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ORIGINAL RESEARCH: CLINICAL TRIAL

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Assessing the efficacy and feasibility of providing metacognitive training for patients with schizophrenia by mental health nurses: A randomized controlled trial

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Abstract

Aim: To evaluate the efficacy of metacognitive group training in reducing psychotic symptoms and improving cognitive insight and functions in people with schizophrenia.

Design: Randomized controlled trial. It was carried out between July 2019 -February 2020.

Methods: Fifty-six patients with schizophrenia were enrolled and randomly assigned to either a control group ($N = 29$) or a metacognitive training group ($N = 27$). Blinded assessments were made at baseline, 1-week post-treatment and at follow-up 3 months after treatment. The primary outcome measure was psychotic symptoms based on the Psychotic Symptom Rating Scales (PSYRATS). Secondary outcomes were assessed by the Beck Cognitive Insight Scale (BCIS), the Personal and Social Performance (PSP) scale and the World Health Organization Disability Assessment Schedule (WHODAS).

Results: Completion at follow-up was high (92.86%). The intention-to-treat analyses demonstrated that patients in the metacognitive training group had significantly greater improvements of the Psychotic Symptom Rating Scales delusion score and total score and the Personal and Social Performance Scale, after 3 months, compared with the control group. The effect size was medium to large. The intention-to-treat analyses also demonstrated that patients in the metacognitive training group had significantly greater reductions of the Psychotic Symptom Rating Scales hallucination score and Beck Cognitive Insight Scale self-certainty score post-treatment, compared with the control group. The effect size was medium to large.

Conclusion: The metacognitive training administered by psychiatric and mental health nurses was effective in ameliorating delusions and social functioning over time and it immediately reduced hallucinations post-treatment.

Impact: Metacognitive training for treating psychosis in patients with schizophrenia is efficacious and administration is clinically feasible in the Portuguese context.

Trial Registration Number: ClinicalTrials.gov ID NCT03891186.

KEYWORDS

Beck Cognitive Insight Scale (BCIS), cognitive insight, mental health nursing, metacognitive training, Personal and Social Performance (PSP) scale, psychiatric nursing, Psychotic Symptom Rating Scales (PSYRATS), psychotic symptoms, randomized controlled trial, schizophrenia, social functioning

1 | INTRODUCTION

Schizophrenia is a complex and severe mental disorder (Lambert et al., 2019) and persistent psychotic symptoms represent a major challenge for patient care (Favrod et al., 2014). Metacognitive training (MCT) for psychosis is a variant of cognitive-behavioural therapy (CBT), but it is particularly targeted at reducing cognitive biases (Moritz & Woodward, 2007). MCT has been applied in many countries and is usually complementary to psychopharmacological intervention. The immediate effect of MCT in reducing delusions in patients is well-established (Eichner & Berna, 2016; Liu et al., 2018), but its long-term effects over time are less clear.

Moreover, as cultural context seems to influence the effects of MCT (Liu et al., 2018), more studies are needed to evaluate its efficacy across different cultures. We believe that MCT can be important for treating many factors associated with the symptoms of schizophrenia, since the treatment aims to change the meta-structure of thinking and judgement. This study addresses the impact of MCT, in a Portuguese population, on psychotic symptoms, cognitive insight and functioning in schizophrenia. Most prior studies on MCT involved psychologists as trainers. However, the training can also be performed by nurses and occupational therapists with experience in treating and communicating with patients with schizophrenia. To explore whether positive effects can also be achieved by non-academic staff, for this study, mental health nurses administered the training.

1.1 | Background

Psychiatric disorders are one of the major enigmas for health professionals. Laboratory tests to confirm the presence of a severe mental disorder do not exist, which poses a challenge to psychiatric nurses in clinical practice. Instead, diagnostic assessment usually relies on observation, verbal and non-verbal communication, as well as on the use of questionnaires. The therapeutic relationship represents the key element of the entire care process. Lopes (2018) considers that nurses should evaluate the impact of symptoms of mental disorders on self-care, taking into consideration the family and community relationships of the patient. In Portugal, after obtaining a general nursing degree, nurses can choose to specialize in one of the existing areas to try to obtain a master's degree that includes a theoretical component and a clinical internship in the area of specialization; and one of these specialties is mental health and psychiatric nursing. The specific skills acquired are regulated by the Order of Nurses (Ordem dos Enfermeiros, 2018, p. 21427); a properly trained nurse has the following characteristics that describe his or her relationship with the patient:

"a) Has good knowledge and awareness of himself as a person and as a nurse through experiences and processes of self-knowledge and personal and professional development;

b) Assists in optimizing mental health throughout the patient's life cycle, family, groups and community;

c) Helps the patient throughout the life cycle to integrate into their family, groups and community and in mental health recovery by mobilizing the dynamics specific to each context;

d) Provides psychotherapeutic, socio-therapeutic, psychosocial and psycho-educational care to the patient throughout their life cycle and mobilizes the context and individual, group or community dynamics to maintain, improve and recover health."

Psychiatric nurses increasingly play an active role in the psychosocial rehabilitation of patients with schizophrenia, using their skills and maintaining the therapeutic relationship with the patient, usually as part of a multidisciplinary team (Pinho et al., 2017). In Portugal, there are specific services which aim to provide psychosocial and psychoeducational interventions to help people with severe mental illness during their recovery process. There are two types of services: those where patients receive treatment during the day and return home to sleep and those where patients live on-site until they are able to be integrated back into the community. In both types, treatment is administered by a multidisciplinary team of nurses, psychiatrists, psychologists, occupational therapists and social workers.

Schizophrenia is a major cause of disability worldwide (Charlson et al., 2018). The Diagnostic and Statistical Manual of Mental Disorders (5th edition) defines the presence of at least two of the following symptoms as criteria for schizophrenia: delusion, hallucination, disorganized speech, grossly disorganized or catatonic behaviour and negative symptoms. At least one of these symptoms should be among the first three listed (American Psychiatric Association, 2014). Significant psychosocial functional impairments are present in many patients who are often unemployed, living in poverty, homeless and experiencing functional difficulties. Patients with schizophrenia frequently rely on support from their families and mental health services (Charlson et al., 2018).

