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

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21 **Background.** Aims were to assess the efficacy of metacognitive training (MCT) in people with a recent onset of psychosis 22 in terms of symptoms as a primary outcome and metacognitive variables as a secondary outcome.

23 Method. A multicenter, randomized, controlled clinical trial was performed. A total of 126 patients were randomized to

24 an MCT or a psycho-educational intervention. The sample was composed of people with a recent onset of psychosis,

25 recruited from nine public centers in Spain. The treatment consisted of eight weekly sessions for both groups.

26 Patients were assessed at three time-points: baseline, post-treatment, and at 6 months follow-up. The evaluator was

27 blinded to the condition of the patient. Symptoms were assessed with the PANSS and metacognition was assessed

28 with a battery of questionnaires of cognitive biases and social cognition.

29 Results. Both MCT and psycho-educational groups had improved symptoms post-treatment and at follow-up, with 30 greater improvements in the MCT group. The MCT group was superior to the psycho-educational group on the Beck

31 Cognitive Insight Scale (BCIS) total (p=0.026) and self-certainty (p=0.035) and dependence self-subscale of irrational

32 beliefs, comparing baseline and post-treatment. Moreover, comparing baseline and follow-up, the MCT group was better

33 than the psycho-educational group in self-reflectiveness on the BCIS (p = 0.047), total BCIS (p = 0.045), and intolerance to

34 frustration (p = 0.02). Jumping to Conclusions (JTC) improved more in the MCT group than the psycho-educational

35 group (*p* = 0.021). Regarding the comparison within each group, Theory of Mind (ToM), Personalizing Bias, and other

36 subscales of irrational beliefs improved in the MCT group but not the psycho-educational group (p < 0.001-0.032).

37 **Conclusions.** MCT could be an effective psychological intervention for people with recent onset of psychosis in order to 38 improve cognitive insight, JTC, and tolerance to frustration. It seems that MCT could be useful to improve symptoms,

39 ToM, and personalizing bias.

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41 **Key words**: Metacognition, metacognitive training, psychological intervention, psychosis, recent onset of psychosis, 42 schizophrenia.

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## 43 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 ther-51 52 apy are mainly addressed at modifying cognitive biases. Several cognitive biases are more prevalent in 53 people with schizophrenia, and some of them are pre-54 sent from the early onset of the disease. Jumping to 55 conclusions (JTC), consisting of acceptance of a situ-56 ation without sufficient evidence, has been shown to 57 58 be more prevalent in people with delusions and with first-episode psychosis than in healthy controls or peo-59 ple with other mental disorders, with differences of up 60 to 73% v. 10% (Garety et al. 1991, 2005; Bentham et al. 61 62 1996; Conway et al. 2002; Falcone et al. 2015a, b; Dudley et al. 2016). Regarding attributional style, a 63 personalized bias has been described in people with 64 psychosis, both in chronic and first-episode psychosis, 65 66 in which patients blame others rather than themselves 67 for negative situations (Bentall et al. 1991; Martin & Penn, 2002; Fornells-Ambrojo & Garety, 2009). Other 68 cognitive biases such as overconfidence in errors and 69 bias against disconfirmatory evidence have been 70 described as being more prevalent in people with per-71 secutory delusion (Kaney & Bentall, 1992; Moritz et al. 72 2005; Moritz & Woodward, 2006), who show higher 73 levels of self-certainty in their decisions. Moreover, 74 75 irrational beliefs that include demands, catastrophic thinking, low frustration tolerance, and conditional 76 77 self-acceptance, are more frequent in people with 78 schizophrenia (Newmark & Whitt, 1983). In addition, social cognition is highly affected in people with 79 schizophrenia and first-episode psychosis (Green 80 et al. 2012; Bora & Pantelis, 2013; Pinkham et al. 2003, 81 82 Pousa et al. 2008). These cognitive biases, as social cognition impairment, are important features in the 83 creation and maintenance of delusions and contribute 84 negatively to the functioning of the patient. 85

