

Randomized control trial to assess the efficacy of metacognitive training compared with a psycho-educational group in people with a recent-onset psychosis

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Background. Aims were to assess the efficacy of metacognitive training (MCT) in people with a recent onset of psychosis in terms of symptoms as a primary outcome and metacognitive variables as a secondary outcome.

Method. A multicenter, randomized, controlled clinical trial was performed. A total of 126 patients were randomized to an MCT or a psycho-educational intervention with cognitive-behavioral elements. The sample was composed of people with a recent onset of psychosis, recruited from nine public centers in Spain. The treatment consisted of eight weekly sessions for both groups. Patients were assessed at three time-points: baseline, post-treatment, and at 6 months follow-up. The evaluator was blinded to the condition of the patient. Symptoms were assessed with the PANSS and metacognition was assessed with a battery of questionnaires of cognitive biases and social cognition.

Results. Both MCT and psycho-educational groups had improved symptoms post-treatment and at follow-up, with greater improvements in the MCT group. The MCT group was superior to the psycho-educational group on the Beck Cognitive Insight Scale (BCIS) total ($p=0.026$) and self-certainty ($p=0.035$) and dependence self-subscale of irrational beliefs, comparing baseline and post-treatment. Moreover, comparing baseline and follow-up, the MCT group was better than the psycho-educational group in self-reflectiveness on the BCIS ($p=0.047$), total BCIS ($p=0.045$), and intolerance to frustration ($p=0.014$). Jumping to Conclusions (JTC) improved more in the MCT group than the psycho-educational group ($p=0.021$). Regarding the comparison within each group, Theory of Mind (ToM), Personalizing Bias, and other subscales of irrational beliefs improved in the MCT group but not the psycho-educational group ($p<0.001-0.032$).

Conclusions. MCT could be an effective psychological intervention for people with recent onset of psychosis in order to improve cognitive insight, JTC, and tolerance to frustration. It seems that MCT could be useful to improve symptoms, ToM, and personalizing bias.

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Introduction

Schizophrenia is a disorder that causes a great burden (Rössler *et al.* 2005; Gustavsson *et al.* 2011). For years antipsychotic medication has been the only option in the treatment of schizophrenia. However, over the last decades great interest has emerged in the effectiveness of psychological interventions (Wykes *et al.* 2008; Morrison *et al.* 2014).

Psychological interventions based on cognitive therapy are mainly addressed at modifying cognitive biases. Several cognitive biases are more prevalent in people with schizophrenia, and some of them are present from the early onset of the disease. Jumping to conclusions (JTC), making a decision without sufficient evidence, has been shown to be more prevalent in people with delusions and with first-episode psychosis than in healthy controls or people with other mental disorders, with differences of up to 73% *v.* 10% (Garety *et al.* 1991, 2005; Bentham *et al.* 1996; Conway *et al.* 2002; Falcone *et al.* 2015a, b; Dudley *et al.* 2016). Regarding attributional style, a personalized bias has been described in people with psychosis, both in chronic and first-episode psychosis, in which patients blame others rather than themselves for negative situations (Bentall *et al.* 1991; Martin & Penn, 2002; Fornells-Ambrojo & Garety, 2009). Other cognitive biases such as overconfidence in errors and bias against disconfirmatory evidence have been described as being more prevalent in people with persecutory delusion (Kaney & Bentall, 1992; Moritz *et al.* 2005; Moritz & Woodward, 2006), who show higher levels of self-certainty in their decisions. Moreover, irrational beliefs that include demands, catastrophic thinking, low frustration tolerance, and conditional self-acceptance, are more frequent in people with schizophrenia (Newmark & Whitt, 1983). In addition, social cognition is highly affected in people with schizophrenia and first-episode psychosis (Green *et al.* 2012; Bora & Pantelis, 2013; Pinkham *et al.* 2003; Pousa *et al.* 2008). These cognitive biases, as social cognition impairment, are important features as well as in the creation and maintenance of delusions and contribute negatively to the functioning of the patient.

Metacognitive training (MCT) is a group therapeutic approach to the treatment of psychotic symptoms based on a cognitive-behavioural model of schizophrenia with a psychoeducational approach addressed to reducing all the aforementioned cognitive biases (Moritz *et al.* 2013a). MCT has demonstrated its efficacy in the reduction of positive symptoms in people with schizophrenia (Moritz *et al.* 2011, 2013b, 2014a, b; Balzan *et al.* 2014; Erawati *et al.* 2014). A recent meta-analysis shows that MCT is useful for the reduction of positive symptoms and delusions, and

acceptance of the intervention is greater than it is for other models (Eichner & Berna 2016). Moreover, other variables such as JTC, quality of life, cognitive insight, and memory also show improvement with MCT (Aghotor *et al.* 2010; Gawęda *et al.* 2015).