Dysfunctional thought processes of patients with delusions cannot be corrected with medication (Liu et al., 2018). The use of psychological interventions to treat specific underlying psychotic symptoms should be used as an adjunct to conventional approaches

(So et al., 2015). MCT was developed by Moritz and collaborators in 2007 and has been studied in several countries. It is a therapeutic program that aims to prevent and reduce delusions by modifying the specific cognitive biases of psychosis; particularly, jumping to conclusions and exhibiting overconfidence in false judgments (Eichner & Berna, 2016; Moritz et al., 2014). The Australian Psychiatric Association, the German Psychiatric Association and the German Psychological Association now recommend MCT for the treatment of psychotic disorders (Moritz & Lysaker, 2018).

MCT focuses on metacognitive experience (e.g. specific cognitive biases of the psychosis that the patient is not necessarily consciously aware of that are made explicit and challenging; Moritz & Lysaker, 2018). Many patients with psychosis have a low awareness of these biases (Moritz et al., 2016) and MCT aims to improve metacognitive awareness of these cognitive biases (Moritz et al., 2014). MCT group therapy avoids addressing issues related to personal delusions, leaving these issues to be treated by individual therapy. Thus, patients do not need to talk about their experiences unless they want to share them with the group (Moritz & Lysaker, 2018).

MCT also aims to raise cognitive insight, the concept of which was initially developed by Beck in 2004 and is important for treating schizophrenia. It encompasses the capacity of patients to reflect on their distorted beliefs and interpretations and helps them respond to corrective feedback based on a metacognitive approach. Cognitive insight, according to Beck, involves self-reflection and self-certainty. Improved cognitive insight in schizophrenia may reduce delusions (Riggs et al., 2012) and training can help patients accept their diagnoses (Moritz et al., 2017).

MCT applied to patients with psychosis has shown favourable results in reducing delusions (Eichner & Berna, 2016; Ishikawa et al., 2020; Liu et al., 2018; Philipp et al., 2019). A Portuguese trial studied the preliminary efficacy of Metacognitive and Social Cognition Training (MSCT; 18 sessions) in schizophrenia, but no effect on positive symptoms was found, contrary to expectation (Rocha & Queirós, 2013).

With respect to cognitive insight and functioning, studies have been scarce, and the results of the few studies have been conducted are not fully conclusive. Some randomized controlled trials (RCTs) that aimed to prove the efficacy of MCT in improving cognitive insight reported different conclusions: MCT improved self-reflectiveness, but not self-certainty (Lam et al., 2015); MCT improved self-certainty, but only immediately post-intervention, without affecting self-reflectiveness (Ochoa et al., 2017); or MCT had no significant effects (Ishikawa et al., 2020; van Oosterhout et al., 2014). In respect to functional improvements, some studies proved the efficacy of MCT in improving social functioning (Ishikawa et al., 2020; Naughton et al., 2012; Ussorio et al., 2016), but another study reported no significant improvements (Gawęda et al., 2015).

MCT can be considered a psychotherapeutic and psycho-educational intervention that can be applied by mental health and psychiatric nurses within the capacity of their specific skillset. This study is the first RCT of MCT in schizophrenia assessing a Portuguese population. It is also the first study where the MCT was applied by mental health and psychiatric nurses working in clinical practice. Given the close therapeutic relationship between these nurses and their patients and the level of trust shared, as nurses are part of the daily therapeutic plan with a specific skill set, we believe that these factors may contribute to the efficacy of MCT. This is a novel assessment that has never been performed in previous studies. Specifically, this study intended to test the efficacy of MCT on psychotic symptoms, cognitive insight and functioning in patients with schizophrenia.

2 | THE STUDY

2.1 | Aim

The study aimed to evaluate the efficacy of MCT administered in a group setting in people with schizophrenia and to determine its effects on psychotic symptoms, cognitive insight and functioning.

The hypotheses were as follows:

- Cognitive insight in the MCT group will be better than that in the control group at the end of the programme and at follow-up;
- Functionality in the MCT group will be better than that in the control group at the end of the programme and at follow-up;
- The severity of psychotic symptoms in the MCT group will be lower than that in the control group at the end of the programme and follow-up.

2.2 | Design and methods

2.2.1 | Study design

This study was an RCT.

All procedures followed the CONSORT (Consolidated Standards of Reporting Trials) guidelines for the four phases: enrolment, intervention allocation, follow-up and data analysis. The follow-up assessment was performed 3 months after the conclusion of the MCT programme. The trial has been registered at ClinicalTrials.gov (ID NCT03891186) and the protocol was published by Pinho et al. (2020).

2.2.2 | Participants

The sample was selected by a probabilistic method and participants were randomly allocated to one of two groups (experimental or control). A stratified random sampling method was applied. Participants were stratified by educational level, duration since onset of schizophrenia and type of treatment received.

The sample of the study was composed of 56 patients with schizophrenia from three psychiatric institutions from Portugal. Patient recruitment was based on the following criteria: age between 18-65 years; diagnosis of schizophrenia as evaluated by a psychiatric

assistant; and no changes in antipsychotic medications used within 4 months before the start of the programme. We excluded patients with very severe psychotic symptoms that could have impeded their understanding of the objectives of the sessions.

Eligible participants were recruited by the principal investigator in collaboration with a multidisciplinary team from each institution between July and September 2019. The study was explained to the participants, individually and written informed consent was obtained from each. A baseline assessment was carried out between August-September of 2019 using the psychometric instruments described below (these included the Psychotic Symptoms Rating Scales [PSYRATS], the Personal and Social Performance [PSP] scale, the World Health Organization Disability Assessment Schedule [WHODAS] and the Beck Cognitive Insight Scale [BCIS]).

Participants were randomly allocated to either the MCT group (experimental group) or the control group by a multidisciplinary team from each institution (Figure 1). The control group did not receive MCT. In both groups, treatment as usual (TAU) was maintained. All participants were re-assessed at the end of the programme (post-treatment timepoint) and 3 months after completion (follow-up timepoint) by the principal investigator, who did not know to which group the participants belonged. Plans were in place to apply the MCT to the control group after the follow-up.

