Mentalization-Based Treatment for Concurrent Borderline Personality Disorder and Substance Use Disorder: A Randomized Controlled Feasibility Study

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Keywords
Psychotherapy · Borderline personality disorder · Substance-related disorders · Randomized controlled trial

Abstract

\textbf{Aims:} There is a scarcity of clinical trials on psychological treatments for concurrent borderline personality disorder (BPD) and substance use disorder (SUD). Mentalization-based treatment (MBT) have shown efficacy in several trials on BPD. The aim of the present study was to examine the feasibility and effectiveness of MBT for concurrent BPD and SUD. \textbf{Methods:} Patients (\( n = 46 \)) with concurrent BPD and SUD were randomized either to MBT in combination with SUD treatment (\( n = 24 \)) or to SUD treatment alone (\( n = 22 \)). Outcome was measured after 18 months using objective data, as well as interview and self-report measures. \textbf{Results:} There was no significant difference between the groups on any outcome variable. No suicide attempts occurred in the MBT group in contrast to 4 suicide attempts that occurred in the control group – a difference that did not reach statistical significance (\( p = 0.06 \)). A majority of the therapists did not show sufficient MBT adherence and quality. \textbf{Conclusion:} MBT for patients with concurrent BPD and SD does not appear to be harmful; on the other hand, it is possibly helpful in reducing the risk involved in suicide attempts.

Introduction

Borderline personality disorder (BPD) and substance use disorder (SUD) are both severe psychiatric disorders associated with impaired functioning and increased risk of suicide and premature death [1–3]. Concurrent BPD and SUD indicates even more severity and complexity and such co-morbidity is associated with additionally increased rates of suicidal and self-harming behaviour [4–6]. Patients with this dual diagnosis offer a challenge for treatment providers and there is widespread pessimism among practitioners about the possibilities of successful
Mentalization refers to the capacity to apprehend and make sense of oneself and other humans in terms of subjective states and mental processes, and MBT is based on research findings indicating that recurrent mentalization failures is a core feature among individuals with BPD [25, 26]. MBT for BPD is typically delivered as a combination of individual and group therapy weekly during 18 months and it aims at strengthening the patients mentalizing capacity in order to reduce the BPD core problems such as poor impulse control, emotional instability, impaired interpersonal functioning, unstable self-concept and self-destructiveness [27]. MBT have been tested in 3 RCTs for adult patients with BPD. The first study \( n = 36 \) compared MBT to standard psychiatric care and MBT was superior at termination on all outcome measures, including suicide attempts, self-harm and depression, as well as days of hospitalization and social functioning [28]. The effects of MBT maintained 5 years after termination [29]. The second study \( n = 134 \) compared MBT to structured clinical management and MBT was superior at termination on all outcome measures, including suicide attempts, self-harm and psychiatric symptoms, as well as days of hospitalization [30]. The third study \( n = 85 \) compared MBT to supportive group therapy and MBT was only superior on the global assessment of functioning, while there were clear improvements in both treatments with no significant within-group effects on neither of the other measures [31]. In addition, one study tested MBT for adolescents with depression and self-harming behaviour \( n = 80 \) with TAU as control condition, and the results showed that MBT had superior outcomes on depression and self-harm [32].

Methodology

This research project, MBT for Dual Diagnosis – A RCT was a registered clinical trial (ISRCTN 98982683) approved by the Stockholm Regional Ethical Review Board (Registration number: 2007/642-31/1). All subjects gave their informed consent for participation. The trial was conducted at the Stockholm Centre for treatment [7–9]. The prevalence of SUD among patients diagnosed with BPD has been estimated to be over 50% [10]. Among patients treated for dependence on illicit drugs, the occurrence of co-morbid BPD has been estimated to 18% [11].