However, to our knowledge no study has tested the efficacy of MCT in people with a recent-onset of psychosis. Effective psychological intervention in recent-onset of psychosis is needed due to the importance of early intervention in reducing chronicity and improving the prognosis of the illness. Moreover, aspects related to metacognitive variables have to date scarcely been assessed, if at all.

Therefore, the aim of the present study was to assess the efficacy of group MCT in people with recent-onset of psychosis in terms of symptoms as a primary objective and metacognitive variables as a secondary objective.

Method

Design

A parallel multicenter randomized clinical trial was performed, in which one group received MCT while the other, a psycho-educational group, received sessions of equal frequency and duration. Patients were randomized for inclusion in the study in blocks of four from a list of random numbers in each center provided by the coordinator of the study. The person responsible of the study in each center was the person who assigned participants to each group.

Sample

The sample size needed, based on the results reported by Moritz *et al.* (2011), was 92, considering a 20% dropout rate in the follow-up. In the end, our recruitment effort achieved a total sample of 126 patients. Four of them left the study after enrollment (see Fig. 1). The sample was composed of patients with recent-onset of psychosis (Breitborde *et al.* 2009) treated at one of the nine participating mental health centers: Servicio Andaluz de Salud of Jaén, Málaga and Motril (Granada), Salut Mental Parc Taulí (Sabadell), Hospital de Santa Creu i Sant Pau (Barcelona), Centro de Higiene Mental Les Corts (Barcelona), Institut d'Assistència Sanitària Girona, Hospital Clínic Universitario de Valencia, and Parc Sanitari Sant Joan de Déu (Coordinating center). Patients were enrolled by their clinical therapist. Inclusion criteria were (1) a diagnosis of schizophrenia, psychotic disorder not otherwise specified, delusional disorder, schizoaffective disorder, brief psychotic disorder, or schizophreniform disorder (according to DSM-IV-TR); (2) <5 years from the onset of symptoms; (3) a score during the previous year of ≥ 3 in item

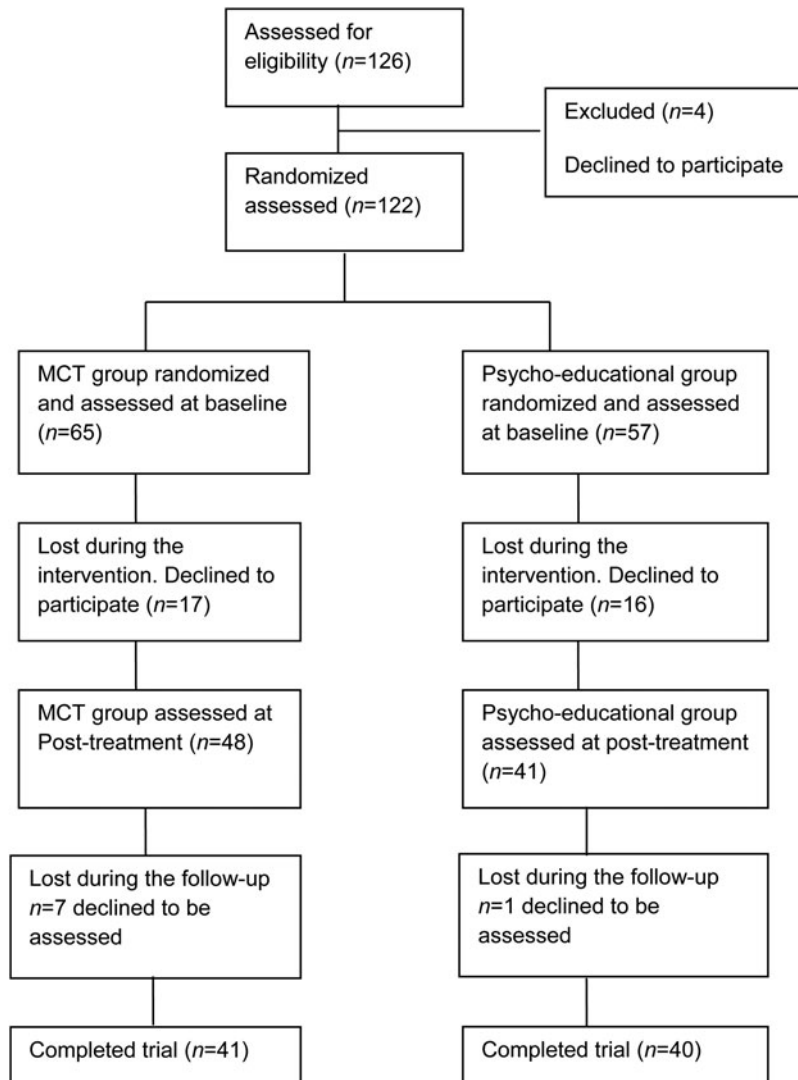


Fig. 1. Trial profile.

delusions, grandiosity, or suspicions of PANSS (according to Moritz *et al.* 2011); and (4) age between 17 and 45 years. Exclusion criteria were (1) traumatic brain injury, dementia, or intellectual disability (pre-morbid IQ \leq 70); (2) substance dependence; and (3) PANSS \geq 5 in hostile and uncooperative and \geq 6 in suspiciousness, to avoid altering the dynamics of the group.

