Impact of clinical severity on treatment response in a randomized controlled trial comparing day hospital and intensive outpatient mentalization-based treatment for borderline personality disorder

Running title: Impact of severity on MBT

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Abstract

This study examined the impact of clinical severity on treatment outcome in two programs that differ markedly in treatment intensity: day hospital mentalization-based treatment (MBT-DH) and intensive outpatient mentalization-based treatment (MBT-IOP) for borderline personality disorder (BPD). A multicenter randomized controlled trial was conducted. Participants include the full intention-to-treat sample of the original trial of *N* = 114 randomized BPD patients (MBT-DH *n* = 70, MBT-IOP *n* = 44), who were assessed at baseline and subsequently every 6 months up to 36 months after start of treatment. Outcomes were general symptom severity, borderline features, and interpersonal functioning. Clinical severity was examined in terms of severity of BPD, general symptom severity, comorbid symptom disorders, comorbid personality disorders, and cluster C personality features. None of the severity measures was related to treatment outcome or differentially predicted treatment outcome in MBT-DH and MBT-IOP, with the exception of a single moderating effect of co morbid symptom disorders on outcome in terms of BPD features, indicating less improvement in MBT-DH for patients with more symptom disorders. Overall, patients with varying levels of clinical severity benefited equally from MBT-DH and MBT-IOP,

indicating that clinical severity may not be a useful criterion to differentiate in treatment intensity.

Keywords: borderline personality disorder, mentalization-based treatment, randomized clinical trial, predictors, treatment response.

Introduction

Mentalization-based treatment (MBT) is an empirically supported treatment for borderline personality disorder (BPD).[1-3] Two types of MBT of different treatment intensity have been developed and empirically evaluated, namely, day hospital MBT (MBT-DH)[4-9] and intensive outpatient MBT (MBT-IOP).[10-13] Although previous results indicated no major overall differences in treatment outcome between MBT-IOP and MBT-DH,[2,14] no studies to date have investigated predictors of differential treatment outcome. Yet, given the large difference in treatment intensity between the two types of MBT, it is important for both the optimization of health-care resource use and for clinical decision making to identify potential patient factors that may be associated with a differential treatment response to MBT-DH versus MBT-IOP. Such studies are all the more important as there is little consensus concerning factors that may be associated with treatment outcome in psychotherapy for BPD in general. A systematic review by Barnicot et al.[15] concluded that pretreatment severity and patient-rated therapeutic alliance were the only consistent positive predictors of treatment outcome in psychotherapy for BPD. Specifically, higher pretreatment severity was positively associated with improvement.[15] However, only 12 studies were included in this systematic review, and even within these studies there was large variability in terms of the operationalization of pretreatment severity and in outcome measures. Moreover, some high-quality studies included in this review found no significant effects of pretreatment severity[16,17] or reported that pretreatment

severity was negatively associated with outcome.[18] For MBT specifically, two recent studies reported that more severe patients showed greater improvement in MBT than in non-specialist treatments.[19,20] In the study of Bateman and Fonagy,[20] the beneficial effect of MBT over non-specialist treatment for more severe patients was specifically associated with the presence of comorbid cluster C personality disorders. This parallels previous findings that comorbid avoidant traits may negatively impact both the natural course and treatment outcome in patients with personality disorder.[21,22]

The current study aims to investigate the impact of clinical severity on the treatment outcome of MBT for BPD patients receiving two types of MBT with varying treatment intensity, that is, MBT-DH versus MBT-IOP. Building on previous studies in this area,[19,20] clinical severity was operationalized in terms of (a) severity of BPD, (b) general symptom severity, (c) comorbid symptom disorders, (d) comorbid personality disorders, and (e) cluster C personality features. Consistent with the meta-analysis of Barnicot et al.,[23] we expected baseline clinical severity to be associated with greater improvement in both types of MBT. Moreover, more severely affected patients were expected to show greater benefits in the MBT-DH program than in MBT-IOP, as MBT-DH involves a substantially higher treatment intensity. Finally, based on findings of previous studies indicating a potential negative impact of comorbid cluster C traits on treatment outcome for BPD,[20,21] we expected patients with cluster C traits to benefit more from MBT-DH than from MBT-IOP, as the holding environment of MBT-DH may provide patients with more opportunities for social learning within a relatively safe social context. By contrast, patients in MBT-IOP may struggle more to generalize treatment effects because the outpatient nature of the program provides less scaffolding.