Although the research literature is extensive on the efficacy of several psychological therapies for BDP [12] and for SUD [13–17] separately, studies focusing on treatment for concurrent BDP and SUD are still scarce. A recent systematic review of psychological treatments for co-occurring SUD and BPD included 10 studies, examining 3 different interventions: dialectical behaviour therapy (DBT), dynamic deconstructive psychotherapy (DDP) and dual-focused schema therapy [18]. However, only 3 of these studies were original reports on randomized controlled trials (RCT) with inclusion criteria of co-occurring BPD and SUD. Two studies examined the effect of DBT in combination with medication, both including only female patients and both with small sample sizes \( n = 28 \) and \( n = 23 \) respectively) [19, 20]. These studies indicated some advantages in outcome of DBT combined with medication, compared to treatment as usual (TAU) [19] and compared to comprehensive validation therapy with 12-step (CVT + 12S) [20]. In the first trial, 42% of the patients in DBT terminated prematurely [19]. In the second trial, the dropout rate in DBT was 36% compared to no dropout in CVT + 12S [20]. The third RCT \( n = 30 \) included both female and male patients in DDP, a type of psychodynamic therapy especially designed for patients with severe personality disorders, and the study showed that improvements were larger in DDP than in TAU [21]. The dropout rate in DDP was 33% [21]. The RCTs conducted on DSFT included patients with SUD and a mixture of different personality disorders, and the studies provided no empirical support for the effectiveness of DSFT [22, 23]. Very high dropout rates were noted in these trials testing dual-focused schema therapy – 77% for homeless dual diagnosis patients [22] and 58% for patients in residential treatment [23].

Mentalization-based treatment (MBT) is a contemporary psychodynamic therapy developed primarily for BPD [24]. Mentalization refers to the capacity to apprehend and make sense of oneself and other humans in terms of subjective states and mental processes, and MBT is based on research findings indicating that recurrent mentalization failures is a core feature among individuals with BPD [25, 26].
MBT for Concurrent BPD and SUD

Dependancy Disorders, Stockholm County Council, in collaboration with the Centre for Psychiatry Research at Karolinska Institutet. Patients were recruited through outpatient addiction treatment services throughout Stockholm County, through case-finding among the social service offices in the region and through advertising in newspapers. The study was originally planned to include 80 (40 + 40) patients, based on a power calculation. However, due to the slow rate of patient enrollment and lack of economical resources, the inclusion period had to stop prematurely at n = 46. Accordingly, focus of the study shifted from efficacy to feasibility and effectiveness. The principal investigator (PI) was responsible for the study being conducted in accordance to the Helsinki Declaration (revised version from 2000) and Good Clinical Practice (GCP). The study was monitored by the Karolinska Trial Alliance (KTA) in accordance to ICH-GCP.

Patients were screened and included between 2009 and 2013, which means that the last patient reached the study endpoint in 2015. Inclusion criteria were males and females aged 18–65 years, fulfilling diagnostic criteria for BPD and substance dependence in accordance with the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) [35], and currently undergoing treatment at a substance dependence treatment clinic. Exclusion criteria were schizophrenia, schizoaffective disorder, bipolar disorder type I, cognitive impairment (including mild cognitive impairment: IQ <85), autism spectrum disorders, psychopathy, participation in psychotherapy outside of the study (ongoing or terminated less than 90 days before inclusion) and not being able to communicate in the Swedish language without an interpreter.

The study was a randomized controlled trial with 2 parallel arms, in which efforts were made to keep external raters unaware of the patient’s treatment assignment. The randomization was conducted by the KTA using an urn procedure. The randomization was made in blocks and the researchers were not informed of the block size. KTA prepared sealed randomization envelopes with information about each patient’s treatment assignment. The project received 248 referrals, of which 84 patients were assessed for eligibility and 46 of them included in the trial as described in the flow diagram in Figure 1.

After inclusion, patients were randomized to either of 2 treatment arms – (1) MBT during 18 months as a complement to standard SUD treatment (2) standard SUD treatment alone.

