Mentalization Based Group Psychotherapy for Psychosis: A Pilot Study to Assess Safety, Acceptance and Subjective Efficacy

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Abstract

Background: Systematic reviews of psychodynamic psychotherapy for individuals with psychosis have reported mixed results. However, mentalization-based therapy (MBT), a manualized psychodynamic psychotherapy, has been proven effective in controlled studies in non-psychotic patients with severe mental disorders. Although MBT is currently being used to treat psychotic patients, to date no studies have evaluated outcomes and treatment-related adverse effects.

Method: An observational study to assess the safety, acceptance, and subjective efficacy of mentalization-based group therapy (MBGT). The therapy assessed in this study was based on the explicit mentalizing techniques described in the MBT manual. The therapy was delivered weekly for a maximum of 12 weeks by two therapists with extensive psychotherapeutic experience at public hospitals. Forty-one patients were included. According to DSM-IV criteria, 29 patients (70.7%) had schizophrenic spectrum disorders and 12 (29.3%) affective spectrum disorders.

Results: In the year prior to therapy, over 65% of patients reported psychiatric hospitalization and none was able to remain employed. Adverse events (all undesirable events experienced during therapy) were observed in 23 patients (56.1%), although the event was considered therapy-related (adverse reaction) in only 3 cases (7.3%). None of the patients dropped out for reasons solely attributable to the MBGT and none expressed a desire to leave the group. Two cases (4.9%) ended their stay in the day hospital ahead of schedule for reasons unrelated to the study therapy. Based on the subjective efficacy questionnaire, 35 patients (85.4%) liked the group therapy and found it interesting while 4 patients (9.8%) reported not liking the therapy. Two participants (4.9%) found the therapy useful but boring.

Conclusions: MBGT is safe and well-accepted by patients with severe psychosis, and most patients considered the treatment to be beneficial. Controlled studies are needed to determine the effectiveness of this therapeutic approach.

Keywords: Psychotherapy, Schizophrenia, Mentalization, Psychodynamic therapy, Adverse effects

Introduction

In 1984, the Boston Psychotherapy Study on Schizophrenia [1,2] showed that reality-adaptive supportive psychotherapy exerts a preferential and specific action on rates of recidivism and role performance when compared to insight-oriented psychodynamic psychotherapy. After that study was published, interest [3-7] in the use of psychodynamic treatment for psychosis [8] began to gradually wane. In the ensuing years, research into the psychosocial treatment of schizophrenia focused primarily on rehabilitation models [9-11], case management [12-14], evidence-based family interventions [15-17], and neurocognitive remediation [18-20]. Similarly, psychoanalysts showed little interest in schizophrenia research. Systematic reviews conducted to evaluate psychodynamic psychotherapy [21-23], one of which was promoted by the International Psychoanalytic Association [24], did not include new experimental studies with schizophrenic patients. In 2001, a Cochrane review [25] found no evidence for any positive effect of psychodynamic therapy for individuals with schizophrenia; moreover, that same review also noted that the adverse effects of this therapy were unknown because none of the studies evaluated in the review had evaluated this aspect of treatment. A more recent survey, carried out in Denmark and involving patients experiencing their first psychotic episodes [26], showed mixed results. Given this background, the supporting evidence for the value of psychodynamic psychotherapy for psychosis is limited, as Fonagy [27] pointed out in a recent review.

During the late 20ᵗʰ and early 2¹ˢᵗ centuries, the application of psychotherapy to treating schizophrenia was mostly focused on -somewhat controversially [28,29]- the new cognitive therapies [30-34] that aim to improve the core symptoms of psychosis (hallucinations and delusions) and social cognitive remediation [35]. Concurrently, a large number of specific psychodynamic psychotherapies for various non-psychotic disorders have manualized their implementation, and numerous controlled studies have proven the effectiveness of these manualized interventions [21-23,32,36]. One of these treatments is mentalization-based therapy (MBT) for borderline personality disorder (BPD) [37], a treatment that utilizes...
both individual and group therapy. Several studies have found MBT to be moderately to highly effective, findings that have been replicated by other studies [38-40]. In a study [41] carried out by our group to assess a psychotherapeutic program that integrated MBT and other group therapies in patients with severe personality disorders (45% of which had transient psychotic episodes), we found that this combined therapy was effective in improving several pragmatic variables.