Interventions

The interventions consisted of eight weekly group sessions of MCT (experimental group) in its third edition or psycho-educational (control group). The therapists were trained during a 2-day workshop by Steffen Moritz, author of MCT, and Lisa Schilling.

The MCT program included eight modules: Attributional style (1), Jumping to conclusions (2, 7), Changing beliefs (3), Empathy (4, 6), Memory (5),

and Depression and self-esteem (8), worked through with PowerPoint presentations with different examples and material on all these topics.

In the psycho-educational group the modules were: Healthy habits (1); Risk Behaviors (2), Prevention of relapse (3), Video forum (4, 5), Resources of work (6), Leisure activities (7), and Resources available in the community (8). Material for each weekly module was previously agreed upon by all participating centers to unify interventions. Both interventions were performed in the patients' habitual center of care.

Outcomes

Patients were assessed at baseline, post-treatment, and 6 months follow-up. The evaluator was blinded to the condition of the patients. The evaluators were trained in the scales of the study, scoring >0.70 in inter-rater reliability.

Symptoms were the primary outcome and were assessed with the Positive and Negative Syndrome Scale (PANSS; Kay *et al.* 1987; Peralta & Cuesta, 1994).

The Global Assessment of Functioning (GAF; Endicott, 1976) was used to assess symptoms and social adaptation.

A battery of questionnaires regarding cognitive biases and social cognition was included in order to assess the secondary outcomes:

- Beck Cognitive Insight Scale (BCIS; Beck *et al.* 2004; Gutiérrez-Zotes *et al.* 2012) consists of a self-administered scale assessing cognitive insight, containing self-reflectiveness and self-certainty subscales, and a composite index. Cronbach's alpha in the Spanish validation for self-reflectiveness was 0.59 and 0.62 for self-certainty.
- Jumping to Conclusions (JTC) was assessed with the beads task in which the subject must take a decision regarding the probability of the extracted bead belonging to one of two jars. In task 1 the probability is 85:15 and in task 2 it is 60:40. JTC was considered as taking a decision after extracting one or two beads (Brett-Jones *et al.* 1987).
- Irrational beliefs were assessed with the Irrational Belief Test (TCI; Calvete & Cardeñoso, 2001). The scale is composed of ten subscales: needing acceptance from others, high expectations, guilt, intolerance to frustration, worry and anxiety, emotional irresponsibility, avoidance of problems, dependence, helplessness, and perfectionism. Cronbach's alpha in the Spanish validation for the subscales oscillated between 0.63 and 0.79.
- Attributional style was assessed with the Internal, Personal and Situational Attributions Questionnaire (IPSAQ; Kinderman & Bentall, 1996), including two subscales: Externalizing and Personalizing Bias.
- The Hinting Task was used to assess Theory of Mind (ToM; Corcoran *et al.* 1995; Gil *et al.* 2012). In order to avoid learning, three different stories were used in each assessment taking into account their validity and the level of difficulty according to the scores obtained in the Spanish validation of the questionnaire. Cronbach's alpha of the Spanish version of the instrument was 0.64.
- Emotional perception was assessed with the Emotional Recognition Test Faces (Baron-Cohen *et al.* 1997), composed of 20 photographs that express ten basic and ten complex emotions.

Ethical aspects

The project was evaluated by the research and ethics committees of the coordinating center and each center included in the study. The participants signed

informed consent for participation in the study. The study was recorded in Clinical Trials (Identifier: NCT02340559).

Statistical analysis

The differences between each assessment were compared by group with Student's *t* test and ANCOVA. McNemar association was used to compare JTC between each assessment. A general linear model for repeated measures was performed in order to compare the longitudinal effect of the intervention. A complementary analysis was performed in order to assess the intra-group differences using a comparison means for repeated measures. The analyses were performed imputing data from the last evaluation in follow-up and without imputation. The results shown corresponded to those with no imputed data. All the analyses were controlled for number of sessions, not a significant variable. Effect sizes of the comparison were analyzed with the Cohen's *d*.

Results

Fig. 1 is the flowchart of participants in each of the three assessments. The analyses were performed with the total number of patients that completed the baseline and post-treatment assessment ($n = 89$) and follow-up ($n = 81$). Percentage of drop-outs in the post-treatment assessment was 27% in the MCT group and 28.1% in the psycho-educational group. Mean number of sessions attended was 4.95 (s.d. = 2.98) for the psycho-educational group and 5.53 (s.d. = 2.46) for the MCT group. No statistical differences were found. The best attended sessions of the MCT group were: attributional style (1), jumping to conclusions (2), memory (5) and depression and self-esteem (8); while changing beliefs session had lower adherence (3).

The study started in June 2011 and inclusion of patients was closed by December 2013. The study with the follow-up was closed in August 2014.