A practical training course on MCT was conducted in June 2019 by two researchers of this study with all psychiatric and mental

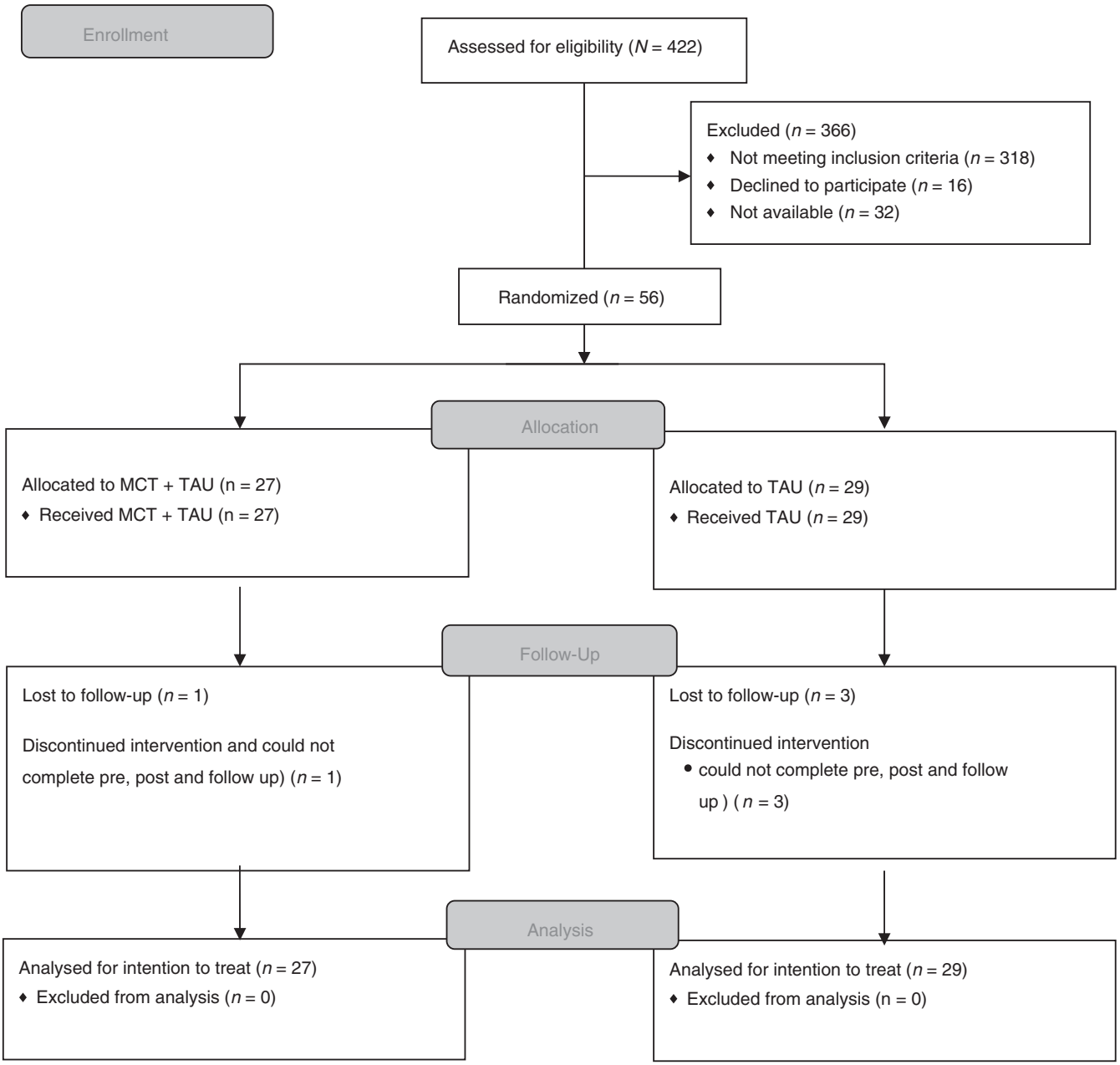

FIGURE 1 CONSORT flow diagram

health nurses who provided the MCT. It was applied in two sessions per week for a total of eight sessions between August and October 2019. MCT was provided face-to-face in a group setting in a quiet room.

2.2.3 | Sample size

Sample size calculation was conducted using G*power (Erdfelder et al., 1996) based on the theory that small to medium effect sizes have been found for improvements associated with MCT (Moritz et al., 2013). Effect sizes were calculated using partial η^2 values. The sample size was previously calculated assuming an effect size like those of a previous study (Moritz et al., 2013), with an alpha = 0.05 and power = 0.80. A total sample size of 36 (18 participants per group) was considered to be necessary to detect an effect for the primary outcome measure (PSYRATS delusion score) based on the partial η^2 = 0.04 reported by Moritz et al., 2013, based on a repeated-measures ANOVA. We considered a dropout of 10%.

2.2.4 | Study intervention

TAU

All participants continued to receive TAU at the three participating institutions. TAU in one of the three institutions was a psychosocial rehabilitation programme for community patients. In the other two institutions, patients were in long-term care and participated in other rehabilitation activities. All of the participants received treatment from mental health psychiatric nurses, psychiatrists, psychologists, social workers and occupational therapists. The control group did not participate in the MCT programme in this trial.

MCT for psychosis

MCT was first developed by Moritz and collaborators in 2003/2004 (Moritz & Woodward, 2007; Moritz, Vitzthum, et al., 2010; Moritz, Woodward, et al., 2010) and training has been updated since that time. The most recent Portuguese update is version 6.3 (Moritz et al., 2017). Specific terms were adapted for Portugal, but the examples were kept the same for consistency across countries. However, the exact intervention and examples could be tailored by the therapist to meet specific group needs. This training is currently available in 37 languages.