Patients

Of the 46 included patients, 24 were randomized to MBT and 22 were randomized to the control condition. The mean age at inclusion was 36.7 (SD 9.6), in the range from 20 to 54 years. Other patient characteristics including psychiatric diagnoses are described in Table 1.

Treatment and Therapists

The MBT included a combination of individual therapy and group therapy during 18 months. The MBT therapists worked together in a team with regular supervision and team meetings, in which the therapists shared information about the patients and discussed their mutual therapeutic work.

Nine therapists participated in the trial – 7 females and 2 males, aged 44–60 when the project began. All therapists had at least basic psychotherapy training with psychodynamic orientation, and 7 of them also had advanced psychotherapy training, they being Swedish licensed psychotherapists. As for the professional background, 3 were psychologists, 3 were social workers, 1 was a nurse and 2 were psychiatric aides. They all had several years of experience in working with SUD as well as MBT training in the form of the MBT Basic Course (3 days) taught by Anthony Bateman and Peter Fonagy. Before entering the project, all therapists conducted a training treatment that was videotaped, judged for treatment integrity using version 4 of the MBT adherence scale and approved by MBT supervisors and the project leader. During the project, 3 therapists conducted both individual and group therapy, 5 conducted only individual therapy and 1 conducted only group therapy. The therapists were in MBT supervision once a week during the project period. Samples of individual therapy sessions from the project were tested by independent raters for therapist MBT adherence and quality using the final version of the scale [36].

Measures

The patients’ diagnoses on DSM-IV Axes I and II were established using the Structured Clinical Interview for DSM-IV Disorders I (SCID-I) [37] and II (SCID-II) [38]. Screening for cognitive impairment was done using the subscales Vocabulary and Block Design from Wechsler Adult Intelligence Scale – 3rd edition [39]. The results on these 2 subtests have shown correlation of r = 0.90 with total intelligence quote [40, 41].
The frequency of deliberate self-harm behaviour was investigated using the short version of the self-report scale Deliberate Self-Harm Inventory (DSHI-9) [46] in a Swedish translation that has shown satisfactory reliability [47].

Psychiatric symptoms were measured with the Swedish version of the Symptom Checklist-90-Revised [48, 49], which has shown a satisfactory reliability (Cronbach’s α = 0.97) [50]. As the 9 subscales are highly correlated, the Global Symptom Index (GSI) was used as an aggregate measure.

Interpersonal problems were investigated using a shortened version (64 items) of the self-report scale Inventory of Interpersonal Problems (IIP) [51]. The total mean score was used as a global measure of the level of interpersonal problems.

Reflective functioning (RF) as measured with the Reflective Functioning Scale [52] was used to assess the level of explicit mentalizing about attachment relationships. These assessments were based on the Brief Reflective Functioning Interview, which is a semi-structured interview including 11 questions about the relationship with one parent and one current important relationship [53, 54].

Measurements were conducted at baseline (screening and inclusion visits) and after 6, 12 and 18 months. Endpoint was after 18 months, which signified termination of MBT treatments. Except for the screening instruments (SCID-I and II, Wechsler Adult Intelligence Scale – 3rd edition, AQ and Psychopathy Checklist: Screening Version) only used at baseline, the same set of measures were used at all 4 time points (baseline, 6, 12 and 18 months) – that is, BPDSI-IV, TLFB, DSHI-9, Symptom Checklist-90-Revised, IIP and RF. At endpoint after 18 months, SCID-I and II interviews were repeated.

Three additional outcome variables were used based on objective data: Number of adverse events (AE), suicide attempts specifically, and days in inpatient care. The type of events defined as AEs included relapse in substance abuse, overdose and psychiatric or somatic illness, as well as violent acts and self-harm behaviour. Suicide attempts and other AE were recorded via direct contact with patients and health care staff, as well as from reviewing the case records. As the responsibility for treatment of substance abusers in Sweden is shared by the health care system organized under the county councils and the social services, inpatient care for SUD patients could take place at addiction treatment services and psychiatric clinics (both belonging to the health care system), as well as treatment facilities operating under the social services. Number of days of inpatient care was monitored for each patient during the study. The number of days of hospitalization within the health care system were controlled and adjusted retrospectively through collecting data from the Stockholm County Council’s registers.