Table 1 indicates the sociodemographic characteristics of the two groups, MCT and psycho-educational. No statistical differences were found regarding any sociodemographic or clinical characteristics between the two groups at baseline.

Table 2 shows that there was no difference in PANSS assessment at baseline and post-treatment, and baseline and follow-up, between the two groups.

Table 3 shows that BCIS self-certainty, BCIS composite index, and dependence of the TCI improved in the MCT group *v.* the psycho-educational group between baseline and post-treatment. Between baseline and follow-up there are differences in the groups in BCIS

Table 1. Sociodemographic characteristics of the sample

	Psycho-educational group		MCT group	
	N	%	N	%
Gender				
Men	41	71.9	44	67.7
Women	16	28.1	21	32.3
Marital status				
Single	47	82.4	53	81.5
Married	5	8.8	8	12.3
Divorced	5	8.8	4	6.2
Level of education				
Primary	18	31.6	26	40.0
Secondary	25	43.8	25	38.5
University	14	24.6	14	21.5
Employment status				
Work	6	10.5	14	21.5
Student	8	14.0	12	18.5
Incapacity	10	17.5	13	20.0
Unemployed	23	40.5	19	29.3
Others	10	17.5	7	10.7
	Mean	S.D.	Mean	S.D.
Age	28.21	6.73	27.05	7.94
Age at onset	26.03	6.57	25.16	7.79
Years of psychosis duration	2.46	2.07	2.15	2.01
Number of hospitalizations	1.34	1.21	1.16	1.54
Antipsychotic dose, mg/d ^a	519.49	534.58	472.53	703.89

MCT, Metacognitive Training.

^a Antipsychotic drug doses are expressed as chlorpromazine equivalence.

self-reflectiveness, BCIS composite index, and intolerance to frustration of the TCI.

Regarding the effect of the intervention taking into account three assessments (baseline, post-treatment, and follow-up) together, a general linear model for repeated measures was performed. The PANSS positive was significant for time effect ($p=0.001$) but not for the time \times group interaction ($p=0.316$). The PANSS negative had a significant effect of time ($p=0.005$), but no effect for time \times group interaction was found ($p=0.651$). Regarding the PANSS general, a clear effect of time was found ($p<0.001$), but no effect for time \times group interaction was detected ($p=0.107$). Finally, the PANSS total was significant for time ($p<0.001$) but not for the time \times group interaction ($p=0.193$). Regarding general functioning, GAF score indicated that there was an effect of time ($p=0.004$) but not of group ($p=.54$). On the self-reflectiveness

subscale of the BCIS, there was an effect of time ($p=0.027$) and a trend in the time \times group interaction ($p=0.067$). The self-certainty subscale of the BCIS showed no effect of time ($p=0.182$) but a trend in time \times group interaction was detected ($p=0.081$). Finally, the Composite Index of the BCIS showed that the MCT group improved more than the psycho-educational group over time, with $p=0.042$ for the time \times group interaction, and $p=0.038$ the effect of time. The IPSAQ personalized bias showed no effect of time ($p=0.395$) but a trend for time \times group interaction was seen ($p=0.087$). As to irrational beliefs, intolerance to frustration showed an improvement in the MCT group compared to the psycho-educational group over time ($p=0.016$).

The number of patients who jumped to conclusions in each assessment by group is shown in Fig. 2. Regarding the MCT group, significant differences were found between baseline and post-treatment regarding the 85:15 task of JTC ($p=0.021$) and a trend toward significance at follow-up ($p=0.057$).

A supplementary analysis was performed comparing differences between baseline and post-treatment and baseline and follow-up in each group, independently. The results are presented in Table 4, indicating more significant values and greater effect in the comparison of PANSS subscales in the MCT group than in the psycho-educational group. Moreover, significant values were found in the MCT group for GAF, Personalizing bias, Hinting task, and some subscales of the TCI that were not found in the psycho-educational group.

Discussion

The results are unique in that this is the first study to observe the effectiveness of MCT in people with recent onset of psychosis, which is of clinical relevance, given early intervention is important in reducing chronicity and improving prognosis. Both the MCT and the psycho-educational groups showed reduced clinical symptoms. Moreover, MCT presented greater improvements than the psycho-educational group in cognitive insight, irrational beliefs, and JTC.

