Metacognition and Cognitive Biases in the Treatment of Psychosis

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Chapter 4

Metacognitive group training for schizophrenia spectrum patients with delusions: a randomized controlled trial

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Abstract

BACKGROUND: Metacognitive training (MCT) for patients with psychosis is a psychological group intervention that aims to educate patients about common cognitive biases underlying delusion formation and maintenance, and to highlight their negative consequences in daily functioning. In this chapter the results of an RCT presented.

METHOD: In this randomized controlled trial, 154 schizophrenia spectrum patients with delusions were randomly assigned to either MCT + treatment as usual (TAU) or TAU alone. Both groups were assessed at baseline, and again after 8 and 24 weeks. The trial was completed fully by 111 patients. Efficacy was measured with the Psychotic Symptom Rating Scales (PSYRATS) Delusions Rating Scale (DRS), and with specific secondary measures referring to persecutory ideas and ideas of social reference (the Green Paranoid Thoughts Scale, GPTS), cognitive insight (the Beck Cognitive Insight Scale, BCIS), subjective experiences of cognitive biases (the Davos Assessment of Cognitive Biases Scale, DACOBS) and metacognitive beliefs (the 30-item Metacognitions Questionnaire, MCQ-30). Economic analysis focused on the balance between societal costs and health outcomes (quality-adjusted life years, QALYs).

RESULTS: Both conditions showed a decrease of delusions. MCT was not more efficacious in terms of reducing delusions, nor did it change subjective paranoid thinking and ideas of social reference, cognitive insight or subjective experience of cognitive biases and metacognitive beliefs. The results of the economic analysis were not in favour of MCT + TAU.

CONCLUSIONS: In the present study, MCT did not affect delusion scores and self-reported cognitive insight, or subjective experience of cognitive biases and metacognitive beliefs. MCT was not cost-effective.

Introduction

There is increasing evidence for the effectiveness of cognitive behavioral therapy for psychosis (CBTp) as an add-on therapy to pharmacotherapy (Gould, Mueser, Bolton, Mays, & Goff, 2001; Wykes, Steel, Everitt, & Tarrier, 2008). CBTp has evolved over the years, whereby initial focus on the content of dysfunctional thinking has broadened to an additional focus on cognitive processes and biases (Garety, Kuipers, Fowler, Freeman, & Bebbington, 2001; Morrison, 2001). Cognitive processes and biases, responsible for distortions in the gathering, appraisal and processing of information, are linked to psychosis in general and, in particular, to positive symptoms such as (persecutory) delusions (Freeman, 2007; van der Gaag, 2006). The most prominent biases and processes are the jumping to conclusions bias (JTC) (Fine, Gardner, Craigie, & Gold, 2007; So et al., 2012), problems in theory of mind (Brune, 2005), false-negative and false-positive errors in memory (Aleman, Hijman, de Haan, & Kahn, 1999; Moritz, Woodward, Cuttler, Whitman, & Watson, 2004) together with overconfidence in errors (Moritz & Woodward, 2006b), a bias against disconfirmatory evidence (Moritz & Woodward, 2006a; Woodward, Moritz, & Chen, 2006; Woodward, Moritz, Cuttler, & Whitman, 2006) and biases in attributional style (Bentall, Kinderman, & Kaney, 1994; Mehl et al., 2010; Moritz, Woodward, Burlon, Braus, & Andresen, 2007).

Based on this research on cognitive processes and biases, Moritz and Woodward developed the metacognitive training (MCT). MCT is a group training of eight sessions based on two principles. The first principle is knowledge translation: cognitive biases are explained in a comprehensible way and are linked to delusion formation. The second principle is teaching awareness of the possible negative consequences of cognitive biases. The aim is to make patients aware of these biases (Moritz & Woodward, 2007).