Mentalizing is a form of social cognition that allows us to perceive and interpret human behavior in terms of intentional mental states [37]. Although MBT was initially developed for BPD, there is growing recognition that mentalization deficits can occur across all severe psychological disorders [42]. Mentalization is the ability to think about states of mind (e.g., thoughts, feelings, intentions), and deficiencies in this ability may complicate the development of a therapeutic alliance and treatment engagement [37,43]. MBT can effectively treat self pathology (e.g., impaired capacity to infer mental states in oneself and others) related to trauma occurring in the context of early relationships with caregivers [42,43]. It has been increasingly recognized that individuals with psychotic-spectrum disorders [43] may present disturbances in thinking abilities related to awareness of the self and others, and meta-analyses have shown that mentalization is anomalous among schizophrenic patients and in individuals with attenuated psychotic symptoms [42]. Likewise, the functionality of an individual with schizophrenia corresponds closely to scores on social cognition scales, especially the Theory of Mind, which is one of the dimensions of mentalization [44-46]. Although MBT is currently being used with psychotic patients [42,43,46,47], to date, to our knowledge, the adverse effects, results, and applicability of MBT in the treatment of psychosis have not been investigated.

Based on our previous experience with the psychotherapeutic program for personality disorders described above, we have developed a mentalization-based form of group psychotherapy (MBGT) for psychotic patients at our day hospital (DH). In recent years, awareness of the importance of early assessment of new psychotherapy approaches has been growing. Just as occurs in psychopharmacology research, it has become clear that it is essential to assess the safety of specific therapeutic approaches to determine whether these are safe or “harmful” for patients [25,48,49].

Given the scant knowledge regarding the safety of MBGT, we conducted the present study to determine the potential adverse effects if any-of this therapy. Secondly, we also assessed patient acceptance of this treatment and their perceived subjective benefits of the intervention. Finally, we evaluated the potential differences in outcomes according to patients’ classification on the psychotic spectrum (schizophrenic vs. affective).

Material and Methods

Study and design

This was a descriptive, observational ambispective study. Patients diagnosed with a psychotic disorder participated in a 12-week MBGT program. The primary aims of the study were to assess the safety, acceptance and subjective efficacy of the treatment. The study was conducted at a DH within the public mental health network in the metropolitan area of Barcelona. Safety and acceptance were assessed one week after each session and subjective efficacy was evaluated at the end of the 12-week group therapy. At admission, all patients signed an informed consent form approved by the local ethics committee, in which they agreed to participate in various therapeutic groups and to complete all assessment instruments. Refusal to participate in certain therapies and/or assessments in no case implied exclusion from the DH.

Participants and procedure

The study sample was selected from all patients with a psychotic disorder admitted to the DH from November 2012 to March 2014 (n = 53). The DH offers a 4-month treatment plan held from Monday to Friday. A variety of group therapies are offered, including MBGT.

Patients are admitted to the DH unless they present grossly disorganized behavior, severe suicide risk, daily substance withdrawal symptoms or severe, uncontrolled, episodic affective behavior. Inclusion criteria for MBGT were as follows: a) DSM-IV criteria [50] for schizophrenia, schizoaffective disorder, or unspecified psychotic disorder (schizophrenic spectrum), or b) DSM-IV criteria [50] for bipolar I disorder with the most recent episode being either manic with psychotic symptoms, mixed with psychotic symptoms or depressive with psychotic symptoms- or recurrent major depressive disorder with psychotic symptoms (affective spectrum). In addition to the aforementioned criteria, additional inclusion criteria included previous attendance and toleration of 2-3 weeks of some of the structural low demand activities conducted at the beginning of the DH stay (welcoming group, good morning group, health workshop, etc.). The exclusion criteria were as follows: a) severe (≥ 6) poverty of speech as defined in the PANNS [51] and/or b) severe (≥ 5) conceptual disorganization as defined in the BPRS [52], or c) insufficient knowledge of the Spanish language.