Symptoms improved considerably in both treatment groups. However, the complementary analyses show that the MCT group presented greater improvements with greater effect size, especially in the follow-up (some of them superior to 0.8). Although other studies performed in people with schizophrenia have found a clear improvement in symptoms in MCT groups, compared with control and cognitive remediation, our results indicated a slight improvement when compared to a psycho-educational group (Favrod *et al.*

Table 2. Differences in clinical outcomes between MCT and psycho-educational groups

	Psycho-educational group			MCT group			Comparison between groups		
	Baseline	Post-treatment	Follow-up	Baseline	Post-treatment	Follow-up	Difference baseline v. post-treatment	Difference baseline v. follow-up	<i>p</i> value (effect size)
	Mean (s.d.)	Mean (s.d.)	Mean (s.d.)	Mean (s.d.)	Mean (s.d.)	Mean (s.d.)	Difference (effect size)	<i>p</i> value (effect size)	
PANSS positive	12.28 (4.07)	10.87 (3.53)	10.75 (3.45)	12.16 (4.24)	10.73 (3.48)	9.78 (3.18)	0.733 (0.074)	0.281 (0.241)	
PANSS negative	15.12 (5.41)	14.23 (4.82)	13.48 (5.51)	14.20 (6.49)	13.75 (6.51)	12.51 (6.09)	0.729 (0.074)	0.584 (0.122)	
PANSS general	27.36 (6.24)	25.48 (6.82)	24.23 (4.94)	27.50 (7.27)	25.63 (6.04)	23.95 (6.01)	0.196 (0.279)	0.152 (0.326)	
PANSS total	54.86 (12.81)	50.36 (13.01)	48.41 (11.42)	53.86 (15.59)	50.10 (13.82)	46.33 (13.71)	0.498 (0.147)	0.206 (0.287)	

MCT, Metacognitive Training; PANSS, Positive and Negative Syndrome Scale.

2014; Windell *et al.* 2015). However, it is important to note the greater improvements of MCT in the follow-up, coinciding with the results of Moritz *et al.* (2014a, b) after 3 years of follow-up, suggesting a 'sleeper' effect of MCT, implying that work in the sessions could have an important effect in the future. Moreover, MCT had a clear effect in follow-up not only on positive symptoms but also negative and general symptoms as well, suggesting more improvement in functionality (Windell *et al.* 2015). It is likely that the strategies worked on in the group were indirectly related to symptoms and could be useful in preventing future relapses. In our study, people with psychosis of recent onset showed improvement in positive symptoms with both interventions. It should be taken into account that levels of symptoms at baseline were very low, indicating a possible floor effect that made it difficult to detect the superiority of one intervention over the other due to the restriction in range. In contrast, people with schizophrenia in other studies scored higher in symptoms (Moritz *et al.* 2011) suggested that in order to avoid the floor effect future studies should recruit subjects with at least mild delusional symptoms.

The MCT group had a clear effect in cognitive insight, in the post-treatment and follow-up, according to (Lam *et al.* 2015) and contrary to van Oosterhout *et al.* (2014). The psycho-educational group scored worse on the self-reflectiveness subscale at all time points while the MCT group showed a reduction in their scores on the self-certainty subscale, indicating better scores for the composite index for people who attended the MCT intervention. The reduction of levels of self-certainty is relevant because in reducing this bias, patients achieve a lower confidence in the interpretation of their own ideas (Beck *et al.* 2004) and possibly prevent these ideas from becoming delusions. Moreover, MCT acts as a preventive intervention regarding self-reflectiveness, because patients from the psycho-educational group scored worse throughout the clinical trial, obtaining similar scores to chronic patients with schizophrenia (Beck *et al.* 2004). Improvement in insight, which is one of the core results found, has been associated with treatment adherence, higher metacognition, and fewer symptoms in people with first episode of psychosis and schizophrenia (Myers *et al.* 2014; Lysaker *et al.* 2015; Vohs *et al.* 2015).

People from the MCT group decreased in intolerance to frustration and in dependence compared with people from the psycho-educational group. Intolerance to frustration may cause the patient to be over-concerned and manifest early appearance of negative emotional responses such as irritability, guilt, anger, and lower cognitive flexibility (Stanković & Vukosavljević-

Table 3. Differences in functioning and metacognitive variables between MCT and psycho-educational groups at baseline compared to post-treatment, and baseline compared to follow-up