MCT is a therapy developed to treat the positive symptoms of psychosis and is composed of eight modules addressing common cognitive issues and biases for solving problems in psychosis. The topics of MCT include the following: attribution blaming and taking credit (Module 1), jumping to conclusions (Modules 2 & 7), changing beliefs (Module 3), deficits in theory of mind and social cognition (Modules 4 & 6), overconfidence in (memory) errors (Module 5) and depression and low self-esteem (Module 8). Each module consisted of one session.

Each session aims to convey knowledge about cognitive distortions, such as false memory and overconfidence and to help patients reflect critically on their biases and acquire new problem-solving strategies. Each session lasted 45–60 min and followed a protocol defined in the 'Metacognitive Training for Psychosis (MCT)' manual (Moritz et al., 2017). Each module was supported by multimedia slides and homework exercises. Other support materials like videos could be used.

Each module represents a style of thinking that is recognized as contributing to the development of delusions (e.g. distortions in the assignment of meanings). Each is presented through examples and exercises and the fallibility of human cognition is discussed and illustrated. The therapist also shows participants how exacerbation of thought biases can cause problems in daily life, such as increasing the likelihood of delusions. Examples that happen in psychosis are discussed and participants are encouraged to share their own experiences. Non-adaptive coping strategies (e.g. avoidance and suppression of thought) are highlighted and suggestions are provided for substitution by adaptive strategies. The aim of MCT is to teach participants not to make hasty judgments without adequate information and to reflect on their own thought patterns. At the end of each session, the therapist gives a brochure to the participants with exercises to help them train at home. For example in Module 1 (attribution blaming and taking credit) the homework gets the participant thinking about a real situation, (e.g. a friend missing a meeting) and has them assign various possible causes, which are related to the self, others or the situational circumstances.

MCT is an open programme, so patients can join at any time during each cycle and if a participant misses a session, no repetition is necessary. The MCT is not designed to require the modules to be completed sequentially.

A yellow and a red card are handed to group members at the end of the first session. The yellow card aims to remind them to reconsider the available evidence before making hasty or false decisions, which could have momentous consequences. On the red card, the individual is asked to list contacts of persons and institutions that could be helpful in the event of a crisis. All these materials are available at www.uke.de/mct.

2.2.5 | Data collection and outcome measures

The psychometric instruments were applied to all participants in the study through an interview at each of the three different assessment times (before the first session, after the last session [post-treatment] and 3 months after the last session [follow-up]) . Sociodemographic and clinical data were collected to characterize the sample at baseline (age, sex, marital status, cohabitation, educational level, professional/employment status, duration of mental disorder, number of psychiatric hospitalizations, type of treatment and substance use history).

Primary outcome

The PSYRATS (Haddock et al., 1999) are semi-structured interviews that provide a detailed measurement of delusions and hallucinations.

The PSYRATS consist of 17 items and two subscales: one scale assesses hallucinations (11 items), whereas the other scale assesses delusions (6 items). Each item is assessed on a five-point Likert scale (range: 0–4). It has been validated for the Portuguese population (PSYRATS hallucination subscale, $\alpha = 0.96$; PSYRATS delusion subscale, $\alpha = 0.89$; Telles-Correia et al., 2017).

Secondary outcomes

The BCIS (Beck et al., 2004) was administered to evaluate cognitive insight through a self-report questionnaire; the scale consists of 15 items, with two subscales for self-reflectiveness and self-certainty. BCIS is in the process of being validated for the Portuguese population by the researchers of this study (dimension of self-reflectiveness, $\alpha = 0.70$; dimension of self-certainty, $\alpha = 0.70$).

The WHODAS 2.0 was developed by the WHO to evaluate the level of functioning. It consists of 12 items administered as a self-report questionnaire and has been validated for the Portuguese population ($\alpha = 0.86$; Moreira et al., 2015).

The PSP (Morosini, Magliano, Brambilla, Ugolini, & Pioli, 2000) was developed to assess patients' social functioning with regards to four main areas: socially useful activities, personal and social relationships, self-care and disturbing and aggressive behaviours. It has been validated for the Portuguese population ($\alpha = 0.79$; Brissos et al., 2012).

The PSYRATS, BCIS, WHODAS 2.0 and PSP were administered to both groups before the first MCT session (baseline) and a week after the end of the eight sessions (post-treatment). Three months later, these psychometric instruments were re-administered during a follow-up evaluation in both groups.

Subjective appraisal of the interventions

At the end of the MCT, an anonymous questionnaire was administered to the experimental group to assess the acceptability, feasibility and subjective efficacy of the interventions. The questionnaire closely followed one that was administered in previous trials (Moritz, Kerstan, et al., 2011; Moritz, Veckenstedt, et al., 2011; Moritz et al., 2013; Moritz & Woodward, 2007). Moritz and Woodward (2007) recommend that this scale only be used in a descriptive fashion.

2.2.6 | Data analysis

The analyses were conducted by assuming both a per-protocol (PP) and an intention to treat (ITT) strategy. The PP analyses considered participants who completed the three assessments (pre-treatment, post-treatment and follow-up). The ITT analyses considered all participants who completed at least the pre-treatment.

A descriptive analysis was used to characterize the sample. Chi-square tests or unpaired *t* tests were used for group comparisons of sex, age, level of formal education, number of hospitalizations, years of disease and type of treatment received. To compare baseline characteristics between groups, *t* tests were used. A mixed-model repeated-measures ANOVA was performed to compare treatment groups (MCT + TAU vs. TAU) across time (Pre- vs. Post-treatment and Pre-treatment vs. Follow-Up). Differences were considered significant when $p < .05$. The data were analysed using IBM Statistical Package for the Social Sciences (SPSS®) version 24.0 software for Windows.

2.2.7 | Validity and reliability

The study protocol was registered in the Clinical Trials Registry Platform and published by the authors (Pinho, et al., 2020). The psychometric instruments used have already been validated for the Portuguese population. The MCT intervention has been used in other countries and the studies have been published. The psychiatric nurses that applied the intervention were properly trained beforehand. The same investigator administered the questionnaires (LP) at all three timepoints and she had clinical and research experience in treating and investigating schizophrenia. This researcher was blinded and did not know to which groups the participants belonged. All data were collected through face-to-face interviews. The data collection was conducted at three different institutions and the MCT was administered by three different psychiatric nurses, which increased the sample representativeness.