### Statistical Analysis

The original power calculation was based on the power table provided by Kazdin [55]. For the between-group effect, we expected at least $d = 0.7$, which meant that with $80\%$ power and $\alpha = 0.05$ each arm should include 33 patients. As we expected $20\%$ attrition, we decided that the trial should include 40 + 40 patients. Due to the recruitment problems in the project, our initial power calculation had to be revised. The power was approximately $65\%$, given $n = \ldots$

#### Table 1. Patient characteristics at inclusion ($n = 46$)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>$n$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>37</td>
<td>80.4</td>
</tr>
<tr>
<td>Married/living together with partner</td>
<td>13</td>
<td>28.2</td>
</tr>
<tr>
<td>Has children</td>
<td>24</td>
<td>52.2</td>
</tr>
<tr>
<td>Tertiary education started</td>
<td>12</td>
<td>26.1</td>
</tr>
<tr>
<td>Employed or student</td>
<td>7</td>
<td>15.2</td>
</tr>
<tr>
<td>Born in Sweden</td>
<td>39</td>
<td>84.8</td>
</tr>
</tbody>
</table>

**Current axis I psychiatric disorder**

<table>
<thead>
<tr>
<th>Disorder</th>
<th>$n$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major depressive disorder</td>
<td>13</td>
<td>28.3</td>
</tr>
<tr>
<td>Bipolar II</td>
<td>3</td>
<td>6.5</td>
</tr>
<tr>
<td>PTSD</td>
<td>7</td>
<td>15.2</td>
</tr>
<tr>
<td>Any anxiety disorder excluding PTSD</td>
<td>30</td>
<td>65.2</td>
</tr>
<tr>
<td>Any eating disorder</td>
<td>3</td>
<td>6.5</td>
</tr>
<tr>
<td>Somatoform disorder</td>
<td>1</td>
<td>2.2</td>
</tr>
<tr>
<td>Any psychotic disorder</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Current axis I substance use disorder**

<table>
<thead>
<tr>
<th>Substance</th>
<th>$n$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>21</td>
<td>45.7</td>
</tr>
<tr>
<td>Amphetamines</td>
<td>6</td>
<td>13.0</td>
</tr>
<tr>
<td>Cannabis</td>
<td>3</td>
<td>6.5</td>
</tr>
<tr>
<td>Opioids</td>
<td>18</td>
<td>39.1</td>
</tr>
<tr>
<td>Sedatives, hypnotics, anxiolytics</td>
<td>10</td>
<td>21.7</td>
</tr>
</tbody>
</table>

**Current axis II personality disorder**

<table>
<thead>
<tr>
<th>Disorder</th>
<th>$n$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paranoid</td>
<td>9</td>
<td>19.6</td>
</tr>
<tr>
<td>Schizoid</td>
<td>1</td>
<td>2.2</td>
</tr>
<tr>
<td>Schizotypal</td>
<td>3</td>
<td>6.5</td>
</tr>
<tr>
<td>Antisocial</td>
<td>10</td>
<td>21.7</td>
</tr>
<tr>
<td>Borderline</td>
<td>46</td>
<td>100</td>
</tr>
<tr>
<td>Histrionic</td>
<td>1</td>
<td>2.2</td>
</tr>
<tr>
<td>Narcissistic</td>
<td>6</td>
<td>13.0</td>
</tr>
<tr>
<td>Avoidant</td>
<td>6</td>
<td>13.0</td>
</tr>
<tr>
<td>Dependent</td>
<td>3</td>
<td>6.5</td>
</tr>
<tr>
<td>Obsessive compulsive</td>
<td>6</td>
<td>13.0</td>
</tr>
<tr>
<td>Depressive</td>
<td>9</td>
<td>19.6</td>
</tr>
<tr>
<td>Passive aggressive</td>
<td>8</td>
<td>17.4</td>
</tr>
</tbody>
</table>

PTSD, posttraumatic stress disorder.