	Psychoeducational group			MCT group			Comparison between groups	
	Baseline	Post-treatment	Follow-up	Baseline	Post-treatment	Follow-up	Differences between baseline and post-treatment	Differences between baseline and follow-up
	Mean (s.d.)	Mean (s.d.)	Mean (s.d.)	Mean (s.d.)	Mean (s.d.)	Mean (s.d.)	<i>p</i> value (effect size)	<i>p</i> value (effect size)
GAF	59.26 (11.08)	62.73 (12.26)	63.68 (11.67)	63.05 (13.97)	66.69 (12.03)	69.41 (11.35)	0.482 (−0.151)	0.55 (−0.133)
Self-reflectiveness BCIS	16.46 (4.71)	15.95 (4.36)	14.63 (4.51)	15.36 (5.15)	16.04 (5.13)	16.29 (7.07)	0.164 (−0.298)	0.047 (−0.449)
Self-certainty BCIS	8.51 (3.49)	8.07 (3.67)	7.63 (2.88)	8.66 (3.63)	6.96 (3.23)	7.39 (3.59)	0.035 (0.456)	0.489 (0.155)
Composite index BCIS	7.95 (5.44)	7.88 (5.92)	7.00 (5.38)	6.70 (6.52)	9.08 (7.03)	8.90 (8.49)	0.026 (−0.488)	0.045 (−0.452)
Externalizing bias IPSAQ	1.11 (3.98)	1.44 (4.08)	1.84 (3.47)	0.46 (3.62)	0.43 (2.71)	1.46 (3.31)	0.751 (0.068)	0.723 (−0.081)
Personalizing bias IPSAQ	1.23 (0.64)	1.27 (0.67)	1.19 (0.96)	1.31 (0.72)	1.19 (0.68)	1.01 (0.51)	0.271 (0.238)	0.056 (0.559)
Hinting task	4.63 (1.19)	4.80 (1.50)	4.65 (1.17)	4.85 (1.05)	5.12 (1.26)	5.14 (1.01)	0.577 (−0.119)	0.127 (−0.343)
Emotional recognition faces	17.54 (1.89)	17.63 (2.08)	17.38 (2.27)	17.68 (1.60)	17.63 (1.81)	18.05 (1.56)	0.300 (0.222)	0.458 (−0.166)
Need of acceptance from others TCI	23.91 (5.52)	22.37 (5.03)	23.20 (4.79)	24.30 (6.13)	23.68 (4.96)	23.15 (5.38)	0.628 (−0.104)	0.822 (0.051)
High expectations TCI	16.46 (4.38)	17.00 (3.73)	16.45 (4.49)	17.86 (3.86)	17.04 (3.46)	15.51 (3.91)	0.149 (0.313)	0.121 (0.351)
Guilt TCI	22.91 (6.29)	22.05 (5.85)	21.60 (5.58)	24.98 (6.14)	24.45 (5.43)	23.73 (5.80)	0.77 (−0.063)	0.65 (0.102)
Intolerance to frustration TCI	21.54 (3.89)	21.29 (3.81)	22.55 (2.98)	22.27 (3.59)	21.09 (3.23)	20.71 (4.03)	0.466 (0.157)	0.014 (0.562)
Worry and anxiety TCI	16.72 (4.16)	16.39 (3.24)	16.33 (3.08)	16.94 (3.82)	16.17 (3.38)	15.49 (3.91)	0.412 (0.177)	0.401 (0.189)
Emotional irresponsibility TCI	20.79 (6.65)	20.37 (6.02)	20.53 (5.62)	19.88 (7.32)	19.45 (6.28)	19.05 (6.62)	0.823 (0.048)	0.743 (0.073)
Avoidance problems TCI	9.04 (3.12)	9.37 (2.49)	9.18 (2.92)	8.80 (7.32)	8.87 (2.94)	8.24 (2.52)	0.897 (−0.028)	0.892 (0.03)
Dependence TCI	20.46 (4.62)	21.29 (5.22)	21.48 (4.58)	21.50 (4.72)	19.94 (4.47)	21.20 (4.94)	0.020 (0.508)	0.196 (0.292)
Helplessness TCI	23.58 (7.12)	21.85 (7.61)	22.53 (5.42)	22.28 (6.49)	22.77 (5.99)	21.41 (4.94)	0.250 (−0.249)	0.906 (−0.027)
Perfectionism TCI	16.72 (4.57)	16.80 (5.27)	16.83 (4.89)	18.66 (4.01)	17.45 (4.26)	17.93 (3.82)	0.350 (0.202)	0.814 (0.053)

MCT, Metacognitive Training; GAF, Global assessment of functioning; BCIS, Beck Cognitive Insight Scale; IPSAQ, Internal, Personal and Situational Attributions Questionnaire; TCI; Irrational Belief Test.