Metacognitive training (MCT) is a group therapeutic 86 approach to the treatment of psychotic symptoms 87 88 based on a cognitive-behavioural model of schizophre-89 nia with a psychoeducational approach addressed to 90 reducing all the aforementioned cognitive biases (Moritz et al. 2013a). MCT has demonstrated its efficacy 91 92 in the reduction of positive symptoms in people with schizophrenia (Moritz et al. 2011, 2013b, 2014a, b; 93 Balzan et al. 2014; Erawati et al. 2014). A recent 94 meta-analysis shows that MCT is useful for the reduc-95 tion of positive symptoms and delusions, and 96

acceptance of the intervention is greater than it is for 97 other models (Eichner & Berna 2016). Moreover, 98 other variables such as JTC, quality of life, cognitive 99 insight, and memory also show improvement with 100 MCT (Aghotor *et al.* 2010; Gawęda *et al.* 2015). 101

However, to our knowledge no study has tested the 102 efficacy of MCT in people with a recent-onset of psychosis. Effective psychological intervention in recentonset of psychosis is needed due to the importance 104 of early intervention in reducing chronicity and 106 improving the prognosis of the illness. Moreover, 107 aspects related to metacognitive variables have to 108 date scarcely been assessed, if at all. 109

Therefore, the aim of the present study was to assess110the efficacy of group MCT in people with recent-onset of111psychosis in terms of symptoms as a primary objective112and metacognitive variables as a secondary objective.113

# Method

# Design

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A parallel multicenter randomized clinical trial was 116 performed, in which one group received MCT while 117 the other, a psycho-educational group, received ses-118 sions of equal frequency and duration. Patients were 119 randomized for inclusion in the study in blocks of 120 four from a list of random numbers in each center pro-121 vided by the coordinator of the study. The person 122 responsible of the study in each center was the person 123 who assigned participants to each group. 124

# Sample

The sample size needed, based on the results reported 126 by Moritz et al. (2011), was 92, considering a 20% drop-127 out rate in the follow-up. In the end, our recruitment 128 effort achieved a total sample of 126 patients. Four of 129 them left the study after enrollment (see Fig. 1). The 130 sample was composed of patients with recent-onset of psychosis (Breitborde et al. 2009) treated at one of 132 the nine participating mental health centers: Servicio 133 Andaluz de Salud of Jaén, Málaga and Motril 134 (Granada), Salut Mental Parc Taulí (Sabadell), 135 Hospital de Santa Creu i Sant Pau (Barcelona), 136 Centro de Higiene Mental Les Corts (Barcelona), 137 Institut d'Assistència Sanitària Girona, Hospital 138 Clínico Universitario de Valencia, and Parc Sanitari 139 Sant Joan de Déu (Coordinating center). Patients 140 were enrolled by their clinical therapist. Inclusion cri-141 teria were (1) a diagnosis of schizophrenia, psychotic 142 disorder not otherwise specified, delusional disorder, 143 schizoaffective disorder, brief psychotic disorder, 144 or schizophreniform disorder (according to DSM-145 IV-TR); (2) <5 years from the onset of symptoms; (3) 146 a score during the previous year of  $\ge 3$  in item 147



Fig. 1. Trial profile.

delusions, grandiosity, or suspicions of PANSS 148 (according to Moritz et al. 2011); and (4) age between 149 17 and 45 years. Exclusion criteria were (1) traumatic 150 brain injury, dementia, or intellectual disability (pre-151 152 morbid IQ  $\leq$  70); (2) substance dependence; and (3) PANSS  $\geq 5$  in hostile and uncooperative and  $\geq 6$  in 153 154 suspiciousness, to avoid altering the dynamics of the 155 group.