All patients were assessed by a referral therapist by means of a clinical interview in accordance with the DSM-IV criteria. The assessment protocol included a sociodemographic survey, a questionnaire on adverse events (Table 2) and a brief questionnaire on perceived intervention benefit. Of the 53 psychotic patients admitted to the DH during the designated period, seven refused to participate in any therapeutic activities -they implemented an intensive outpatient psychiatric treatment lasting from 15-45 days- and three had already planned other activities at the same time and day of the week that the MBGT was conducted. Two patients were excluded, respectively, due to exclusion criteria b and c. Therefore, the final sample included 41 patients with a psychotic disorder, 29 (70.7%) with a diagnosis of a schizophrenic spectrum disorder, and 12 (29.3%) with a diagnosis of an affective spectrum disorder.

Intervention

MBGT is a group psychotherapy technique based on MBT, a manualized psychodynamic psychotherapy developed by Bateman and Fonagy [37] that combines individual and group therapy. Mentalization, a form of social cognition, is a multidimensional construct that is organized around four polarities, one of which involves explicit mentalization vs the implicit mentalization pole [37]. Explicit mentalization is conscious, verbal, and reflective; it requires attention, intention, awareness, and effort. By contrast, implicit or automatic mentalization is nonconscious, nonverbal, and unreflective [53]. The therapy assessed in this study was based on the explicit mentalizing techniques and on exercises included in the MBT manual [37]. Specifically, the therapy focuses on four topics: understanding motives (4 sessions), understanding attitudes (4 sessions), understanding emotions (2 sessions), and, finally, understanding what makes me “me” (2 sessions). The explicit MBGT is a weekly course lasting 50 minutes per session with a maximum of 12 sessions (weeks) and a maximum of 10 patients (usually 6-8) per group. MBGT was conducted by two therapists with extensive psychotherapeutic experience in public hospitals and ≥ 10 years of training in psychodynamic psychotherapy. The senior therapist has participated in several MBT seminars taught by Anthony Bateman. This is an open group therapy, although new patients are not allowed to join the group if a particular topic is unfinished or if 7 or more sessions have already been completed. Patients are allowed to continue therapy regardless of the number of absences. Each group session starts with a brief exercise to refresh the mentalization concept. Patients sit in front of a table, facing a blackboard on which that day’s task is shown. They are encouraged (but not required) to write down on a sheet of paper whatever they are mentalizing after each exercise.

In the context of the present study, a specific patient response to each question is noted on the blackboard in the room and collected or checked by the therapists under any circumstances. Patients sit in front of a table, facing a blackboard on which the patient is mentalizing after each session. Patient responses to each question are noted on the blackboard in the room and collected or checked by the therapists under any circumstances.

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discussed (mentalyzed) and the participants are reminded that, if they so wish, they can discuss in more depth at their individual treatment sessions any of the topics that arise in the group sessions. Initially, we wrote a first draft of the MBGT manual for psychotic patients and carried out a group that received 10 sessions (rather than 12). After all the comments and suggestions had been collected and analyzed from this initial 10-session group, the final version of the MGBT manual was written.

**Outcome variables and information sources**

To our knowledge, no previous studies have evaluated the use of MBGT in psychotic patients, and its safety profile is therefore unknown [22,27]. For this reason, the main outcome variable in the present study was patient safety. To detect potential iatrogenic effects, both objective and subjective variables were measured, as follows:

a) objective variables (hospital admission, psychiatric emergency, suicidal behavior and self-injury, and unexpected antipsychotic dose changes) highly specific to detect a worsening of the psychosis, but with low sensitivity; b) objective variables (unexpected clinical consultation or pharmacological dose changes) which are sufficiently sensitive to detect mild clinical changes in the psychosis, but with low specificity; c) objective variables whose sensitivity and specificity is moderate, such as unexpected DH discharge; d) subjective variables (of varying degrees of specificity and sensitivity) related to the group, such as withdrawal from the MBGT (even though the patient may continue participating in other groups at the DH), leaving the group session for any reason or reporting discomfort during the group sessions. Safety was assessed according to the guidelines of the Spanish Agency of Drugs and Health Care Products [54]. A list of potential undesirable events that might occur during the MBGT was drawn up (Table 2). First, all undesirable events experienced by patients (adverse event) were recorded in the ad hoc questionnaire and then these were assessed by a member of the research team to determine whether or not they were any indications that the event could had been caused by the therapy (adverse reaction). Data on suspicious events were verified against the notes in the patients’ medical records. In addition, the treating psychiatrist(s) and group therapists were questioned to further assess the event. Any discrepancy was by consensus decision. An example of an adverse event would be an unplanned prescription of benzodiazepines to a patient with akathisia, although this would worsen in 48-72 hours, requiring that the drug dose be reduced. All adverse events and reactions were registered both as dichotomous variables (present or absent) and as count variables (number of events). Another outcome variable was acceptance of MBGT, assessed by: a) number of premature withdrawals from the group, b) explicit desire for withdrawal from the group, and c) frequency and number of absences from the therapy sessions. Finally, subjective efficacy was evaluated at the end of the group therapy program through a brief, anonymous questionnaire. On this brief questionnaire, subjects were asked whether or not they liked the group and if they found it interesting. At the end of the form, the participants were given space to write open comments about their perceptions of the experience.

**Statistical analysis**

The statistical analysis was performed with the SPSS program, version 22.0. Count and continuous variables were described by means with standard deviation (SD), and categorical variables by absolute frequencies and percentages. All values were calculated with reference to the total sample and also to the two different spectrum categories (schizophrenic spectrum vs. affective spectrum). Group differences were compared using chi-square statistics with Yates correction. The Fisher Exact Probability Test was used when requirements for dichotomous variables were not met. The U Mann-Whitney Test was used for count variables and the Student's t-test for continuous variables after comparing the variances between the two samples. Values of p < 0.05 were considered significant.

**Results**

**Sample description**

The demographic profile of the total sample is summarized in Table 1. Notably, none of the patients was employed in the previous year.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Schizophrenic spectrum (n = 29)</th>
<th>Affective spectrum (n = 12)</th>
<th>Total (n = 41)</th>
<th>$\chi^2$</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>n 79.3 %</td>
<td>n 58.3 %</td>
<td>n 73.2 %</td>
<td>-</td>
<td>0.247</td>
</tr>
<tr>
<td>Female</td>
<td>n 20.7 %</td>
<td>n 41.7 %</td>
<td>n 26.8 %</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not working</td>
<td>n 100.0 %</td>
<td>n 100.0 %</td>
<td>n 100.0 %</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Disability Pension</td>
<td>n 44.8 %</td>
<td>n 50.0 %</td>
<td>n 46.3 %</td>
<td>-</td>
<td>0.904</td>
</tr>
<tr>
<td>Income Support</td>
<td>n 41.4 %</td>
<td>n 33.3 %</td>
<td>n 39.0 %</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>n 13.7 %</td>
<td>n 16.7 %</td>
<td>n 14.6 %</td>
<td>-</td>
<td>0.037</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>College graduate</td>
<td>n 0.0 %</td>
<td>n 0.0 %</td>
<td>n 0.0 %</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>n 10.4 %</td>
<td>n 50.0 %</td>
<td>n 22.0 %</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Job training</td>
<td>n 31.0 %</td>
<td>n 16.7 %</td>
<td>n 26.8 %</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>School graduate or less</td>
<td>n 58.6 %</td>
<td>n 33.3 %</td>
<td>n 51.2 %</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Psychiatric inpatient admission</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latest 12 months</td>
<td>n 62.1 %</td>
<td>n 97.0 %</td>
<td>n 65.9 %</td>
<td>-</td>
<td>0.494</td>
</tr>
<tr>
<td>Lifetime</td>
<td>n 75.9 %</td>
<td>n 91.7 %</td>
<td>n 80.5 %</td>
<td>0.399</td>
<td></td>
</tr>
<tr>
<td>Mean SD</td>
<td>n 82.1 SD 42.2</td>
<td>n 4.7 SD 33.8</td>
<td>n 9.0 SD</td>
<td>-3.42</td>
<td>0.006</td>
</tr>
<tr>
<td>Number of psychiatric admissions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latest 12 months</td>
<td>n 0.7 %</td>
<td>n 0.7 %</td>
<td>n 0.7 %</td>
<td>-0.50</td>
<td>0.617</td>
</tr>
<tr>
<td>Lifetime</td>
<td>n 2.4 %</td>
<td>n 2.3 %</td>
<td>n 2.4 %</td>
<td>-1.76</td>
<td>0.078</td>
</tr>
</tbody>
</table>