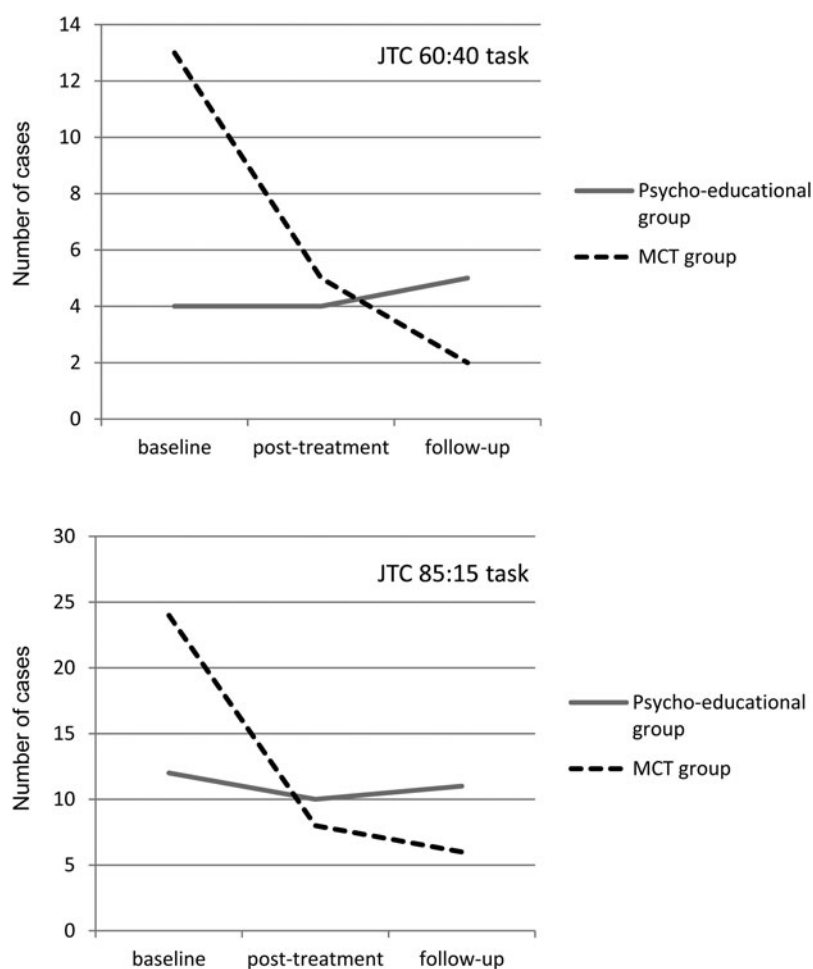


Fig. 2. Number of patients jumping to conclusions in each task (85:15 and 60:40) between the two groups in the three assessments.

Gvozden, 2011). Both variables could be related to depression and self-esteem (Xu *et al.* 2013). In this line, MCT may act as a protective intervention for depressive symptoms and as an elicitor of improved self-esteem.

JTC improved in the MCT group but not in the psycho-educational group; however, the changes were produced only in the 85:15 task, and were clearly significant only in post-treatment. Curiously, despite randomization, the psycho-educational group presented less JTC at baseline than the MCT group. These results suggest that JTC could be reduced by MCT training (Menon *et al.* 2008), although the possible floor effect in the psycho-educational group should be considered. Our results are in accordance with previous studies that found that MCT is useful in reducing JTC in people with schizophrenia (Aghotor *et al.* 2010), and taking into account the theoretical model of Salvatore *et al.* (2012), it could therefore help prevent the emergence of delusions.

Although no differences were found in the comparison between groups, in the intergroup comparison personalizing bias presented an improvement in the MCT group but not in psycho-educational group in the follow-up, with a high effect size (up to 0.9). This is an interesting result because higher scores on this subscale are associated with higher levels of paranoid ideation and persecutory delusions (Kinderman & Bentall, 1996; Mehl *et al.* 2014). In the same line, ToM improved in the MCT group but not in the psycho-educational group in the follow-up, and with a mild effect size. It did not improve in the analysis between groups. However, scores on the ToM task were high even at baseline, suggesting that the patients included were not sufficiently impaired in this area, contrary to a previous meta-analysis (Bora & Pantelis, 2013). Another possibility might be that the test used did not detect deficits in ToM, as suggested by Langdon *et al.* (2014). Regarding emotional recognition there was no improvement in either of the two groups,

Table 4. Differences in each group between baseline and post-treatment and baseline and follow-up

	Psycho-educational group		MCT group	
	Differences baseline <i>v.</i> post-treatment	Differences baseline <i>v.</i> follow-up	Differences baseline <i>v.</i> post-treatment	Differences baseline <i>v.</i> follow-up
	Difference mean <i>p</i> value (effect size)	Difference mean <i>p</i> value (effect size)	Difference mean <i>p</i> value (effect size)	Difference mean <i>p</i> value (effect size)
PANSS positive	-1.41 0.04 (-0.333)	-1.53 0.04 (-0.337)	-1.43 0.011 (-0.382)	-2.38 0.001 (-0.533)
PANSS negative	-0.90 0.22 (-0.195)	-1.65 0.133 (-0.242)	-0.45 0.218 (-0.18)	-1.69 0.001 (-0.578)
PANSS general	-1.88 0.78 (-0.044)	-3.13 0.113 (-0.26)	-1.88 0.008 (-0.403)	-3.55 <0.001 (-0.845)
PANSS total	-4.50 0.25 (-0.187)	-6.45 0.045 (-0.332)	-3.76 0.005 (-0.429)	-7.53 <0.001 (-0.897)
GAF	3.46 0.096 (0.27)	4.41 0.063 (0.302)	3.64 0.03 (0.317)	6.37 0.016 (0.394)
Self-reflectiveness BCIS	-0.51 0.076 (-0.285)	-1.83 <0.001 (-0.66)	0.68 0.727 (0.051)	0.93 0.88 (0.024)
Self-certainty BCIS	-0.44 0.675 (0.066)	-0.88 0.63 (-0.077)	-1.69 0.004 (-0.436)	-1.27 0.244 (-0.185)
Composite Index BCIS	-0.07 0.146 (-0.232)	-0.95 0.003 (-0.51)	2.38 0.088 (0.252)	2.20 0.516 (0.102)
Personalizing Bias IPSAQ	0.04 0.46 (0.118)	-0.04 0.75 (-0.078)	-0.12 0.397 (-0.125)	-0.30 <0.001 (-0.905)
Hinting Task	0.17 0.509 (0.104)	0.02 0.891 (0.022)	0.28 0.125 (0.225)	0.30 0.032 (0.347)
High expectations TCI	0.54 0.485 (0.11)	-0.01 0.907 (0.019)	-0.82 0.144 (-0.219)	-2.35 0.013 (-0.413)
Emotional irresponsibility TCI	-0.42 0.22 (-0.194)	-0.26 0.428 (-0.127)	-0.43 0.03 (-0.331)	-0.83 0.138 (-0.239)
Dependence TCI	0.84 0.412 (0.129)	-0.26 0.304 (0.165)	-1.56 0.007 (-0.416)	-0.31 0.429 (-0.126)