#### 156 Interventions

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

162 The MCT program included eight modules: 163 Attributional style (1), Jumping to conclusions (2, 7), 164 Changing beliefs (3), Empathy (4, 6), Memory (5), and Depression and self-esteem (8), worked through165with PowerPoint presentations with different examples166and material on all these topics.167

In the psycho-educational group the modules 168 were: Healthy habits (1); Risk Behaviors (2), Prevention 169 of relapse (3), Video forum (4, 5), Resources of work 170 (6), Leisure activities (7), and Resources available in the 171 community (8). Material for each weekly module was 172 previously agreed upon by all participating centers to 173 unify interventions. Both interventions were performed 174 in the patients' habitual center of care. 175

## Outcomes

Patients were assessed at baseline, post-treatment, and1776 months follow-up. The evaluator was blinded to the178condition of the patients. The evaluators were trained179in the scales of the study, scoring >0.70 in inter-rater180reliability.181

Symptoms were the primary outcome and were
assessed with the Positive and Negative Syndrome
Scale (PANSS; Kay *et al.* 1987; Peralta & Cuesta, 1994).
Global Assessment of Functioning (GAF; Endincott,
1976) was used to assess symptoms and social
adaptation.

188 A battery of questionnaires regarding cognitive189 biases and social cognition was included in order to190 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 balls tasks in which the subject must take a decision regarding the probability of the extracted ball 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 balls (Brett-Jones *et al.* 1987).

Irrational beliefs were assessed with the Irrational 205 ٠ Belief Test (TCI; Calvete & Cardeñoso, 2001). The 206 scale is composed of ten subscales: needing accept-207 208 ance from others, high expectations, guilt, intoler-209 ance to frustration, worry and anxiety, emotional irresponsibility, avoidance of problems, depend-210 ence, helplessness, and perfectionism. Cronbach's 211 alpha in the Spanish validation for the subscales 212 oscilated between 0.63 and 0.79. 213

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 218 (ToM; Corcoran et al. 1995; Gil et al. 2012). In order to 219 220 avoid learning, three different stories were used in 221 each assessment taking into account their validity and the level of difficulty according to the scores 222 223 obtained in the Spanish validation of the question-224 naire. Cronbach's alpha of the Spanish version of 225 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.

#### 230 Ethical aspects

The project was evaluated by the research and ethicscommittees of the coordinating center and eachcenter included in the study. The participants signed

informed consent for participation in the study. The 234 study was recorded in Clinical Trials (Identifier: 235 NCT02340559). 236

#### Statistical analysis

The differences between each assessment were com-238 pared by group with Student's *t* test and ANCOVA. 239 McNemar association was used to compare JTC 240 between each assessment. A general linear model for 241 repeated measures was performed in order to compare 242 the longitudinal effect of the intervention. A comple-243 mentary analysis was performed in order to assess 244 the intra-group differences using a comparison 245 means for repeated measures. The analyses were per-246 formed imputing data from the last evaluation in 247 follow-up and without imputation. The results 248 shown corresponded to those with no imputed data. 249 All the analyses were controlled for number of ses-250 sions, not a significant variable. Effect sizes of the com-251 parison were analyzed with the Cohen's *d*. 252

# Results

Fig. 1 is the flowchart of participants in each of the 254 three assessments. The analyses were performed with 255 the total number of patients that completed the base-256 line and post-treatment assessment (n=89) and 257 follow-up (n = 81). Percentage of drop-outs in the post-258 treatment assessment was 27% in the MCT group and 259 28.1% in the psycho-educational group. Mean number 260 of sessions attended was 4.95 (s.D. = 2.98) for the 261 psycho-educational group and 5.53 (s.d. = 2.46) for the 262 MCT group. No statistical differences were found. 263 The best attended sessions of the MCT group were: 264 attributional style (1), jumping to conclusions (2), 265 memory (5) and depression and self-esteem (8); while 266 changing beliefs session had lower adherence (3). 267

The study started in June 2011 and inclusion of 268 patients was closed by December 2013. The study 269 with the follow-up was closed in August 2014. 270

Table 1 indicates the sociodemographic characteris-271tics of the two groups, MCT and psycho-educational.272No statistical differences were found regarding any273sociodemographic or clinical characteristics between274the two groups at baseline.275

Table 2 shows that there was no difference in PANSS276assessment at baseline and post-treatment, and base-277line and follow-up, between the two groups.278

Table 3 shows that BCIS self-certainty, BCIS compos-279ite index, and dependence of the TCI improved in the280MCT group v. the psycho-educational group between281baseline and post-treatment. Between baseline and282follow-up there are differences in the groups in BCIS283

 Table 1. Sociodemographic characteristics of the sample

	Psycho-educational group		MCT group	
	Ν	%	Ν	%
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/dª	519.49	534.58	472.53	703.89

MCT, Metacognitive Training.