Screening for autism spectrum disorders was done using the Autistic-Spectrum Quotient (AQ) [42]. Patients who fulfilled criteria for either antisocial or narcissistic personality disorder were screened for psychopathy using the Psychopathy Checklist: Screening Version [43].

The BPD Severity Index-IV (BPDSI-IV) was used to yield a quantitative index of the current severity of BPD symptoms. The measure assesses BPD manifestations in detail, within the last 3 months. The measure is operationalized as number of days of inpatient care.

Three additional outcome variables were used based on objective data: Number of adverse events (AE), suicide attempts specifically, and days in inpatient care. The type of events defined as AEs included relapse in substance abuse, overdose and psychiatric or somatic illness, as well as violent acts and self-harm behaviour. Suicide attempts and other AE were recorded via direct contact with patients and health care staff, as well as from reviewing the case records. As the responsibility for treatment of substance abusers in Sweden is shared by the health care system organized under the county councils and the social services, inpatient care for SUD patients could take place at addiction treatment services and psychiatric clinics (both belonging to the health care system), as well as treatment facilities operating under the social services. Number of days of inpatient care was monitored for each patient during the study. The number of days of hospitalization within the health care system were controlled and adjusted retrospectively through collecting data from the Stockholm County Council’s registers.

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Results

Treatment Retention and Dosage

For patients randomized to MBT (n = 24), the treatment duration was in average 15.5 months (SD 4.1, range 3–18) with a mean of 63.3 MBT sessions (SD 26.7, range 10–116). Of the patients randomized to the control group (n = 22), 11 received some sort of psychotherapy (CBT, MI, PDT, MBT [one patient], mindfulness group, supportive therapy). Control group patients received on average 10.7 therapy sessions (SD 14.7, range 0–45).

Outcome on Objective Measures

In the intention-to-treat (ITT) analysis, 4 suicide attempts occurred (committed by 3 patients) in the control group in contrast to no suicide attempt in the MBT group. A comparison between the groups using Mann-Whitney U test showed only a trend towards significance (p = 0.06). No patient died during the study. The number of AE was 33 in the MBT group (with maximum of 5 AE per patient) and the corresponding number of AE in the control group was 53 (with a maximum of 10 AE per patient). However, comparing the groups using Mann-Whitney U test revealed no significant difference (p = 0.40). In the MBT group (n = 24), 11 patients had a few days of hospitalization with an average of 16.2 days (SD 37.6, range 0–151), and in the control group (n = 22), 7 patients had a few days of hospitalization, with the average of 33.2 days (SD 68.5, range 0–237). However, a comparison between the groups showed no significant difference (p = 0.74).