The development of MCT is a good example of translational research in which knowledge about the previously mentioned biases is converted to a teaching module. However, although the assumptions may be valid, the question remains whether MCT is in itself effective. Previous uncontrolled studies showed promising results on delusion scores (Favrod, Maire, Bardy, Pernier, & Bonsack, 2011; Ferwerda, de Boer, & van der Gaag, 2010), whereas controlled but underpowered studies showed inconclusive results. Relative to an active control, Moritz et al. (2011) with 2 x 24 patients found significant results on JTC and positive symptoms of the Positive and Negative Syndrom Scale (PANSS), but not on the Psychotic Symptom Rating Scale (PSYRATS) total score; it should be mentioned that in their study group MCT was complemented by individual CBT. Another study by Moritz et al. (2011) with 2 x 18 patients (MCT versus wait-list control) with comorbid substance disorder found no effects on the PANSS, Psychosis Rating Scales total score (PSYRATS) and JTC, to which must be added that significant change was found on PSYRATS item level ('intensity of delusional distress') and that changes in JTC approached

trend level, both in favour of the MCT-group. The trial of Kumar et al. (2010) with 2 x 8 patients, reported better performance of MCT, but the group x time effects were non-significant. Aghotor et al. (2010) with 16 vs. 14 patients found no effects on PANSS and JTC, although MCT did slightly better, approaching a medium effect size for positive symptoms. Ross et al. (2011) modified the JTC modules and improved the didactic and change-inducing characteristics. They tested the efficacy with 2 x 17 patients and detected significant effects on the 60:40 JTC task, but not on the 85:15 JTC task; the patients with a severe JTC bias did not change. Overall, the available data are indecisive, mainly because most prior trials were underpowered.

In preparation of this trial we did an uncontrolled pilot/ feasibility study with patients scoring 68 or higher on the Green Paranoid Thoughts Scale (GPTS), which means they were having a paranoid psychotic episode (Ferwerda et al., 2010). Florid psychotic symptoms did not disturb the atmosphere in the group. The patients participated and were interested. They evaluated the training very positive and 93% would recommend the training to others. In the pilot we found large and significant effects on delusions (DRS), suspicious thoughts and delusions of reference (GPTS) and improved self-reflectiveness (BCIS). This made us decide to run a trial with moderately to severely deluded patients (GPTS ≥ 50).

The current study is sufficiently powered to assess relevant differences in efficacy between MCT + Treatment as usual (TAU) and TAU alone. In addition, the economic consequences of MCT + TAU are evaluated.

The hypotheses examined in this study are:

1) MCT will reduce delusions compared to TAU;
2) MCT will reduce subjective ideas of social reference and persecutory ideas compared to TAU;
3) MCT will reduce the subjective experience of cognitive biases, and dysfunctional metacognitive beliefs compared to TAU;
4) MCT will improve cognitive insight compared to TAU; and
5) MCT is cost-effective.

Methods

Trial design

This study was a multi-center, singleblind, parallel-group randomized clinical trial (RCT) conducted in the Netherlands. It was registered in the Dutch Trial Register (NTR 2307). The study was approved by the local Ethics Committee (NL28883.097.09). Measurements took place at baseline, at 8 weeks at the end of training and at follow-up 24 weeks after baseline.

Participants

Eligible participants were adults aged 18–65 years with a psychotic disorder in the DSM-IV schizophrenic spectrum (American Psychiatric Association, 2000). Based on positive results of the pilot study in paranoid patients (Ferwerda et al., 2010) in the current trial participants were selected who met the criteria for at least moderate delusional symptoms, i.e. ideas of social reference and/or persecutory ideas on the Green Paranoid Thought Scales (GPTS) score ≥ 50 (Green et al., 2008). The diagnosis was established by the Schedules for Clinical Assessment in Neuropsychiatry (SCAN) (World Health Organization, 1999). Exclusion criteria were primary addiction, insufficient understanding of the Dutch language and an IQ < 70. The study was conducted at six psychiatric hospitals in the Netherlands between April 2010 and February 2012. Participating hospitals were Reinier van Arkel group (N = 23), GGZ Noord Holland Noord (N = 22), Parnassia Psychiatric Institute (N = 55), GGZ Drenthe (N = 16), GGZ Delfland (N = 16) and Yulius (N = 22).