<sup>a</sup> Antipsychotic drug doses are expressed as

chlorpromazine equivalence.

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

286 Regarding the effect of the intervention taking into 287 account three assessments (baseline, post-treatment, and follow-up) together, a general linear model for 288 repeated measures was performed. The PANSS posi-289 tive was significant for time effect (p=0.001) but not 290 for the time × group interaction (p = 0.316). The 291 PANSS negative had a significant effect of time (p =292 293 0.005), but no effect for time × group interaction was found (p = 0.651). Regarding the PANSS general, a 294 clear effect of time was found (p < 0.001), but no effect 295 for time  $\times$  group interaction was detected (p = 0.107). 296 297 Finally, the PANSS total was significant for time (p < 0.001) but not for the time × group interaction 298 (p=0.193). Regarding general functioning, GAF score 299 indicated that there was an effect of time (p=0.004)300 but not of group (p=.54). On the self-reflectiveness 301

subscale of the BCIS, there was an effect of time (p =302 0.027) and a trend in the time × group interaction (p =303 0.067). The self-certainty subscale of the BCIS showed 304 no effect of time (p = 0.182) but a trend in time × 305 group interaction was detected (p = 0.081). Finally, the 306 Composite Index of the BCIS showed that the MCT 307 group improved more than the psycho-educational 308 group over time, with p = 0.042 for the time × group 309 interaction, and p = 0.038 the effect of time. The 310 IPSAQ personalized bias showed no effect of time 311 (p=0.395) but a trend for time × group interaction 312 was seen (p = 0.087). As to irrational beliefs, intolerance 313 to frustration showed an improvement in the MCT 314 group compared to the psycho-educational group 315 over time (p = 0.016). 316

The number of patients who jumped to conclusions 317 in each assessment by group is shown in Fig. 2. 318 Regarding the MCT group, significant differences 319 were found between baseline and post-treatment 320 regarding the 85:15 task of JTC (p = 0.021) and a 321 trend toward significance at follow-up (p = 0.057). 322

A supplementary analysis was performed compar-323 ing differences between baseline and post-treatment 324 and baseline and follow-up in each group, independ-325 ently. The results are presented in Table 4, indicating 326 more significant values and greater effect in the com-327 parison of PANSS subscales in the MCT group than 328 in the psycho-educational group. Moreover, significant 329 values were found in the MCT group for GAF, 330 Personalizing bias, Hinting task, and some subscales 331 of the TCI that were not found in the psycho-332 educational group. 333

### Discussion

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The results are unique in that this is the first study to 335 observe the effectiveness of MCT in people with 336 recent onset of psychosis, which is of clinical rele-337 vance, given early intervention is important in redu-338 cing chronicity and improving prognosis. Both the 339 MCT and the psycho-educational groups showed 340 reduced clinical symptoms. Moreover, MCT pre-341 sented greater improvements than the psycho-342 educational group in cognitive insight, irrational 343 beliefs, and JTC. 344

Symptoms improved considerably in both treatment 345 groups. However, the complementary analyses show 346 that the MCT group presented greater improvements 347 with greater effect size, especially in the follow-up 348 (some of them superior to 0.8). Although other studies 349 performed in people with schizophrenia have found a 350 clear improvement in symptoms in MCT groups, compared with control and cognitive remediation, our 352 results indicated a slight improvement when compared to a psycho-educational group (Favrod *et al.* 354

	Psycho-educ	ational group		MCT group			Comparison between groups	
	Baseline	Post-treatment	Follow-up	Baseline	Post-treatment	Follow-up	Difference baseline $v$ . post-treatment	Difference baseline <i>v.</i> 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)
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)