2.3 | Ethical considerations

The study was conducted while respecting all ethical principles outlined in the Declaration of Helsinki and its subsequent revisions (World Medical Association, 2013). Approval was obtained from all the institutions' ethics committees. All participants were informed of the study's objectives, methodology, benefits and possible risks. All patients signed written informed consent forms. Participant confidentiality was maintained throughout all study procedures. Participants were informed that they could withdraw their participation at any time without penalty. Only members of the research team and health professionals who were in charge of the care of the participants had access to participant data. These data will be destroyed 6 months post publication.

3 | RESULTS

3.1 | Baseline characteristics

Baseline characteristics for demographic and treatment-related data were similar across groups (see Table 1). There were slightly more men than women (53.6%), with a mean age of 50.55 years (±8.75). Participants were mostly single (69.6%). Three out of four participants had the disorder for more than 20 years and 55.3% were hospitalized more than five times. All the participants were receiving antipsychotic medication at the time of baseline assessment.

TABLE 1 Baseline characteristics

Characteristic	Mean (*SD*) MCT group (*N* = 27)	Control group (*N* = 29)	Statistic	*p* value
Demographic data				
Gender				
Male	14	16	$\chi^2(1) = 0.06$	$p = .803$
Female	13	13		
Age	48.30 (9.89)	52.66 (7.14)	$t\ (54) = 1.91$	$p = .062$
Formal education	8.07 (2.96)	7.34 (3.98)	$t\ (54) = 0.78$	$p = .438$
Treatment-related data				
Hospitalizations (including present)				
Once	2	2	$\chi^2(3) = 1.94$	$p = .585$
2–5 times	9	12		
6–10 times	5	8		
>10 times	11	7		
Years of disease				
<5	1	2	$\chi^2(4) = 1.36$	$p = .851$
5–10	2	1		
10–20	4	4		
>20	20	22		
Type of treatment				
Community	9	7	$\chi^2(1) = 0.58$	$p = .447$
Hospitalization	18	22		
Psychopathology				
PSYRATS				
Delusion score	9.41 (8.82)	10.86 (8.38)	$t\ (54) = -0.63$	$p = .53$
Hallucination score	11.04 (13.46)	8.66 (14.43)	$t\ (54) = 0.64$	$p = .53$
Total score	20.44 (19.39)	19.52 (18.42)	$t\ (54) = 0.18$	$p = .86$
BCIS				
Self-reflectiveness	11.11 (5.18)	10.86 (5.93)	$t\ (54) = 1.67$	$p = .87$
Self-certainty	8.74 (3.63)	7.31 (3.89)	$t\ (54) = 1.42$	$p = .16$
Total score	2.37 (6.39)	3.55 (8.00)	$t\ (54) = -0.608$	$p = .55$
PSP	57.19 (10.46)	54.15 (11.01)	$t\ (54) = 1.06$	$p = .30$
WHODAS 2.0	21.96 (7.68)	24.86 (5.70)	$t\ (54) = -1.61$	$p = .11$

3.2 | Outcomes

Based on repeated measures ANOVA and the effect on the primary outcome measure (PSYRATS delusion subscale) that had a partial $\eta^2 = 0.244$ post-intervention, we calculated the effect size (0.5681); the power of our sample is nearly 1, with 52 participants. Most of the participants of the MCT group participated in all eight sessions; only eight participants did not (two participated in five sessions; two participated in six sessions and four participated in seven sessions).

PP and ITT analyses did not differ (i.e. for all analyses, the level of significance ($p < .05$) remained unchanged). Between-group differences are shown in Table 2. For the PSYRATS delusion score, hallucination score and total score and the PSP score, the MCT group was superior relative to the control condition at both post-treatment follow-up timepoints. For the BCIS self-certainty score and the BCIS total score, significant effects were observed in the MCT group relative to the control group at the 1-week post-treatment timepoint, but not at the 3-month follow-up. The observed effect sizes were at least medium to large or very large ($\eta_p^2 > 0.095$).

For the PSYRATS delusion score and total score and the PSP score, within-group significant effects were observed in the MCT group, but not the control group. For the PSYRATS hallucination score and the BCIS total score, significant within-group effects were observed in the MCT group 1-week post-treatment, but not at the 3-month follow-up (see Table 2). None of the within-group effects was significant for the control group.

TABLE 2 Group differences across time on measures of psychotic symptoms, cognitive insight and functioning