$\chi^2$ = Chi-square statistics. SD = Standard Deviation. t = t-Test value. z = z Ratio. p = p value

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Patients with a schizophrenic spectrum disorder were significantly younger and had a lower educational level than those with an affective spectrum disorder. Over 65% of patients in the study required psychiatric hospitalization during the previous year. The average number of lifetime hospitalizations was 2.3 admissions/patient (range 0-11). No significant between-group differences were present in terms of baseline clinical variables (Table 1).

Outcome variables

Twenty-three patients (56.1%) experienced an adverse event (Table 2) during the study; however, there was sufficient evidence in only 3 cases (7.3%) to suspect that the adverse reaction might be therapy-related. Of all the adverse events assessed, only two (0.5%) explicitly discomfort (7.3%) and withdrawal from the group (2.4%) were considered adverse reactions. No between-group differences in the rate of adverse reactions were observed (Table 3). In terms of therapy acceptance, none of the patients dropped out due to MBGT alone and none expressed a desire to leave the group. Two patients (4.9%) ended their stay in HD ahead of schedule, but this was unrelated to participation in the MBGT. Nearly half (48.8%) of patients missed at least one MBGT session (Table 3), but in most cases the absence was not MBGT-specific but rather because the patient did not come to the HD that particular day; only four patients (9.8%) left the DH prior to the MBGT session. Notably, patients in the affective spectrum group had significantly more absences, both in percentage terms and in the average number of absences (Table 3).

On the subjective efficacy questionnaire, 35 patients (85.4%) indicated that they liked the group and found it interesting while 4 (9.8%) reported not liking the therapy, and 2 (4.9%) said it was useful but boring. In the text box allowed for open comments, 26 patients (63.4%) explicitly said that MBGT had helped them to better know themselves, 21 (51.2%) said that the therapy had helped them to reflect on their situation, 11 (26.8%) stated that it helped them to get to know other people better, and 7 (17.1%) said the therapy had improved their interpersonal relationships. Finally, 2 patients (4.9%) said that they found the MBGT to be very difficult. No significant between-group differences were observed in terms of subjective efficacy. It is worth quoting two patients directly because their comments (one positive and one negative) illustrate both points of view. The positive comment (patient 1) was: "I felt that this group is unlike other activities. It is good to stop and think even when I talk about the people around me; this makes me feel like I can learn from myself". The negative comment (patient 2) was: "I did not like it because you have to explain too much about yourself and that is dangerous. I do not like it and less so if there are people in front of me. Besides, comments and questions are unimportant".

Discussion

The main aims of the present study were to determine the safety, patient acceptance, and subjective efficacy of MBGT. The results indicate that this therapy is safe and well-accepted by patients with severe psychotic disorders, both for schizophrenic as well as affective spectrum disorders. Importantly, most patients also believed that the therapy was beneficial.