Table 2. Outcome for MBT versus control group, completer analysis

<table>
<thead>
<tr>
<th>Measure</th>
<th>MBT (n = 12–13)</th>
<th>Control (n = 10–13)</th>
<th>Effect of time</th>
<th>Effect of time × treatment</th>
<th>Effect sizes (positive values between groups in favour of MBT; positive values within group reflects improvement over time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPDSI-IV</td>
<td>24.6 (10.4)</td>
<td>17.0 (9.1)</td>
<td>25.8 (6.6)</td>
<td>20.7 (9.1)</td>
<td>F(1, 24) = 12.9, p = 0.001 F(1, 24) = 0.46, ns</td>
</tr>
<tr>
<td>Drinking, days</td>
<td>1.6 (2.3)</td>
<td>9.1 (9.9)</td>
<td>0.5 (1.3)</td>
<td>2.8 (4.4)</td>
<td>F(1, 21) = 7.9, p = 0.01 F(1, 21) = 2.3, ns</td>
</tr>
<tr>
<td>Days with any drug use</td>
<td>0.08 (0.29)</td>
<td>1.3 (3.0)</td>
<td>0.90 (0.30)</td>
<td>0.18 (0.60)</td>
<td>F(1, 21) = 2.0, ns</td>
</tr>
<tr>
<td>GSI</td>
<td>1.3 (0.83)</td>
<td>2.0 (0.71)</td>
<td>1.5 (0.49)</td>
<td>1.9 (0.32)</td>
<td>F(1, 23) = 34.1, p &lt; 0.001 F(1, 23) = 1.9, ns</td>
</tr>
<tr>
<td>IIP</td>
<td>2.0 (0.62)</td>
<td>1.5 (0.54)</td>
<td>2.2 (0.60)</td>
<td>1.7 (0.56)</td>
<td>F(1, 24) = 58.0, p &lt; 0.001 F(1, 24) = 0.48, ns</td>
</tr>
<tr>
<td>DSHI-9</td>
<td>1.8 (3.6)</td>
<td>2.3 (5.5)</td>
<td>3.2 (4.4)</td>
<td>2.2 (4.8)</td>
<td>F(1, 24) = 0.11, ns</td>
</tr>
<tr>
<td>RF</td>
<td>3.3 (1.2)</td>
<td>2.8 (1.2)</td>
<td>4.2 (1.3)</td>
<td>3.8 (1.6)</td>
<td>F(1, 20) = 2.7, ns</td>
</tr>
</tbody>
</table>

ns, non-significant.

Outcome on Self-Report and Interview Measures

Outcome analyses were made both in the form of completer analyses and ITT analysis with the last observation carried forward. Throughout all measures, completer and ITT analyses gave equivalent results and therefore only the results from completer analyses are described here (Table 2). Outcome analyses of the self-report and interview measures were seriously challenged by the high attrition rates, as only 24 out of 46 patients came to the measurements at endpoint 18 months (13 out of 24 patients in MBT, and 11 out of 22 patients in the control group).

With regard to severity of BPD in terms of BPDSI-IV, there was a significant effect of time (F[1, 24] = 12.9; p = 0.001) showing improvements in both the MBT and the control conditions. However, there was no significant difference between the conditions, as shown by the lack of effect of time x treatment (F[1, 24] = 0.46; p = 0.50). As for alcohol use, the results on the number of drinking days showed a significant effect of time (F[1, 23] = 34.1, p < 0.001) indicating increased drinking in both groups. There was no effect on time x treatment (F[1, 21] = 2.3; p = 0.15), indicating no significant difference between MBT and control condition. Also, for heavy episodic drinking (HED), there was a significant effect of time (F[1, 21] = 8.2; p = 0.01) showing increase of binge drinking in both groups.
No effect of time \times treatment (F[1, 21] = 1.4; p = 0.26) was detected. No significant changes were detected regarding deliberate self-harm, as indicated by no effect of time on DSHI-9 (F[1, 24] = 0.11; p = 0.75). The treatment conditions did not significantly differ on DSHI-9, which was shown in the absence of effect of time \times treatment (F[1, 24] = 0.78; p = 0.39). As for psychiatric symptoms, the results on GSI showed a significant effect of time (F[1, 23] = 34.1; p < 0.001) indicating increased symptom distress in both conditions. There was no significant difference on GSI between MBT and control condition as indicated by no effect of time \times treatment (F[1, 23] = 1.9; p = 0.18). Intercorrelation problems decreased in both conditions as indicated by a significant effect of time on IIP (F[1, 24] = 58.0; p < 0.001). However, the absence of a significant effect of time \times treatment on IIP (F[1, 24] = 0.48, p = 0.50) showed that the 2 treatment conditions did not differ on this measure. In addition, mentalizing capacity as measured with RF remained unchanged in both conditions as indicated by no effect of time (F[1, 20] = 2.7; p = 0.12). There was no significant difference between the treatment conditions regarding RF as shown by the non-significant effect of time \times treatment (F[1, 20] = 0.09, p = 0.76).