Interventions

In the experimental condition, in addition to TAU patients received MCT, a group intervention intended for 3–10 patients (Moritz, 2009). Each of eight sessions was conducted either by a clinical psychologist, psychiatrist, occupational therapist or psychiatric nurse. In any case at least one of the trainers was a psychologist with more than two years of experience as a clinician treating psychotic patients. Although most contributing therapists already were successful trainers in the pilot study. All of them were trained by an experienced trainer (JF; acknowledged as such by S. Moritz, the developer of MCT) during an eight hour training course. During the trial each trainer attended two or more supervision sessions. MCT are eight highly structured modules presented by using powerpoint presentations and diversion from the correct order of slides and group activities is practically impossible, thereby enforcing treatment adherence and fidelity. Small exercises characterize the modules. Patients practiced in order to counteract cognitive biases such as jumping to conclusions. The recommendated dosage of two parallel sessions in one week fits in inpatient programs, but as most patients were outpatients we decided to have therapy sessions once a week, because most outpatients considered two times per week as too much effort and travelling.

In the TAU condition patients received standard treatment for psychotic patients, which consists of medication prescribed by a psychiatrist and/or outpatient treatment by a social-psychiatrist nurse and/or a psychologist.

Outcomes

The primary outcome was delusions measured with the PSYRATS-DRS (Delusion Rating Scale; Haddock, McCarron, Tarrier, and Faragher (1999). This instrument is a well-known semi-structured interview, which measures qualitative and quantitative aspects of delusions and has good inter-rater and retest reliability. The validity is considered good, as assessed by internal consistency, sensitivity to change, and in relation to the PANSS (Drake, Haddock, Tarrier, Bentall, & Lewis, 2007). In this trial a Cronbach's α of .83 was found.

The secondary outcomes were as follows: The GPTS (Green et al., 2008) (hypothesis 2) is a questionnaire that measures ideas of social reference (part A) and persecutory ideas (Part B) with 32 items on a 5-point Likert scale. The internal consistency is good with a Cronbach's $\alpha > 0.70$ and the test is considered valid and sensitive to change.

The subjective experience of cognitive biases and metacognitive beliefs (hypothesis 3) were tested with the Davos Assessment of Cognitive Biases Scale (DACOBS; van der Gaag et al. (2013) and the Metacognitive Questionnaire 30 which follows the metacognitive approach by Wells (MCQ-30; Wells and Cartwright-Hatton (2004). The DACOBS is a questionnaire that measures the subjective experience of cognitive bias using 42 items on a 7-point Likert scale. In the present study we used the subscale subjective problems in (social) cognition. The DACOBS is considered a reliable and valid instrument for use in clinical practice and research (Cronbach's α 0.90; van der Gaag et al., 2013). The MCQ-30 is a questionnaire that measures metacognitive beliefs via 30 items on a 4-point Likert scale. The manual distinguishes between cognitive self-confidence, positive views, cognitive self-awareness, uncontrollability and danger and need-for-control; the validity and reliability are satisfactory (Cronbach's α 0.72–0.92; Spada, Mohiyeddini, and Wells (2008).

The Beck Cognitive Insight Scale (BCIS; Beck, Baruch, Balter, Steer, and Warman (2004) was used to measure aspects of cognitive insight (hypothesis 4). The BCIS is a 15-item self-report scale measuring two constructs: the ability to acknowledge fallibility, labeled self-reflectiveness and certainty about belief and judgments, and labeled self-certainty. The BCIS has demonstrated good convergent, discriminant, and construct validity with inpatients (Beck et al., 2004) and improvement in cognitive insight and delusionals beliefs are correlated (Riggs, Grant, Perivoliotis, & Beck, 2012).

The EQ-5D is a standardized measure of health status developed by the EuroQoL Group (EuroQol Group, 1990) to provide a simple, generic measure of health for clinical and economic appraisal. The results of the EQ-5D were used to calculate Quality Adjusted Life Years (QALYs), which were included in the cost-utility analysis (hypothesis 5).

A detailed questionnaire on cost aspects (Hakkaart-van Roijen, van Straten, Donker, & Tiemens, 2002) was used to measure health and societal costs. This instrument focused on healthcare consumption (including hospital admissions, contacts with healthcare professionals, medication use) as well as societal aspects, e.g. informal care and productivity losses. In addition, all costs of providing MCT were documented in detail.

Sample size

To detect a medium effect size (power of 0.80, and α of 0.05) a sample size of 64 participants per condition (n = 128) is required. Considering that attrition rates of 15–20% are relatively common, we aimed to include 154 patients.