Domain, variable	Mean (*SD*)						Per-protocol statistics (pre-post)	Per-protocol statistics (pre-follow up)	Intention-to-treat statistics (pre-post)	Intention-to-treat statistics (pre-follow up)
	MCT group ($N = 26$)			Control group ($N = 26$)						
	Pre-treatment	Post-treatment	Follow up	Pre-treatment	Post-treatment	Follow up				
PSYRATS										
Delusion score	8.88 (8.56)	1.69 (3.94)****	3.08 (4.72)****	9.92 (8.05)	10.27 (8.21)$^{[n.s.]}$	10.65 (7.78)$^{[n.s.]}$	Time: $F(1,50) = 13.32$, $p = .001$, $\eta_p^2 = 0.210$; Interaction: $F(1,50) = 16.15$, $p < .001$, $\eta_p^2 = 0.244$	Time: $F(1,50) = 6.45$, $p = .014$, $\eta_p^2 = 0.114$; Interaction: $F(1,50) = 10.69$, $p = .002$, $\eta_p^2 = 0.176$	Time: $F(1,54) = 17.84$, $p < .001$, $\eta_p^2 = 0.248$; Interaction: $F(1,54) = 16.12$, $p < .001$, $\eta_p^2 = 0.230$	Time: $F(1,54) = 8.26$, $p = .006$, $\eta_p^2 = 0.133$; Interaction: $F(1,54) = 9.69$, $p = .003$, $\eta_p^2 = 0.152$
Hallucination score	10.12 (12.82)	4.31 (9.11)***	6.31 (10.89)**	8.35 (14.20)	7.65 (12.42)$^{[n.s.]}$	5.58 (10.16)$^{[n.s.]}$	Time: $F(1,50) = 8.82$, $p = .005$, $\eta_p^2 = 0.150$; Interaction: $F(1,50) = 5.46$, $p = .024$, $\eta_p^2 = 0.098$	Time: $F(1,50) = 7.36$, $p = .009$, $\eta_p^2 = 0.128$; Interaction: $F(1,50) = 0.18$, $p = .670$, $\eta_p^2 = 0.004$	Time: $F(1,54) = 9.94$, $p = .003$, $\eta_p^2 = 0.155$; Interaction: $F(1,54) = 6.73$, $p = .012$, $\eta_p^2 = 0.111$	Time: $F(1,54) = 8.61$, $p = .005$, $\eta_p^2 = 0.137$; Interaction: $F(1,54) = 0.42$, $p = .518$, $\eta_p^2 = 0.008$
Total score	19.00 (18.24)	6.00 (12.19)****	9.38 (14.00)****	18.27 (17.75)	17.92 (16.19)$^{[n.s.]}$	16.23 (13.14)$^{[n.s.]}$	Time: $F(1,50) = 15.34$, $p < .001$, $\eta_p^2 = 0.235$; Interaction: $F(1,50) = 13.79$, $p < .001$, $\eta_p^2 = 0.216$	Time: $F(1,50) = 14.68$, $p < .001$, $\eta_p^2 = 0.227$; Interaction: $F(1,50) = 6.21$, $p = .016$, $\eta_p^2 = 0.110$	Time: $F(1,54) = 19.04$, $p < .001$, $\eta_p^2 = 0.261$; Interaction: $F(1,54) = 15.14$, $p < .001$, $\eta_p^2 = 0.219$	Time: $F(1,54) = 18.13$, $p < .001$, $\eta_p^2 = 0.251$; Interaction: $F(1,54) = 6.68$, $p = .013$, $\eta_p^2 = 0.110$
BCIS										
Self-reflectiveness	11.27 (5.21)	13.12 (5.49)$^{[n.s.]}$	12.31 (5.34)$^{[n.s.]}$	10.81 (6.21)	10.88 (5.85)$^{[n.s.]}$	12.62 (5.48)$^{[n.s.]}$	Time: $F(1,50) = 2.16$, $p = .148$, $\eta_p^2 = 0.041$; Interaction: $F(1,50) = 1.83$, $p = .182$, $\eta_p^2 = 0.035$	Time: $F(1,50) = 3.57$, $p = .065$, $\eta_p^2 = 0.067$; Interaction: $F(1,50) = 0.26$, $p = .612$, $\eta_p^2 = 0.005$	Time: $F(1,54) = 2.55$, $p = .116$, $\eta_p^2 = 0.045$; Interaction: $F(1,54) = 2.72$, $p = .105$, $\eta_p^2 = 0.048$	Time: $F(1,54) = 3.86$, $p = .055$, $\eta_p^2 = 0.067$; Interaction: $F(1,54) = 0.20$, $p = .658$, $\eta_p^2 = 0.004$

(Continues)

TABLE 1 (Continued)

Domain, variable	Mean (*SD*)						Per-protocol statistics (pre-post)	Per-protocol statistics (pre-follow up)	Intention-to-treat statistics (pre-post)	Intention-to-treat statistics (pre-follow up)
	MCT group ($N = 26$)			Control group ($N = 26$)						
	Pre-treatment	Post-treatment	Follow up	Pre-treatment	Post-treatment	Follow up				
Self-certainty	8.62 (3.65)	6.50 (3.20)**	7.27 (4.00)[n.s.]	7.54 (4.05)	8.08 (4.06)[n.s.]	8.08 (4.22)[n.s.]	Time: $F(1,50) = 2.93$, $p = .093$, $\eta_p^2 = 0.055$; Interaction: $F(1,50) = 8.31$, $p = .006$, $\eta_p^2 = 0.142$	Time: $F(1,50) = 0.474$, $p < .494$, $\eta_p^2 = 0.009$; Interaction: $F(1,50) = 2.58$, $p = .114$, $\eta_p^2 = 0.049$	Time: $F(1,54) = 3.46$, $p = .068$, $\eta_p^2 = 0.060$; Interaction: $F(1,54) = 8.72$, $p = .005$, $\eta_p^2 = 0.139$	Time: $F(1,54) = 0.54$, $p = .467$, $\eta_p^2 = 0.010$; Interaction: $F(1,54) = 2.46$, $p = .123$, $\eta_p^2 = 0.044$
Total score	2.65 (6.34)	6.62 (7.34)**	5.04 (7.94)[n.s.]	3.27 (8.36)	2.81 (7.56)[n.s.]	4.54 (8.16)[n.s.]	Time: $F(1,50) = 4.23$, $p = .045$, $\eta_p^2 = 0.078$; Interaction: $F(1,50) = 6.75$, $p = .012$, $\eta_p^2 = 0.119$	Time: $F(1,50) = 2.94$, $p < .092$, $\eta_p^2 = 0.056$; Interaction: $F(1,50) = 0.27$, $p = .603$, $\eta_p^2 = 0.005$	Time: $F(1,54) = 5.02$, $p = .029$, $\eta_p^2 = 0.085$; Interaction: $F(1,54) = 8.26$, $p = .006$, $\eta_p^2 = 0.133$	Time: $F(1,54) = 3.23$, $p = .078$, $\eta_p^2 = 0.056$; Interaction: $F(1,54) = 0.30$, $p = .587$, $\eta_p^2 = 0.005$
PSP	56.96 (10.60)	70.28 (9.08)****	69.88 (8.97)****	55.54 (10.63)	57.54 (11.06)[n.s.]	56.85 (7.70)[n.s.]	Time: $F(1,49) = 26.37$, $p < .001$, $\eta_p^2 = 0.350$; Interaction: $F(1,49) = 14.29$, $p < .001$, $\eta_p^2 = 0.226$	Time: $F(1,50) = 19.48$, $p < .001$, $\eta_p^2 = 0.280$; Interaction: $F(1,50) = 12.98$, $p = .001$, $\eta_p^2 = 0.206$	Time: $F(1,54) = 28.35$, $p < .001$, $\eta_p^2 = 0.344$; Interaction: $F(1,54) = 12.37$, $p = .001$, $\eta_p^2 = 0.186$	Time: $F(1,54) = 23.24$, $p < .001$, $\eta_p^2 = 0.301$; Interaction: $F(1,54) = 11.03$, $p = .002$, $\eta_p^2 = 0.170$
WHODAS 2.0	22.31 (7.62)	22.50 (5.96)[n.s.]	24.31 (8.30)[n.s.]	24.23 (5.50)	25.46 (5.53)[n.s.]	25.19 (6.45)[n.s.]	Time: $F(1,50) = 0.66$, $p = .422$, $\eta_p^2 = 0.013$; Interaction: $F(1,50) = 0.35$, $p = .557$, $\eta_p^2 = 0.007$	Time: $F(1,50) = 1.36$, $p = .250$, $\eta_p^2 = 0.026$; Interaction: $F(1,50) = 0.17$, $p = .685$, $\eta_p^2 = 0.003$	Time: $F(1,54) = 0.751$, $p = .390$, $\eta_p^2 = 0.014$; Interaction: $F(1,54) = 0.133$, $p = .717$, $\eta_p^2 = 0.002$	Time: $F(1,54) = 1.05$, $p = .311$, $\eta_p^2 = 0.019$; Interaction: $F(1,54) = 0.432$, $p = .514$, $\eta_p^2 = 0.008$

