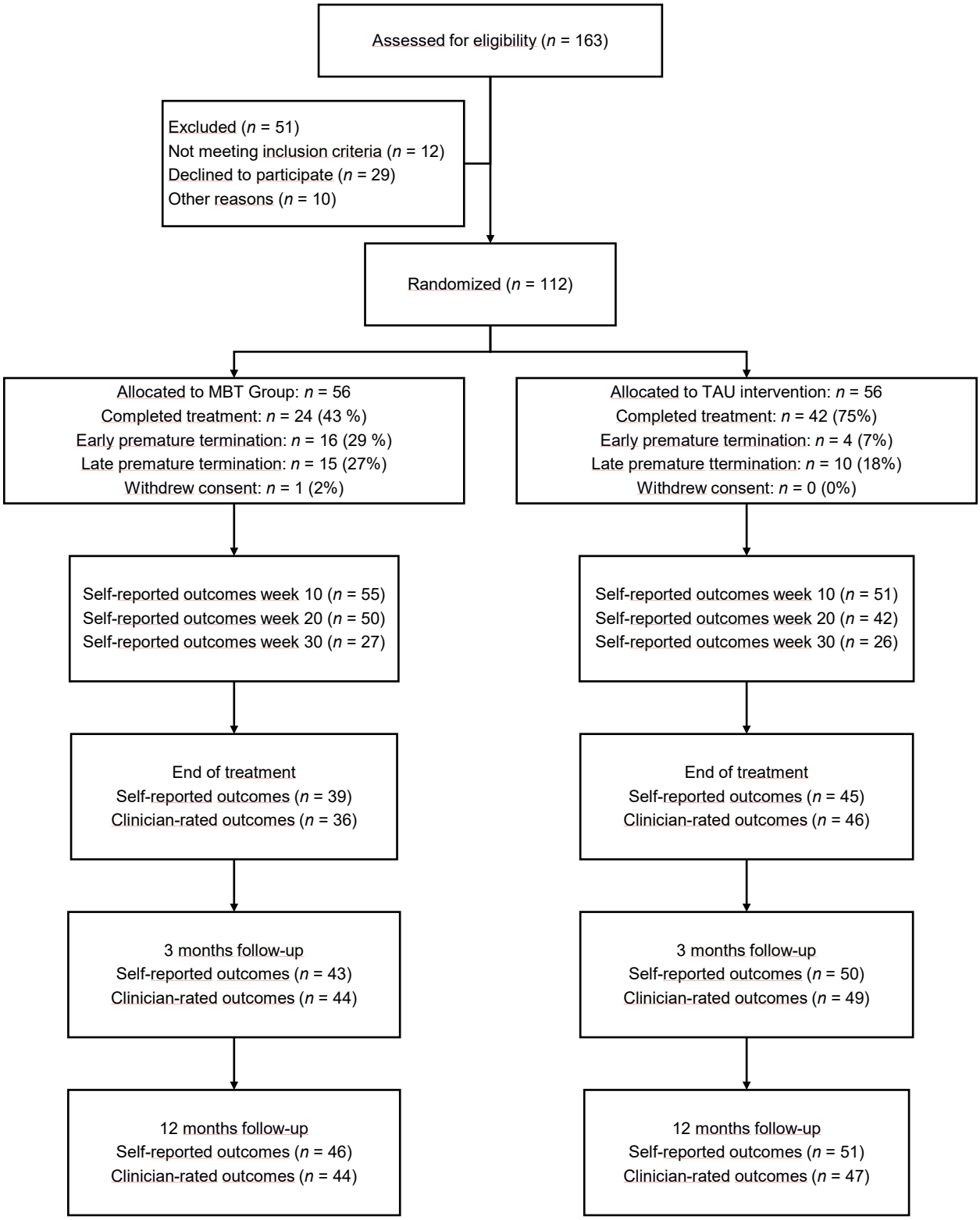

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Table 1. Secondary outcomes on BPD features and symptoms at end of treatment, and 3 and 12 months follow-up. Group means (SD) for the two therapies (available cases), and covariate-adjusted group difference with 95% confidence intervals