Randomization and blinding

After providing informed consent, patients were included and randomly allocated to either MCT+TAU or TAU alone. The random allocation lists were generated by a web-based automated randomization system. The randomization was stratified to research site with blocks of ten. The allocation list was kept in a remote secure location and the different sites confirmed the randomization status to the randomization bureau. Independent research assistants who were blind for condition did the assessments. The assessments were conducted at locations other locations then the training locations. Assistants were asked to report any unblinding of the assessments.

Statistical analysis

Results were analyzed on an intention-to-treat (ITT) basis using SPSS version 19 with linear mixed models (LMM). LMM is the recommended method in longitudinal studies. It uses all available data, without deleting subjects with missing data. Additionally, a cost-utility analysis was conducted (hypothesis 5). Unit prices per cost type were based on Dutch standard prices for the year 2011. The bootstrap method (Efron & Tibshirani, 1993) was applied to provide information on the uncertainty of the results of the economic evaluation.

Results

Figure 4.1 shows the flow of participants: 154 patients were randomized and measured at baseline (M_{site} = 26 participants; range 16–55, M_{exp} = 8.3 participants; range 6–9). None of the participants were excluded. There were no adverse events and no unblinding was reported.

128 participants were available for measurement at the end of treatment (MCT + TAU: n = 58; TAU: n = 70), and 111 were available for measurement at follow-up (MCT + TAU: n = 51;

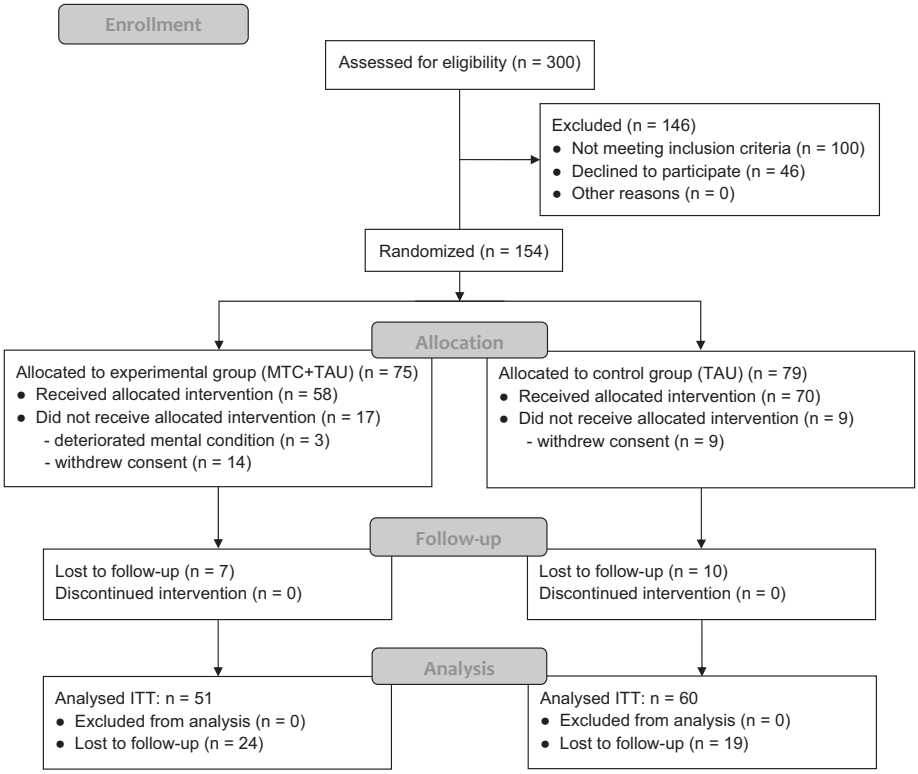

Figure 4.1 Flow diagram of the study population and data analysis.
MTC + TAU = metacognitive training + treatment as usual; TAU = treatment as usual only; ITT = intention-to-treat basis.