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

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

2014; Windell et al. 2015). However, it is important to 355 note the greater improvements of MCT in the 356 follow-up, coinciding with the results of Moritz et al. 357 (2014*a*, *b*) after 3 years of follow-up, suggesting a 358 'sleeper' effect of MCT, implying that work in the ses-359 sions could have an important effect in the future. 360 Moreover, MCT had a clear effect in follow-up not 361 only on positive symptoms but also negative and gen-362 eral symptoms as well, suggesting more improvement 363 in functionality (Windell et al. 2015). It is likely that the 364 strategies worked on in the group were indirectly 365 related to symptoms and could be useful in preventing 366 future relapses. In our study, people with psychosis of 367 recent onset showed improvement in positive symp-368 toms with both interventions. It should be taken into 369 account that levels of symptoms at baseline were 370 very low, indicating a possible floor effect that made 371 it difficult to detect the superiority of one intervention 372 over the other due to the restriction in range. In con-373 trast, people with schizophrenia in other studies scored 374 higher in symptoms (Moritz et al. 2011) suggested that 375 in order to avoid the floor effect future studies should 376 recruit subjects with at least mild delusional symp- 377 toms. 378

The MCT group had a clear effect in cognitive 379 insight, in the post-treatment and follow-up, according 380 to (Lam et al. 2015) and contrary to (van Oosterhout 381 et al. 2014). The psycho-educational group scored 382 worse on the self-reflectiveness subscale at all time 383 points while the MCT group showed a reduction in 384 their scores on the self-certainty subscale, indicating 385 better scores for the composite index for people who 386 attended the MCT intervention. The reduction of levels 387 of self-certainty is relevant because in reducing this 388 bias, patients achieve a lower confidence in the inter-389 pretation of their own ideas (Beck et al. 2004) and pos-390 sibly prevent these ideas from becoming delusions. 391 Moreover, MCT acts as a preventive intervention 392 regarding self-reflectiveness, because patients from 393 the psycho-educational group scored worse through-394 out the clinical trial, obtaining similar scores to chronic 395 patients with schizophrenia (Beck et al. 2004). 396 Improvement in insight, which is one of the core 397 results found, has been associated with treatment 398 adherence, higher metacognition, and fewer symptoms 399 in people with first episode of psychosis and schizo-400 phrenia (Myers et al. 2014; Lysaker et al. 2015; Vohs 401 et al. 2015). 402

People from the MCT group decreased in intolerance 403 to frustration and in dependence compared with people from the psycho-educational group. Intolerance to 405 frustration may cause the patient to be over-concerned 406 and manifest early appearance of negative emotional 407 responses such as irritability, guilt, anger, and lower 408 cognitive flexibility (Stanković & Vukosavljević- 409

	Psychoeducational group			MCT group			Comparison between groups	
	Baseline	Post-treatment	Follow-up	Baseline	Post-treatment	Follow-up	Differences between baseline and post-reatment	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)

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

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.

410 Gvozden, 2011). Both variables could be related to 411 depression and self-esteem (Xu *et al.* 2013). In this 412 line, MCT may act as a protective intervention for 413 depressive symptoms and as an elicitor of improved 414 self-esteem.

415 JTC improved in the MCT group but not in the psycho-educational group; however, the changes 416 were produced only in the 85:15 task, and were clearly 417 significant only in post-treatment. Curiously, despite 418 randomization, the psycho-educational group pre-419 sented less JTC at baseline than the MCT group. 420 These results suggest that JTC could be reduced by 421 MCT training (Menon et al. 2008), although the pos-422 sible floor effect in the psycho-educational group 423 should be considered. Our results are in accordance 424 425 with previous studies that found that MCT is useful in reducing JTC in people with schizophrenia 426 (Aghotor et al. 2010), and taking into account the theor-427 etical model of Salvatore et al. (2012), it could therefore 428 429 help prevent the emergence of delusions.