As the therapists varied in MBT adherence and quality, we tested if these factors were related to outcome. However, change in severity of BPD among patients in the MBT arm was not significantly correlated with therapist average MBT adherence and quality. Furthermore, we tested whether change in severity of BPD among patients in the MBT arm was related with the number of MBT-sessions, but the correlation was not significant.

As about half of the patients were lost to follow-up in both the MBT and the control group, we found it important to test whether there was any systematic difference between the groups with regard to which patient completed and which patient dropped out. We investigated the difference between completers and dropouts, separately for the MBT and the control group, based on a number of baseline features that could have a major prognostic impact – gender, age, initial reflective functioning, opiate dependence, cluster A PD, antisocial PD, number of PDs and AQ score. No significant difference was found between completers and dropouts in neither MBT nor the control group.

**MBT Adherence and Quality**

Despite significant efforts to train and supervise the therapists in the MBT model, most of the them had poor average results on the MDT adherence tests: only 2 therapists passed the threshold for adequate MBT, while the remaining 7 failed to do so [56].

**Discussion**

The present study is the largest randomized controlled trial of a psychological treatment for patients with concurrent BPD and SUD carried out up to this date, with a final sample size of n = 46. However, the sample size is smaller than the pre-established recruitment target and similar to previous studies with this patient population, the present study had high attrition and low attendance in therapy as its major limitations. Given that the study targeted a group with a severe psychiatric co-morbidity with high incidence of suicide-related behaviours, it is noteworthy that no patient died during the study. Furthermore, in contrast to 4 suicide attempts among the patients with standard SUD treatment alone, there were no suicide attempts in the MBT group – a difference that was close to statistical significance. In addition, there was no indication that MBT increased the occurrence of AEs or days of hospitalization. With regard to outcome based on self-report and interview measures, no significant differences were detected between the intervention and the control group.

Limitations of the present study include the suboptimal MBT adherence and quality, and the small sample size with high attrition. These shortcomings severely affect the internal validity of the study. The missing advantage of MBT compared to standard SUD treatment might be caused by the insufficient MTB performance of the employed therapists. It is a challenging task to treat dual diagnosis patients, but the therapists’ suboptimal MBT adherence might also be affected by shortcomings in the organizational implementation of MBT. For example, the MBT team was larger than recommended, the MBT therapists devoted too few hours per week to MBT, and the MBT team lacked the specific functions of a team manager, social counsellor and nurse. The fact that half of the patients in the control group received some form of psychotherapy also decreased the internal validity. The reduction of the sample size from planned n = 80 to actual n = 46 did not only decrease the statistical power but also increased the risk for heterogeneity between the groups with regard to baseline features. Low statistical power increases the risk for both types 1 and 2 errors. Patients with BPD and co-morbidity of any SUD present a large heterogeneity, which increases the need for a large sample size for reducing the risk of the outcome being affected by confounding variables and large variance in the dependent variables.
The strengths of the study include its randomized controlled design; continuous independent monitoring; a combination of interview/self-report measures and register outcomes; and adherence to ICH-GCP. The study focused on patients with a specific psychiatric co-morbidity, for which there are few treatment outcome studies, and it is the first randomized controlled trial of MBT for this patient population. Furthermore, the trial was conducted in a naturalistic clinical context in a public addiction clinic, which adds to its external validity.

The results of the present study indicate that MBT in combination with standard SUD treatment for patients with concurrent BPD and SUD has no harmful effect and might be helpful in reducing risk for suicide attempts. MBT was conducted with suboptimal adherence to the treatment principles and was not found to be significantly more effective than the control condition on a range of self-report and interview measures. The attendance in therapy was low and the frequency of premature termination was high, which is in agreement with the results of previous studies with similar patient populations [19–23]. Thus, MBT had no significantly better effect on therapy retention than previously employed interventions. The data from the present study will be made available for meta-analyses of the effectiveness of MBT in BPD/SUD following the completion of future trials.

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Disclosure Statement

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