TAU: n = 60). No site differences were found on attrition rates. Table 4.1 presents baseline data of the study population. Significant differences were found on BCIS self-reflectiveness, MCQ-30 cognitive self-consciousness, MCQ-30 beliefs about uncontrollability and MCQ-30 beliefs about need to control. For each prescribed antipsychotic medication chlorpromazine equivalences (Woods, 2003) were calculated and on baseline no differences in medication levels between groups were found (M_{exp} = 379.5, SE = 70.5; $M_{control}$ = 284.0, SE = 38.0; t(151) = 1.206, p > .05) and in general level of medication did not differ between groups over time.

Table 4.2 shows the mean and standard deviations of primary and secondary outcome measures at baseline, at end of treatment and at follow-up, and the group x time interactions (p-value). No significant group x time interactions were found in favour of the hypotheses 1, 2, 3 and 4. The only statistically significant finding was that the results on the paranoid delusions (GPTS-B) was in favour of the control group. In all cases, after adding all significant

Table 4.1 Characteristics of the experimental group (metacognitive training+treatment as usual) and the control group (treatment as usual only) at baseline

	Experimental (n = 75)	Control (n = 79)
Age (years), mean (SD)	38.3 (11.1)	36.8 (8.7)
Education by levels, mean (SD) [a]	3.7 (1.7)	3.6 (1.7)
Sex ratio, M/F	54/21	56/23
Diagnosis		
Schizophrenia	52	46
Psychotic disorder NOC	9	9
Schizoaffective disorder	3	5
Others (5 categories)	11	19
Medication		
No medication	5	7
AP ≥ 4 months	41	46
AP + MS ≥ 4 months	11	9
AP + tranquilizers	11	9
Others (3 categories)	7	8
PSYRATS impact of delusions	13.5 (4.7)	12.5 (5.2)
GPTS total: mean (SD)	97.1 (21.7)	96.5 (24.2)
GPTS A social reference:	50.0 (11.2)	48.4 (10.8)
GPTS B persecutory ideas	47.1 (12.3)	48.2 (15.6)
DACOBS subjective cognitive problems	27.3 (6.3)	26.2 (6.5)
DACOBS social cognition problems	29.4 (5.4)	28.5 (6.4)
BCIS self-reflectiveness	15.7 (4.6)*	13.8 (4.5)*
BCIS self-certainty	8.5 (3.1)	8.3 (3.3)
MCQ-30 cognitive confidence	13.1 (4.3)	13.1 (4.9)
MCQ-30 positive beliefs about worry	12.2 (4.1)	12.6 (4.7)
MCQ-30 cognitive self-consciousness	17.4 (3.7)*	15.7 (4.1)*
MCQ-30 beliefs about uncontrollability	17.0 (4.2)*	15.5 (4.3)*
MCQ-30 beliefs about need to control	15.1 (3.4)*	13.8 (4.5)*

AP, antipsychotic medication; MS, mood stabilizer medication; GPTS, Green Paranoid Thought Scales; DACOBS, Davos Assessment of Cognitive Biases Scales; BCIS, Beck Cognitive Insight Scale; PSYRATS, Psychotic Symptom Rating Scale; MCQ-30, Metacognitions Questionnaire.
* significant at p-value < .05 a 0–1: no to primary education, 2–4: low-to-medium (vocational) education, 5–7: higher education

differences at baseline as covariates, the results remained non-significant. There was insufficient statistical power to assess site effects. In prior MCT research it is common to consider item-scores on the DRS as outcome measures. Inspection of the items did not lead to other conclusions.

Table 4.2 Data on primary and secondary outcome measures at baseline, and at 8 weeks after end of training (T1) and at follow-up 24 weeks post-baseline (T2). Group x Time interactions on outcome variables: p-values at T1 and at follow-up (intention-to-treat basis).