Abbreviation: n.s., not significant.

*$p < .05$ (within-subject differences across time determined by use of pairwise t test).

**$p < .01$ (within-subject differences across time determined by use of pairwise t test).

***$p < .005$ (within-subject differences across time determined by use of pairwise t test).

****$p < .001$ (within-subject differences across time determined by use of pairwise t test).

TABLE 3 Subjective assessment of the MCT interventions at post-treatment ($N = 25$)

	Yes	No
The training was useful and sensible.	25 (100%)	0
I had to force myself to go to the training regularly.	8 (32%)	17 (68%)
In everyday life, I do not apply the lessons learned.	13 (52%)	12 (48%)
The training was an important part of my treatment programme.	23 (92%)	2 (8%)
I would have liked to spend the time doing something else.	10 (40%)	15 (60%)
The training was fun.	24 (96%)	1 (4%)
A lot of what I learned during training is useful to daily life.	24 (96%)	1 (4%)
The goals and rationale of the training were clear to me.	24 (96%)	1 (4%)
I would recommend the training to others.	21 (84%)	4 (16%)
I found it beneficial that the training was administered in a group.	25 (100%)	0

3.3 | Subjective assessment of the training

Most parameters were positively appraised by participants (see Table 3). All participants rated the MCT as useful and sensible and found it beneficial that the training was administered in a group setting. More than 90% of the participants considered the MCT fun, useful to daily life and an important part of their treatment programme; they also confirmed that the goals and rationale of the MCT were clear to them. In total, 84% of participants would recommend the training to others.

4 | DISCUSSION

The current trial was the first to evaluate the efficacy of the MCT programme in a Portuguese sample (a prior study employed a mixed intervention). Unlike in previous studies where MCT was usually administered by psychologists, in this trial, it was applied by mental health and psychiatric nurses, which proved to be feasible and, apparently, did not compromise the treatment efficacy.

With respect to MCT efficacy, for the PSYRATS delusion score, significant improvements were observed in the MCT group relative to the control group, with a high effect size. This is in line with prior RCTs that also used PSYRATS assessments (Briki et al., 2014; Favrod et al., 2014; Moritz et al., 2013). Delusion scores also decreased in a previous study that used individualized MCT (Andreou et al., 2017). With respect to the PSYRATS hallucination score, our study only found a significant improvement at the post-intervention timepoint compared with that at baseline. Another RCT showed similar results for the MCT group (Briki et al., 2014). However, in another study that used PSYRATS measurements, no significant changes were observed in any PSYRATS domains between groups. These non-significant results may be due to a low severity of psychotic symptoms at baseline in the sample (Gawęda et al., 2015). A meta-analysis of RCTs of MCT that included calculations of 11 different effect sizes of outcome measures immediately post-intervention showed that MCT had a moderate immediate effect on delusions (Liu et al., 2018). In our sample, the effect sizes were very large (PP: $\eta_p^2 = 0.244$) post-intervention. With respect to the longer-term effects of MCT on delusion at 6 months post-intervention, four effect sizes were analysed in the same meta-analysis, with the results showing that MCT had a moderate lasting effect (Liu et al., 2018). In our sample, the effect size was also very large (PP: $\eta_p^2 = 0.176$) at the follow-up timepoint (3 months post-intervention). MCT aims to change the cognitive infrastructure of thinking of the patients to make them reflect on their cognitive biases, to think about their own thought patterns and to start questioning their delusions.

The group MCT programme was also efficacious in improving social functioning. Based on the PSP scale, significant improvements were observed in the MCT group relative to the control group. A study that administered a version of the MCT protocol tailored for youths also observed similar PSP changes (Ussorio et al., 2016). Other studies that used the General Assessment of Functioning (GAF) scale, which measures patients' psychological, social and occupational functioning, also showed positive improvements in social functioning in the MCT group (Ishikawa et al., 2020; Naughton et al., 2012; Yildiz et al., 2019). However, another study that used the GAF measure observed no significant differences between groups, but their sample consisted of patients who had severe problems in organizing their everyday activities and self-care (Gawęda et al., 2015), which may explain the discrepancies. The improvement of social functioning in the MCT group may be associated with the improvement of positive symptoms, although a previous systematic review identified no conclusive relationship between positive symptoms and functioning in schizophrenia and more studies are needed (Pinho et al., 2018). However, that review only evaluated studies that used the Quality of Life Scale (QLS). Moreover, group activity in the MCT sessions may have contributed to improving the social functioning of the participants; therefore, we consider that group interventions could be beneficial in this regard. MCT aims to change thought patterns and patients could be more sociable if they are able to decrease their distrust of others and overcome the biases that have an impact on their social behaviours (especially attributional style).