Materials & Methods

This study was approved by the Medical Ethical Committee of Erasmus Medical Center, Rotterdam, the Netherlands (NL38571.078.12), and the study was registered at the Netherlands Trial Register, https://www.trialregister.nl/ (identifier: NTR2292). Written informed consent was obtained from all participants. Inclusion and exclusion criteria, patient characteristics, and randomization procedures, including study enrollment and allocation, have been described in detail elsewhere.[14] Participants included the full intention-to-treat sample of the original trial of *N* = 114 BPD patients who were randomly allocated to MBT-DH (*n* = 70) and MBT-IOP (*n* = 44) in a multicenter trial at three mental health-care institutes in the Netherlands. Clinical severity indices were assessed at baseline, before randomization. Outcome was assessed at baseline, start of treatment and subsequently every 6 months up to 36 months after start of treatment.

Measures

Outcome measures The primary outcome measure was general symptom severity as assessed by the Global Severity Indicator (GSI) of the Brief Symptom Inventory (BSI).[24,25] Secondary outcome measures were (a) interpersonal functioning as assessed by the Inventory of Interpersonal Problems (IIP)[26,27] and (b) borderline features as measured by the Personality Assessment Inventory (PAI-BOR).[28]

Predictors/moderators Five indices of baseline clinical severity were used: (a) severity of BPD, assessed by means of the number of BPD criteria based on the Structured Clinical Interview for DSM-IV Axis II Personality Disorders (SCID-II);[29] (b) general symptom severity, as assessed by means of the GSI of the BSI, (c) the number of comorbid symptom disorders as measured by the Structured Clinical

Interview for DSM-IV Axis I Disorders (SCID-I);[30] (d) the number of comorbid personality disorders and the dimensional score on personality disorder features (SCID-II); and (e) the number of, and dimensional score on, cluster C personality features (SCID-II).

Treatment interventions

A detailed description of MBT-DH and MBT-IOP is provided elsewhere.[14] Briefly, both MBT-DH and MBT-IOP involve weekly individual psychotherapy, but the intensity of group therapy in the two treatments differs markedly. MBT-IOP involves two group psychotherapy sessions per week, whereas MBT-DH entails a five days per week day hospital program, with nine group therapy sessions per week, including five group psychotherapy sessions, and art- and writing therapy. Treatment adherence to the MBT model in the intensive treatment phase was rated as adequate by three independent raters and did not differ between MBT-DH and MBT-IOP.

Statistical analyses

All analyses were performed using IBM SPSS Statistics Version 25.0 for Windows based on the intention-to-treat principle. Differences in severity indices at baseline were investigated using two-tailed independent sample *t*-tests. Correlations between severity indices and any of the outcome measures were calculated on observed data using Pearson's product-moment correlation across time points and per time point separately. For predictor and moderator analyses, multilevel modeling was conducted with participants as random effect, to best accommodate the missing data that are an inevitable feature of longitudinal follow-up, and to deal with the dependency of repeated measures within subjects over time. Time points were coded –6, –5, –4, –3, –2, –1, and 0, implying that regression coefficients involving

time measured the rate of change from baseline to 36-month follow-up, and regression intercepts referenced group differences at the last time point. Based on previous models of the data, random slopes were assumed in the models for each outcome variable. Models with higher order time polynomials (i.e., quadratic and cubic time functions) overall did not show a better fit to the data compared with linear models based on the Akaike Information Criterion[31] or Schwarz's Bayesian Information Criterion.[32] For reasons of parsimony, we therefore report linear models. Treatment groups were coded 0 = MBT-IOP and 1 = MBT-DH. Consequently, differences in slope were regarded as differences in the slope of MBT-DH compared with MBT-IOP. For the mixed-model effects, the main effect of group and the respective severity indices as well as the linear rate of change from baseline to 36 months across all levels of severity (for both treatment groups combined) are reported, along with the interaction effects with treatment group. The critical coefficients for each severity indicator are (a) the severity predictor × time interaction, indicating the predictive value of the severity indicator on the rate of change, that is, the overall treatment response over time at varying levels of the severity indicator; and (b) the severity × time × group interaction, indicating the moderating value of the severity indicator on the rate of change, that is, the differential treatment response over time for the MBT-DH and MBT-IOP groups at varying levels of the severity indicator. To check for robustness of our results in a less complex statistical model, we also ran mixed-model analyses for the first, two-way interaction (predictor × time) separately. As this model yielded similar results, only estimates from the three-way interaction model are reported. Results of the two-way interaction model are available upon request from the first author. For the outcome measure BSI, the BSI

general symptom severity index at baseline was omitted from the analyses, as the predictor was considered too proximal to the outcome of interest.