	Baseline		T1			T2		
	MCT + TAU	TAU	MCT + TAU	TAU	Group x Time	MCT + TAU	TAU	Group x Time
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	
DRS	13.5 (4.7)	12.5 (5.2)	11.9 (5.9)	10.4 (5.9)	p = .729	9.8 (6.1)	9.3 (6.6)	p = .544
GPTStot	97.1 (21.7)	96.5 (24.2)	82.4 (28.1)	74.6 (33.2)	p = .101	83.1 (33.4)	74.4 (30.3)	p = .093
GPTSA	50.0 (11.2)	48.3 (10.8)	43.2 (13.6)	38.5 (16.2)	p = .172	41.5 (15.3)	38.5 (15.3)	p = .596
GPTSB	47.1 (12.3)	48.2 (15.6)	39.2 (16.0)	36.1 (17.8)	p = .105	41.6 (19.4)	35.9 (16.5)	p = .017*
Dacobs-Subj.C.P	27.3 (6.3)	26.2 (6.5)	26.6 (6.3)	24.6 (6.6)	p = .187	26.4 (6.8)	23.6 (6.6)	p = .383
Dacobs-Soc.C.P.	29.4 (5.4)	28.5 (6.4)	28.7 (5.3)	26.1 (6.7)	p = .097	27.9 (5.3)	25.9 (6.9)	p = .572
BCIS-SR	15.7 (4.6)	13.8 (4.5)	16.2 (5.2)	14.1 (4.8)	p = .785	15.2 (4.1)	13.8 (5.0)	p = .649
BCIS-SC	8.5 (3.1)	8.3 (3.3)	8.3 (3.1)	8.1 (3.4)	p = .696	8.4 (3.6)	8.7 (3.1)	p = .333
MCQ-CC	13.1 (4.3)	13.1 (4.9)	13.1 (4.7)	12.5 (4.5)	p = .291	13.1 (4.6)	12.2 (5.0)	p = .967
MCQ-PB	12.2 (4.1)	12.6 (4.7)	11.9 (4.0)	12.1 (4.5)	p = .909	12.1 (4.8)	12.1 (4.8)	p = .637
MCQ-CS	17.4 (3.7)	15.7 (4.1)	17.0 (3.7)	15.2 (4.0)	p = .806	16.0 (3.8)	14.5 (4.0)	p = .501
MCQ-BU	17.0 (4.2)	15.5 (4.3)	16.4 (4.8)	14.7 (4.2)	p = .939	16.3 (4.1)	13.8 (4.6)	p = .776
MCQ-NC	15.1 (3.4)	13.8 (4.5)	14.5 (3.9)	13.8 (4.2)	p = .297	14.2 (4.4)	13.1 (4.5)	p = .599

* Significant at p-value < .05; DRS, PSYRATS delusion scales; GPTStot, GPTS total; GPTSA, GPTS ideas of social reference; GPTSB, GPTS persecutory ideas; DACOBS-SuCP, DACOBS subjective cognitive problems; DACOBS-SocCP, DACOBS social cognition problems; BCIS-SR, BCIS self reflection; BCIS-SC, BCIS self certainty; MCQ-CC, MCQ cognitive confidence; MCQ-PB, MCQ positive beliefs about worry; MCQ-CS, MCQ cognitive self-consciousness; MCQ-BU, MCQ beliefs about uncontrollability; MCQ-NC, MCQ beliefs about the need to control thinking.

In addition, for the primary outcome measure (PSYRATS-DRS), per protocol (GLM) analyses with baseline covariates were conducted. Per protocol there were no significant differences for 'condition' at the end of treatment or at follow-up.

Finally, an analysis with only those patients who attended six or more of the eight sessions found no differences with the group who missed three or more sessions.

Results economic evaluation

Table 4.3 shows the various medical and nonmedical costs generated by both groups during the six-month study period. The mean total costs of providing the MCT were €143 per patient, and were largely related to costs of the group sessions provided by the psychologists. In both groups, the costs of hospital admission, sheltered accommodation, homecare, and other informal care, had the largest impact on the total amount of societal costs. The mean total societal costs (based on all cost types in Table 4.3 and patients available for the cost-utility analysis) were estimated at €13,325 in the MCT + TAU group, and at €12,827 in the TAU group. Differences in mean total costs were not statistically significant (95% CI -€4,464 to +€5,563). However, these results should be interpreted with caution as the study was powered to demonstrate differences in health outcomes and not in costs (as is the case for most economic evaluations). Figure 4.2 presents results of the cost-utility analysis, showing the bootstrap simulations based on the EQ-5D results. Mean costs were slightly higher and QALYs were significantly lower in the MCT +