Over 65% of the patients included in this study had been hospitalized during the previous year. Moreover, most had also experienced at least two hospitalizations since their disorder started. If psychiatric admissions can be considered an objective index of clinical severity [55], then it seems safe to say that this study sample consisted of patients with severe psychosis. Another indicator of severity is the

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**Table 2: Outcome variables. Safety**

<table>
<thead>
<tr>
<th>Event</th>
<th>Adverse event</th>
<th>Adverse reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychiatric inpatient admission</td>
<td>1</td>
<td>0.0</td>
</tr>
<tr>
<td>Emergency Room visit</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Suicide attempt</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Self-injury</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Antipsychotic dose changes* (UN)</td>
<td>1</td>
<td>0.0</td>
</tr>
<tr>
<td>DH discharge (UN)</td>
<td>2</td>
<td>0.0</td>
</tr>
<tr>
<td>Clinical consultation (UN)</td>
<td>17</td>
<td>0.0</td>
</tr>
<tr>
<td>Pharmacological dose changes* (UN)</td>
<td>15</td>
<td>0.0</td>
</tr>
<tr>
<td>Discharge of the MBGT</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Leaving the group session</td>
<td>1</td>
<td>2.4</td>
</tr>
<tr>
<td>Reporting discomfort in the session</td>
<td>3</td>
<td>7.3</td>
</tr>
</tbody>
</table>

DH = Day hospital. UN = Unexpected. *Reduction or increase of the dose.

**Table 3: Outcome variables. Safety, acceptance and subjective efficacy in the two diagnostic groups**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Schizophrenic spectrum (n = 29)</th>
<th>Affective spectrum (n = 12)</th>
<th>Total (n = 41)</th>
<th>χ²</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical consultation (UN)</td>
<td>11 (37.9)</td>
<td>6 (50)</td>
<td>17 (41.5)</td>
<td>-</td>
<td>0.507</td>
</tr>
<tr>
<td>Pharmacological dose changes* (UN)</td>
<td>10 (34.5)</td>
<td>5 (41.7)</td>
<td>15 (36.6)</td>
<td>-</td>
<td>0.730</td>
</tr>
<tr>
<td>Reporting discomfort in the session</td>
<td>2 (6.9)</td>
<td>1 (8.3)</td>
<td>3 (7.3)</td>
<td>-</td>
<td>1.000</td>
</tr>
<tr>
<td>Missing group sessions</td>
<td>10 (34.5)</td>
<td>10 (83.3)</td>
<td>20 (48.8)</td>
<td>6.27</td>
<td>0.012</td>
</tr>
<tr>
<td>1 session</td>
<td>3 (10.4)</td>
<td>4 (33.3)</td>
<td>7 (17.1)</td>
<td>-</td>
<td>0.165</td>
</tr>
<tr>
<td>2-3 sessions</td>
<td>5 (17.2)</td>
<td>2 (16.7)</td>
<td>7 (17.1)</td>
<td>-</td>
<td>1.000</td>
</tr>
<tr>
<td>≥ 4 sessions</td>
<td>2 (6.9)</td>
<td>4 (33.3)</td>
<td>6 (14.8)</td>
<td>-</td>
<td>0.050</td>
</tr>
</tbody>
</table>

**Subjective efficacy (group therapy)**

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
<th>Mean</th>
<th>SD</th>
<th>Mean</th>
<th>SD</th>
<th>t or z</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interesting/useful</td>
<td>0.5</td>
<td>0.6</td>
<td>0.6</td>
<td>0.7</td>
<td>0.5</td>
<td>0.6</td>
<td>-0.57</td>
<td>0.569</td>
</tr>
<tr>
<td>Confused/helpful</td>
<td>0.4</td>
<td>0.6</td>
<td>0.6</td>
<td>0.8</td>
<td>0.4</td>
<td>0.6</td>
<td>-0.56</td>
<td>0.576</td>
</tr>
<tr>
<td>Number of missing group sessions</td>
<td>0.9</td>
<td>1.6</td>
<td>2.3</td>
<td>1.3</td>
<td>1.8</td>
<td>2.45</td>
<td>0.014</td>
<td></td>
</tr>
</tbody>
</table>

UN = Unexpected. χ² = Chi-square statistics. SD = Standard Deviation. t = t-Test value. z = z Ratio. p = p value.