PANSS, Positive and Negative Syndrome Scale; GAF, Global assessment of functioning; BCIS, Beck Cognitive Insight Scale; IPSAQ, Internal, Personal and Situational Attributions Questionnaire; TCI; Irrational Belief Test.

contrary to previous research (Ussorio *et al.* 2016). Both groups had good scores in emotional recognition at baseline assessment, so perhaps at this stage of the illness there is not a clear deficit, in contrast to chronic samples (Besche-Richard *et al.* 2012). Moreover, the MCT does not target better emotion recognition but rather modulates confidence for social judgments.

However, some considerations should be taken into account. Regarding the characteristics of the 'control' group for comparison, an active intervention was used in order to control the effect of the group. However, this group was not really 'control' because in two sessions patients were receiving and sharing information regarding risk behaviors and prevention of relapses. The other clinical trials performed with the MCT have used other characteristics in the

comparison groups such as waiting lists and cognitive rehabilitation (Moritz *et al.* 2014b), and this could account for the discrepancies in findings. Another point to take into account is that both groups received an extra intervention (MCT or psycho-education) not considered treatment as usual, which probably helped both groups improve in several areas. Perhaps the MCT group might have improved more if the comparison group had been with treatment as usual. Second, the frequency of sessions in our study was once a week while in other studies it was twice a week. This divergence in the methodology could have influenced the results in some way, producing slower changes in the MCT intervention. Another consideration arises from the setting of the patients; in our study we included only outpatients while in other studies

inpatients were also included (Moritz *et al.* 2013a, b). Another limitation is that the patients were not asked to complete homework in the MCT group and this could be a cause of the lower integration of the areas worked up in the sessions. MCT has been demonstrated to be effective in people with schizophrenia with eight sessions included in the program (Eichner & Berna, 2016). However, in order to further improve the results other interventions could be provided to these patients, such as joint implementation of MCT in group and individualized (Moritz *et al.* 2011), as well as other kinds of interventions addressed to covering similar aspects (Penn *et al.* 2005). Finally, the training has been recently complemented with two modules on self-esteem and dealing with stigma as these domains may also contribute to the formation and maintenance of positive symptoms. Whether these modules augment effects awaits to be established, however.

The strengths of the study include an adequate sample size, the novelty of the characteristics of the sample in terms of early stages and community settings, and its multi-site implementation.

In conclusion, MCT is an effective psychological intervention for people with a recent onset of psychosis, in order to improve psychotic symptoms and cognitive insight, and to reduce irrational beliefs. MCT could be a good treatment choice in clinical practice taking into account the positive results in insight improvement that may act to prevent further psychotic episodes. More studies should be done with this population in order to assess the cost-effectiveness of MCT and the combination of this treatment with others.

Appendix. Spanish Metacognition Study Group

Acevedo A, Anglès J, Argany MA, Barajas A, Barrigón ML, Beltrán M, Birulés I, Bogas JL, Camprubí N, Carbonero M, Carmona Farrés C, Carrasco E, Casañas R, Cid J, Conesa E, Corripio I, Cortes P, Crosas JM, de Apraiz A, Delgado M, Domínguez L, Escartí MJ, Escudero A, Esteban Pinos I, Figueras M, Franco C, García C, Gil V, Giménez-Díaz D, Gonzalez-Casares R, González Higuera F, González-Montoro M^aL, González E, Grasa Bello E, Guasp A, Huerta-Ramos M^a E, Huertas P, Jiménez-Díaz A, Lalucat LL, LLacer B, López-Alcayada R, López-Carrilero R, Lorente E, Luengo A, Mantecón N, Mas-Expósito L, Montes M, Moritz S, Murgui E, Nuñez M, Ochoa S, Palomer E, Paniego E, Peláez T, Pérez V, Planell K, Planellas C, Pleguezuelo-Garrote P, Pousa E, Rabella M, Renovell M, Rubio R, Ruiz-Delgado I, San Emeterio M, Sánchez E, Sanjuán J, Sans B, Schilling L, Sió H, Teixidó M, Torres P, Vila MA, Vila-Badia R, Villegas F, Villellas R.

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Declaration of Interest

None.

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