Results

Patients in MBT-DH (*n* = 70) and MBT-IOP (*n* = 44) did not differ on any of the baseline clinical severity indices (Table 1). Table 2 presents the correlations between the severity indices and outcome measures, showing that almost all of the severity indices were significantly correlated with each of the outcome measures. However, the significant correlations were mainly observed at baseline and mostly not significant during treatment and follow-up, with the exception of BPD features as outcome measure that remained significantly correlated with several severity indices over time.

As summarized in Table 3, against expectations, none of the severity indices were significantly associated with treatment outcome, whether assessed in terms of general symptom severity, borderline features, or interpersonal problems. Moreover, contrary to our hypothesis that more severe patients would benefit more from MBT-DH than from MBT-IOP, severity did not moderate treatment outcome in MBT-DH versus MBT-IOP, as indicated by nonsignificant three-way (predictor × group × time) interactions, with one notable exception. The number of symptom disorders assessed at baseline moderated treatment outcome in terms of borderline features (β = 0.58, 95% CI = 0.08 to 1.07, t = 2.33, p = .022). As shown in Figure 1, whereas patients in MBT-IOP followed a similar trajectory of change in borderline features over time irrespective of the number of comorbid symptom disorders, for patients in MBT-DH a greater number of symptom disorders at baseline was associated with a

slower rate of change in borderline features over time. (For multilevel estimates and model parameters, see Supplemental Table S1)

[insert Figure 1]

Discussion

This study showed that, in contrast to the conclusion of a recent systematic review, clinical severity, operationalized in multiple ways, did not consistently predict or moderate treatment response of BPD patients to two types of MBT. Only the number of symptom disorders was found to moderate treatment outcome in terms of borderline features, with patients with more symptom disorders showing less improvement in borderline features compared with those with fewer symptom disorders in MBT-DH. In MBT-IOP no such effect was observed. It may be conjectured that MBT-DH is better suited for the 'core BPD' subtype[33] whereas MBT-IOP might be better suited for patients with a more heterogeneous clinical presentation evidenced by higher levels of comorbid symptom disorders. MBT-DH, with its higher intensity and possibly more schematic, fixed delivery of treatment, may offer fewer options for tailoring treatment to individual needs or characteristics, such as comorbidities related to symptom disorders. In contrast, MBT-IOP may be better suited for a more personalized approach. This inference holds relevance for clinical decision making, as in daily clinical practice comorbidity with symptom disorders is often used as an indication criterion toward higher intensity programs. Alternatively, the differential impact of the number of symptom disorders on treatment outcome in MBT-DH versus MBT-IOP might be explained by greater care consumption of more severe patients in MBT-IOP. Post-hoc analyses showed no differences in the use of mental health care in MBT-IOP compared to MBT-DH over the three-year follow-up period (see Supplemental table S2). Yet, clinical severity, assessed in terms of the

number of symptom disorders, correlated positively with greater medication use in MBT-IOP, but not in MBT-DH (see Supplemental table S3). This may in part explain why clinical severity was not related to outcome in terms of borderline features in MBT-IOP. Together, these findings suggest that greater attention to presenting symptoms such as depression, anxiety and substance abuse in BPD patients, might improve treatment outcome in MBT, and perhaps serve to improve treatment selection. However, caution is needed in this context, as the moderating effect of symptom disorders may have been a chance finding as none of the other indices of severity was related to outcome, particularly given the many comparisons. Moreover, no other differences were found between the two types of MBT in terms of additional treatment.