For the WHODAS assessments, the results were not significant. WHODAS aims to evaluate functioning across all areas of life, not just social functioning. Perhaps the lack of positive outcomes is related to the fact that people with schizophrenia usually have severely impaired social and occupational functioning, whereas other areas of functioning can remain unaffected. In addition, the version of the WHODAS used in this study contained only 12 items, whereas a longitudinal study of 4,497 patients with schizophrenia that evaluated functioning used WHODAS 2.0, which contained 32 items, which may explain the discrepancies. The latter study showed that the domains of cognition, mobility and participation significantly decreased, but the domains of self-care, cooperation and daily life

activities remained unchanged (Chen et al., 2019). No RCTs were found that evaluated the efficacy of MCT using the WHODAS.

With respect to cognitive insight, the self-reflectiveness score was not significantly different between groups. Contrary to our trial results, another RCT (MCT group + TAU group) conducted in Hong Kong of patients with schizophrenia showed significant improvements in measures of self-reflectiveness in the MCT group compared with the control group (Lam et al., 2015). For the BCIS, our results showed significant improvements from baseline at the post-treatment timepoint in the MCT group for total scores and self-certainty scores relative to the control group, but these results not were maintained at the 3-month follow-up assessment. Similar results were obtained in an RCT conducted in Spain that assessed a sample of 126 patients with a recent onset of psychosis where the participants were randomly assigned to either an MCT group or a psycho-educational intervention group with cognitive-behavioural elements (Ochoa et al., 2017). Other studies also did not observe a significant improvement in cognitive insight in the MCT as evaluated by the BCIS (Ishikawa et al., 2020; van Oosterhout et al., 2014). However, a study with a sample of young patients with psychosis (18–35 years of age) that applied the youth version of the MCT programme showed that this programme was efficacious in improving both components of cognitive insight (self-reflectiveness and self-certainty). The authors conclude that, with respect to cognitive mental flexibility, this robust improvement of cognitive insight could be associated with the young age of the patients and it may be harder to improve cognitive insight in older patients (Ussorio et al., 2016). Therefore, based on the results of this and prior studies, it remains unclear whether MCT is effective in improving cognitive insight. Perhaps this uncertainty can be attributed to the fact that cognitive insight is difficult to change and maybe continuous and daily training with a longer follow-up time is needed. The self-help smartphone app 'MCT & More', available from www.uke.de/mct_app, could help improve cognitive insight over time.

The subjective assessment indicated that the participants in the MCT group were satisfied with the training they received and the study had many other strengths, including internally consistent methodology, a high completion rate, the administration of an internationally validated intervention and the involvement of practicing psychiatric and mental health nurses of the patients' own institutions, who have acquired skills that will allow them to continue administering MCT in the future.

The current trial is the first to administer an eight-session MCT programme in a group setting in a Portuguese population. The results validated the fact that MCT is efficacious in this culture and the programme can be successfully conducted by trained nurses to effectively reduce psychotic symptoms and improve social functioning.

4.1 | Limitations

Some limitations of this trial should be acknowledged. First of all, the sample size should have been larger, but this was not possible due to the difficulty of assessing the participants. However, our sample size *did* meet the minimum requirements to ensure sufficient power to observe a significant effect based on the calculation of the sample size described in the Methods. Second, this study was only single-blind, with only the researcher who applied all the questionnaires not knowing the group. While randomization minimizes differences between treatment groups at the beginning of the study, it does not prevent differential group biases (Karanicolas et al., 2010). Third, the TAU in the control group can also be considered a limitation. The implementation of a placebo or active control intervention would have been superior in this regard. However, all patients continued to participate in psychosocial rehabilitation programmes and continued to undergo the usual interventions, which may have minimized this bias. Fourth, social desirability is also a potential limitation, as participants receiving the intervention may have been trying to please the providers by responding favourably. To mitigate this limitation, the researcher that administered the psychometric assessments was an individual external to the institution; this person did not administer the MCT intervention. Therefore, the participants only had contact with this researcher at the three timepoints when data were collected. Future research should aim to replicate this study with larger samples of patients with schizophrenia with different sociodemographic and clinical characteristics to improve the generalizability of our findings.

5 | CONCLUSION

Our results showed that MCT has an antipsychotic effect in patients with schizophrenia. MCT applied in a group setting significantly reduced delusions and improved social functioning and self-reflectiveness in a Portuguese population. This trial also proved that MCT could be successfully administered by psychiatric and mental health nurses. Given these results and the benefits of MCT, it should become part of psychosocial rehabilitation programmes for people with severe mental illness.

We also recommend that future MCT studies use the self-help smartphone app 'MCT & More' (available at http://www.uke.de/mct_app) to understand its effects in helping to complement MCT. This app is currently undergoing Portuguese language translation. We also recommend comparative studies be conducted with two groups. In the first group, MCT should be applied by mental health and psychiatric nurses who are part of the daily therapeutic plan; the second group should receive MCT by external professionals who do not know the patients. In this way, one can test whether having a pre-established therapeutic relationship with patients influences the efficacy of MCT. Because differential changes in cognitive insight were observed following MCT, we suggest that future trials apply MCT in older and younger samples to compare the results between age groups and the studies should be longitudinal to help understand how MCT outcomes vary over the course of schizophrenia progression.

For clinical practice, we suggest the implementation of MCT groups for patients with schizophrenia in rehabilitation programmes

as soon as possible after diagnosis, so that they become aware of their cognitive biases and begin to train the mind from an early age in an attempt to slow the progression of delusions. We also recommend employing family psychoeducation programmes to compliment MCT. Academically, we recommend that MCT be taught in the psychiatric and mental health nurses' curricula of this specialty master's degree.

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CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

AUTHORS' CONTRIBUTIONS

LGP initiated the study design, acquired of data and drafting the article. CS, FS and CFG contributed to the study design. ZZ and NR provided the theoretical, practical and research knowledge on metacognitive training. All authors analysed and interpreted the data and revising the article critically for important intellectual content. All authors have agreed on the final version.

PEER REVIEW

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DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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