	TAU		MBT		TAU − MBT	95% CI	*p*
Borderline features – Parental report (BPFSP-P)							
End of treatment	68.7	(16.8)	69.1	(12.4)	−0.4	−7.0 to 6.1	.89
Follow-up 3 mo.	65.7	(15.0)	67.6	(12.8)	−2.7	−7.7 to 2.2	.27
Follow-up 12 mo.	62.0	(16.7)	66.9	(14.5)	−3.9	−11.2 to 3.4	.28
Self-harm (RTSHI-A)							
End of treatment	39.0	(13.4)	40.8	(11.2)	−2.7	−6.7 to 1.2	.17
Follow-up 3 mo.	39.2	(12.8)	39.4	(10.0)	0.7	−3.8 to 5.3	.75
Follow-up 12 mo.	39.7	(13.3)	40.4	(9.7)	−0.8	−4.4 to 2.9	.67
Total Borderline Symptoms (ZAN-BPD)							
End of treatment	8.0	(7.3)	8.8	(6.5)	−0.6	−3.9 to 2.7	.70
Follow-up 3 mo.	6.8	(5.2)	7.8	(6.4)	−1.1	−3.6 to 1.3	.36
Follow-up 12 mo.	6.9	(5.9)	6.5	(4.4)	0.4	−2.0 to 2.8	.74
Affects (ZAN-BPD)							
End of treatment	3.9	(3.2)	4.1	(3.1)	−0.0	−1.5 to 1.5	.99
Follow-up 3 mo.	3.8	(2.9)	3.9	(3.2)	−0.2	−1.4 to 1.1	.76
Follow-up 12 mo.	3.4	(3.0)	3.8	(2.5)	−0.4	−1.6 to 0.9	.55
Cognition (ZAN-BPD)							
End of treatment	1.0	(1.6)	1.2	(1.7)	−0.1	−0.9 to 0.6	.75
Follow-up 3 mo.	0.8	(1.1)	1.2	(1.8)	−0.4	−1.0 to 0.3	.25
Follow-up 12 mo.	1.1	(1.6)	0.9	(1.2)	0.3	−0.4 to 0.9	.44
Impulsiveness (ZAN-BPD)							
End of treatment	1.8	(2.1)	1.9	(2.1)	−0.2	−1.1 to 0.8	.70
Follow-up 3 mo.	1.1	(1.5)	1.5	(1.6)	−0.4	−1.1 to 0.4	.34
Follow-up 12 mo.	1.2	(1.7)	1.0	(1.1)	0.2	−0.4 to 0.8	.42
Interpersonal (ZAN-BPD)							
End of treatment	1.3	(1.9)	1.7	(1.5)	−0.4	−1.2 to 0.4	.35
Follow-up 3 mo.	1.1	(1.2)	1.3	(1.5)	−0.2	−0.8 to 0.4	.47
Follow-up 12 mo.	1.2	(1.5)	1.0	(1.4)	0.2	−0.5 to 0.8	.58

Table 2. Secondary outcomes on depression, internalizing and externalizing symptoms, social functioning, and emergency room visits and hospitalizations at end of treatment, and 3 and 12 months follow-up.
Group means (SD) for the two therapies (available cases), and covariate-adjusted group difference with 95% confidence intervals