*Reduction or increase of the dose.
fact that none of the patients was able to remain employed in the year prior to therapy. The magnitude of these two indicators (i.e., the number and frequency of hospitalizations and the inability to remain employed) considered together indicates the severity of the psychosis in the sample studied.

With regards to the potential iatrogenic effects of MBGT, which was the principal aim of the study, we found that the causes of undesirable events were highly variable and included, apart from MBGT, the following: clinical worsening; adverse effects of medication; family conflicts; relationship problems with other patients or DH professionals; and adverse effects of other therapies received at the DH. Due to this heterogeneity, we registered all these adverse events regardless of their potential cause. This allowed us to obtain objective data and thus gain an overall understanding of the potential adverse effects of this therapy. This was useful given that, as in most drug tolerance studies, classifying an adverse event as an adverse reaction is not a straightforward decision. However, the incidence of undesirable events that might indicate a significant clinical worsening was low (Table 2). Although the undesirable events that would detect slight changes in the patient's clinical condition-clinical consultation and unexpected changes in prescribed medications—occurred in more than one-third of cases, these were not considered to be adverse reactions. These adverse reactions appeared in situations related to the group session and they were very uncommon.

MBGT was well-accepted by the patients. Even though nearly half of the participants missed at least one session, in most cases this was because the patient was absent from the DH for the entire day, thus the absence was not specifically related to MBGT. In fact, the most common causes of these absences were the need to process social benefits and clinical instability. In this sense, patients who, during the first 2-3 weeks of their DH treatments, presented clinical instability that negatively impacted their ability to attend the DH every day and/or arrive on time were not excluded from the DH therapies. As a consequence, especially at the beginning, it was not unusual to find that some patients did not come to the DH on at least one day. Not surprisingly, patients with affective spectrum disorders—a priori the most symptomatically unstable patients—presented significantly higher rates of absenteeism (Table 3).

The main strength of this study is that the data were collected as part of the usual health care routine and very few patients were excluded, a fact that reinforces the external validity of the study. The main limitation involves the day hospital setting. Given that patients received a variety of different therapies, we cannot fully assess (i.e., under controlled conditions) effectiveness of MBGT alone in terms of clinical, neurocognitive, met cognitive, or functional improvement. However, this was a pilot study not a controlled clinical trial, and thus group cohesion was insufficient to provide specific advantages (together with the usual antipsychotic treatment) for treating psychosis, and, when indicated, in conjunction with other therapies that have proved useful in these patients [15-20,30-35,57]. Available data suggest that MBT could be especially useful in a particular subgroup of patients: those with a history of child abuse by their caregivers [34]. In our opinion, to confirm this hypothesis, it is necessary to modify the manualized format normally used with non-psychotic patients [37]. For this reason, we asked patients to write what they were mentalizing on a sheet of paper and then we put the relevant details on a blackboard to review the mentalization sequence with the group. This resource is especially helpful in patients with higher cognitive deficits, even in those with high social anxiety, and it was well-received by patients in this study.

The type of MBGT described here includes only explicit mentalizing exercises. We were not able to incorporate implicit mentalization because this was an open group with a short course of therapy (12 sessions), and thus group cohesion was insufficient to work on implicit mentalization. However, it is important to stress that explicit mentalizing groups inevitably use implicit mentalizing [37]. In our experience, when the composition of the group remained constant over several sessions, it is easy to facilitate an implicit mentalizing process. In other words, in a closed group of psychotic patients of longer duration, we hypothesize that the explicit mentalizing group could continue as an implicit mentalizing group.

To conclude, this pilot study indicates that MBGT is safe and well-accepted by severe psychotic patients. The MBT format needs to be adapted to suit these patients for both group and individual therapies. Finally, controlled studies are needed to determine the effectiveness of this therapeutic approach.

Conflict of Interest

The authors declare that there are no conflicts of interest.

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