Although no differences were found in the compari-430 son between groups, in the intergroup comparison per-431 sonalizing bias presented an improvement in the MCT 432 group but not in psycho-educational group in the 433 follow-up, with a high effect size (up to 0.9). This is 434 an interesting result because higher scores on this sub-435 scale are associated with higher levels of paranoid 436 ideation and persecutory delusions (Kinderman & 437 Bentall, 1996; Mehl et al. 2014). In the same line, ToM 438 improved in the MCT group but not in the 439 psycho-educational group in the follow-up, and with 440 a mild effect size. It did not improve in the analysis 441 between groups. However, scores on the ToM task 442 were high even at baseline, suggesting that the patients 443 included were not sufficiently impaired in this area, 444 contrary to a previous meta-analysis (Bora & Pantelis, 445 2013). Another possibility might be that the test used 446 did not detect deficits in ToM, as suggested by 447 Langdon et al. (2014). Regarding emotional recognition 448 there was no improvement in either of the two groups, 449

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

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

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.

450 contrary to previous research (Ussorio et al. 2016). Both 451 groups had good scores in emotional recognition at baseline assessment, so perhaps at this stage of the ill-452 ness there is not a clear deficit, in contrast to chronic 453 samples (Besche-Richard et al. 2012). Moreover, the 454 455 MCT does not target better emotion recognition but 456 rather modulates confidence for social judgments. 457 However, some considerations should be taken into

458 account. Regarding the characteristics of the 'control' group for comparison, an active intervention was 459 460 used in order to control the effect of the group. However, this group was not really 'control' because 461 in two sessions patients were receiving and sharing 462 463 information regarding risk behaviors and prevention of relapses. The other clinical trials performed with 464 the MCT have used other characteristics in the 465

comparison groups such as waiting lists and cognitive 466 rehabilitation (Moritz et al. 2014b), and this could 467 account for the discrepancies in findings. Another 468 point to take into account is that both groups received 469 an extra intervention (MCT or psycho-education) not 470 considered treatment as usual, which probably helped 471 both groups improve in several areas. Perhaps the 472 MCT group might have improved more if the compari-473 son group had been with treatment as usual. Second, 474 the frequency of sessions in our study was once a 475 week while in other studies it was twice a week. This 476 divergence in the methodology could have influenced 477 the results in some way, producing slower changes in 478 the MCT intervention. Another consideration arises 479 from the setting of the patients; in our study we 480 included only outpatients while in other studies 481

inpatients were also included (Moritz et al. 2013a, b). 482 483 Another limitation is that the patients were not asked to complete homework in the MCT group and this 484 could be a cause of the lower integration of the areas 485 worked up in the sessions. MCT has been demon-486 487 strated to be effective in people with schizophrenia with eight sessions included in the program (Eichner 488 & Berna, 2016). However, in order to further improve 489 490 the results other interventions could be provided to these patients, such as joint implementation of MCT 491 492 in group and individualized (Moritz et al. 2011), as well as other kinds of interventions addressed to cover-493 ing similar aspects (Penn et al. 2005). Finally, the train-494 ing has been recently complemented with two 495 modules on self-esteem and dealing with stigma as 496 these domains may also contribute to the formation 497 498 and maintenance of positive symptoms. Whether these modules augment effects awaits to be estab-499 lished, however. 500

501 The strengths of the study include an adequate sam-502 ple size, the novelty of the characteristics of the sample 503 in terms of early stages and community settings, and 504 its multi-site implementation.

In conclusion, MCT is an effective psychological inter-505 506 vention for people with a recent onset of psychosis, in 507 order to improve psychotic symptoms and cognitive insight, and to reduce irrational beliefs. MCT could be 508 a good treatment choice in clinical practice taking into 509 account the positive results in insight improvement 510 that may act to prevent further psychotic episodes. 511 More studies should be done with this population in 512 513 order to assess the cost-effectiveness of MCT and the combination of this treatment with others. 514

#### 515 Appendix. Spanish Metacognition Study Group

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Declaration of Interest	545
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