	TAU		MBT		TAU − MBT	95% CI	*p*
Depression (BDI-Y)							
End of treatment	22.2	(12.3)	23.3	(11.2)	−0.4	−6.5 to 5.6	.88
Follow-up 3 mo.	19.7	(11.2)	24.0	(12.8)	−3.7	−9.6 to 2.2	.21
Follow-up 12 mo.	20.1	(11.4)	21.4	(9.7)	−1.2	−5.4 to 3.1	.58
Externalizing* - Patient report (YSR)							
End of treatment	56.1	(9.4)	54.8	(7.9)	0.2	−4.2 to 4.7	.92
Follow-up 3 mo.	55.1	(9.2)	54.7	(8.4)	0.1	−3.5 to 3.8	.95
Follow-up 12 mo.	57.2	(8.3)	56.9	(9.4)	0.1	−4.4 to 4.5	.98
Internalizing* - Patient report (YSR)							
End of treatment	45.9	(7.0)	48.5	(9.6)	−2.4	−6.9 to 2.1	.29
Follow-up 3 mo.	45.0	(9.0)	48.9	(10.1)	−4.0	−8.4 to 0.5	.08
Follow-up 12 mo.	46.2	(9.3)	45.7	(8.0)	0.7	−4.4 to 5.8	.79
Externalizing* - Parental report (CBCL-P)							
End of treatment	56.5	(11.0)	53.9	(10.5)	3.0	−3.7 to 9.7	.36
Follow-up 3 mo.	57.7	(12.4)	53.9	(10.3)	2.8	−3.7 to 9.3	.38
Follow-up 12 mo.	55.9	(15.0)	53.6	(10.8)	2.9	−3.8 to 9.6	.38
Internalizing* - Parental report (CBCL-P)							
End of treatment	50.1	(9.1)	47.4	(7.7)	2.5	−1.6 to 6.6	.22
Follow-up 3 mo.	50.2	(8.6)	49.2	(7.4)	1.1	−2.8 to 4.9	.57
Follow-up 12 mo.	49.8	(10.5)	47.7	(9.7)	2.5	−2.9 to 7.9	.34
Global Functioning (CGAS)							
End of treatment	46.7	(12.6)	46.1	(13.4)	0.9	−4.9 to 6.7	.75
Follow-up 3 mo.	46.5	(11.4)	46.0	(11.7)	0.9	−3.9 to 5.6	.71
Follow-up 12 mo.	50.4	(11.9)	50.1	(13.6)	0.9	−4.5 to 6.3	.74
Hospital admissions							
End of treatment	1.0	(3.9)	9.3	(42.0)	RR** = 0.03	0.0 to 0.6	.023
Follow-up 3 mo.	0.0	(0.1)	1.2	(6.2)	RR** = 0.01	0.0 to 0.4	.013
Follow-up 12 mo.	0.1	(0.7)	3.2	(12.7)	RR** = 0.00	0.0 to 0.1	.003
Emergency room visits							
End of treatment	0.2	(0.5)	0.5	(1.5)	RR = 0.40	0.2 to 1.0	.046
Follow-up 3 mo.	0.1	(0.2)	0.1	(0.5)	RR = 0.35	0.1 to 1.3	.013
Follow-up 12 mo.	0.2	(0.6)	0.4	(0.9)	RR = 0.50	0.2 to 1.0	.06

*T scores
**RR = risk ratio TAU/MBT

Table 3. Overview of use of psychoactive drugs

	End of treatment		3 months follow-up		12 months follow-up	
	MBT-G	TAU	MBT-G	TAU	MBT-G	TAU
	n = 54	*n* = 56	*n* = 54	*n* = 56	*n* = 55	*n* = 56
	n (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)
ADHD	11 (20)	10 (18)	13 (24)	10 (19)	8 (15)	10 (18)
Anti-psychotics	14 (26)	9 (16)	12 (22)	9 (16)	14 (25)	9 (16)
Anti-depressants	13 (24)	8 (14)	10 (19)	8 (14)	12 (22)	10 (18)
Other	11 (20)	6 (11)	13 (24)	10 (18)	11 (20)	8 (14)
$\geq$ 3 drugs	5 (9)	1 (2)	4 (7)	2 (4)	4 (7)	4 (7)