Finally, comorbid cluster C features did not moderate treatment outcome. As noted, it has been suggested that avoidant features might hamper treatment, particularly with an interpersonally oriented treatment such as MBT.[20] For this reason, we hypothesized that patients with comorbid cluster C features might benefit more from MBT-DH, as it may include more opportunities for social learning within a relatively safe interpersonal context. However, such an effect was not observed, and we also did not find a negative impact of comorbid cluster C traits on overall treatment outcome in MBT, which contrast previous findings in the study by Bateman & Fonagy.[20] The (interplay of) factors impacting patients' ability to generalize therapeutic gains into their lives may be much more complex than captured in the comorbidity of cluster C traits. Over years of evolving psychopathology, some patients may have become socially isolated, whereas others may be surrounded by harmful relationships, both of which can negatively impact the generalization of therapeutic gains. Hence, the comorbidity of cluster C traits might represent a

relatively narrow proxy for assessing the quality of the interpersonal context, which we and others have previously speculated to be of particular importance in (the generalization of) treatment success.[34,35]

Overall, findings from this study suggest that more severe patients with BPD do not necessarily need high-intensity treatments. The general absence of differences in treatment response between the two types of MBT as a function of clinical severity in the current study is consistent with the emphasis in MBT on tailoring treatment to each individual patient's needs.[36] In parallel to recent findings from the same trial suggesting that patients with substantial childhood trauma may benefit more from MBT-DH than MBT-IOP when the domain of interpersonal functioning is considered as the outcome,[37] the current results may highlight the necessity of personalizing treatment. Although in both studies the impact of the respective patient characteristics on differential treatment outcome was fairly low, cross-validation of the few significant findings in future research may guide the adaptation of treatment programs to better accommodate patients' heterogeneous clinical presentations within MBT programs. From a broader perspective, as noted, two previous studies on predictors of outcome in MBT found that more severe BPD patients benefited more from MBT than from generic treatments.[19,20] The fact that clinical severity did not consistently impact treatment outcome in two types of MBT with differing treatment intensity may be a further indication that it may not be the treatment setting or treatment intensity as such, but rather the adherence to a specialist treatment model that is associated with treatment outcome, particularly in more severe patients. From this perspective, more severely affected patients do not necessarily require a higher intensity of treatment, but a structured treatment format with a clear rationale that enables therapists to stay adherent to a model when faced

with the challenges in the therapeutic process often presented by more severe patients.

Future research should examine how contextual factors affect treatment outcomes, including the effects of treatment setting and intensity in relation to the (social) context in which individuals are challenged to generalize therapeutic gains. Moreover, future studies may shed light on the impact of specific treatment components thereby optimizing personalized treatment trajectories. Qualitative research on patients' experiences and perspectives regarding factors relevant for treatment selection, treatment outcomes and generalization could enhance the interpretation of findings.

Findings from this study need to be interpreted in the context of important limitations. First, this study reported post-hoc analyses using data from a trial that was not specifically designed to investigate the impact of severity on outcome in MBT-DH and MBT-IOP. Hence, the current findings should be considered preliminary. Second, although we used multiple indices for the operationalization of severity, clinical severity may not be best conceptualized by means of single indices, but rather as an interaction of various clinical features and contextual factors (such as the quality of the interpersonal environment). The selection of severity indices in this study was based on previous studies,[19,20] to allow comparison across studies. Future research should be aimed at identifying the impact of more complex, composite, and interacting dimensions of severity. Third, there was quite a large proportion of missing data at the 24-, 30-, and 36-month follow-up assessments. Mitigating this concern is that there were no differences in the proportions of missing data between the two treatments.

Conclusions

This study may have important implications for clinical decision making in everyday treatment selection for patients with BPD. The current results may indicate that the intuitively appealing and commonly used criterion of severity may not be a useful indication criterion in selecting BPD patients for whom higher intensity treatment is indicated.

List of abbreviations

MBT	Mentalization-based treatment
MBT-IOP	Intensive outpatient mentalization-based treatment
MBT-DH	Day Hospital mentalization-based treatment
BPD	Borderline personality disorder
GSI	Global Severity Indicator
BSI	Brief Symptom Inventory
PAI-BOR	Personality Assessment Inventory – Borderline subscale
IIP	Inventory of Interpersonal Problems
SCID-II	Structured Clinical Interview for DSM-IV Axis II Personality Disorders
SCID-I	Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I)

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Authors' contributions PL, RV, JJMD, JHK, DLB and DJF designed the study and directed the trial. DLB and PL were responsible for MBT quality aspects within the

trial. DJF and MLS coordinated the trial and data collection. MLS and JJMD were responsible for trial implementation and data collection at the treatment sites. MLS performed the data preparation. MLS and MB performed the data analysis. MLS, MB, DJF, JJVB and PL interpreted the data and drafted the article. JHK, DLB, JJMD and RV revised the manuscript. All authors approved the final manuscript.

Data availability statement The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Conflicts of interest disclosure MS, PL, and DB have been involved in the training and dissemination of MBT. The other authors declare that they have no competing interests.

Ethics approval statement This study was approved by the Medical Ethical Committee of Erasmus Medical Center, Rotterdam, the Netherlands (NL38571.078.12).

Patient consent statement

Written informed consent was obtained from all participants.

Clinical trial registration The study was retrospectively registered at the Netherlands Trial Register, https://www.trialregister.nl/ (identifier: NTR2292).

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Table 1. Descriptives of the severity indices at baseline

	MBT-IOP (*n* = 44)		**MBT-DH (*n* = 70)**		
	Mean	SD	Mean	SD	*p*
Number of BPD criteria	6.39	1.17	6.51	1.33	.61
General symptom severity	1.94	0.74	1.94	0.73	.984
Number of symptom disorders	2.61	2.28	2.59	2.07	.95
Number of comorbid PDs	1.45	0.62	1.33	0.47	.26
Dimensional PD score	102.86	8.43	101.44	7.11	.34
Number of cluster C features	2.64	2.45	2.27	2.19	.413
Dimensional cluster C score	29.59	5.31	28.71	5.05	.38

Abbreviations: BPD = borderline personality disorder. MBT-DH = day hospital mentalization-based treatment. MBT-IOP = intensive outpatient mentalization-based treatment. PD = personality disorder.

Table 2. Pearson's correlation coefficients between severity indices and general symptom severity, borderline features, and interpersonal problems

	Symptom distress (BSI)		**Borderline features (PAI-BOR)**		**Interpersonal problems (IIP)**	
	r	Significant at[b]	*r*	Significant at[b]	*r*	Significant at[b]
Number of BPD criteria	.131**	baseline	.140**	baseline	–.008	–
General symptom severity			.361**	baseline–6–12–18–24–30–36	.318**	baseline–12–18–24–30–36
Number of symptom disorders	.187**	baseline–24	.206**	baseline–18–24	.108*	–
Number of comorbid PDs	.115*	–	.149**	36	.159**	6–12
Dimensional PD score	.216**	baseline	.287**	baseline–12–18–30–36	.203**	baseline
Number of cluster C features	.001**	–	.171	–	.140**	baseline–6
Dimensional score cluster C	.082	baseline–6–12–30–36	.099*	–	.198**	baseline–12

*p-value significant at .05 level, ** p-value significant at .01 level. b. r = Pearson's correlation coefficients over all time points. [b]

These columns indicate the time points (baseline, 6, 12, 18, 24, 30, and/or 36 months after start of treatment) at? which the severity

indices were significantly associated with outcome at < .05 level. Abbreviations: BSI = Brief Symptom Inventory. IIP=Inventory of Interpersonal Problems. PAI-BOR = Personality Assessment Inventory borderline subscale. PD = personality disorder.

Table 3. Summary of *p*-values related to interaction effects of severity indices as predictor of treatment outcome overall and between MBT-IOP and MBT-DH

	Symptom distress (BSI)		**Borderline features (PAI-BOR)**		**Interpersonal problems (IIP)**	
	Predictor×time	Predictor×time×group	Predictor×time	Predictor×time×group	Predictor×time	Predictor×time×group
Number of BPD criteria	.60	.88	.29	.48	.34	.39
Symptom severity			.28	.21	.20	.21
Number of symptom disorders	.77	.53	.53	.02*	.31	.88
Number of comorbid PDs	.21	.32	.50	.70	.91	.31
Dimensional PD score	.28	.29	.07	.84	.86	.41
Number of cluster C features	.11	.23	.72	.58	.29	.22
Dimensional cluster C score	.13	.17	.56	.53	.25	.11

Abbreviations: BSI = Brief Symptom Inventory. IIP=Inventory of Interpersonal Problems. PAI-BOR = Personality Assessment Inventory borderline subscale. PD = personality disorder.