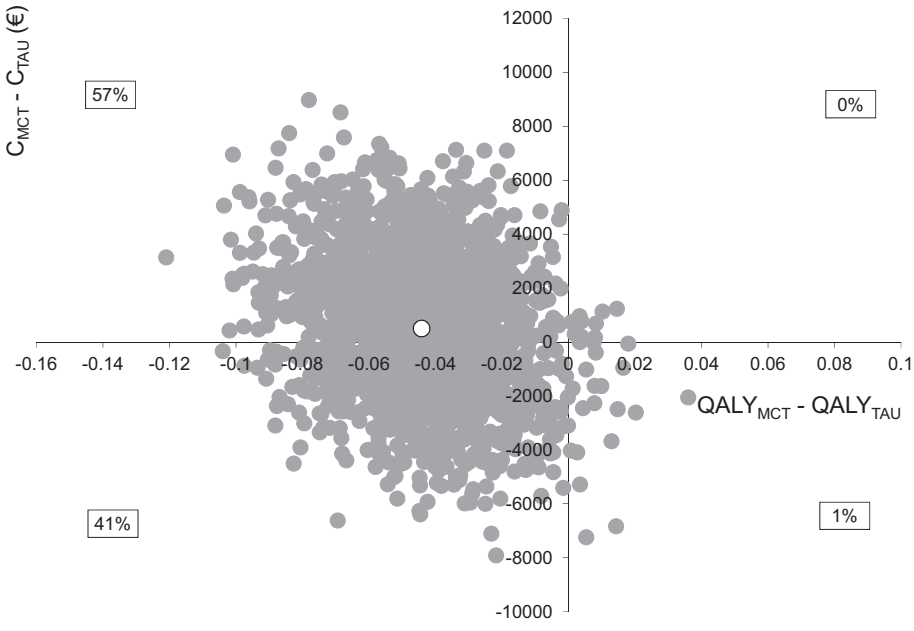

Figure 4.2 Results of the cost-utility analysis (quality-adjusted life years; QALYs).

Table 4.3 Medical and nonmedical costs during the 6-month study period

	MCT (n = 61)		TAU (n = 73)	
Cost types	**Mean costs (SD)**	**%[1]**	**Mean costs (SD)**	**%[1]**
Intervention				
MCT	143 (46)	100	-	0
Inpatient and semi-inpatient care				
Hospital admission	1356 (5940)	15	2813 (8145)	16
Day care	293 (1218)	8	192 (757)	11
Sheltered accommodation	5656 (10444)	25	4366 (9164)	22
Outpatient and community care				
Psychiatrist	175 (358)	62	130 (181)	68
Psychologist	388 (559)	62	216 (327)	47
Group therapy	150 (500)	20	68 (237)	14
Social-psychiatric nurse	237 (285)	75	199 (328)	67
Social worker	26 (93)	13	33 (103)	16
Crisis intervention	26 (89)	8	35 (127)	8
Psychiatric home care	243 (810)	21	201 (607)	19
CAD[2]	0 (-)	0	2 (21)	1
Other outpatient care	246 (654)	30	89 (212)	26
General healthcare				
General practitioner	37 (44)	59	27 (34)	51
Alternative healthcare	2 (9)	5	1 (5)	1
Home care	862 (2214)	28	703 (2640)	19
Emergency care	5 (28)	3	13 (68)	4
Other general healthcare	4 (21)	5	21 (82)	12
Day activity institutions				
Day activity center	84 (183)	31	120 (291)	29
Drop-in center	40 (210)	15	29 (162)	15
Other institutions	53 (252)	10	41 (180)	16
Medication				
Prescribed medication	324 (353)	82	251 (348)	78
Non-prescribed medication	14 (38)	26	13 (66)	23
Nonmedical costs				
Informal care				
Household work	191 (918)	11	72 (251)	14
Other	1260 (2742)	54	912 (1476)	58
Out-of-pocket costs	28 (142)	10	12 (61)	7
Productivity losses				
Unpaid work	25 (124)	5	178 (766)	18
Paid work	333 (1142)	13	65 (447)	4

[1] Percentage of patients using the cost types concerned.
[2] Consultation officer for alchohol and drug addiction.
MCT = metacognitive training + treatment as usual; TAU = treatment as usual.

TAU group. About 57% of the bootstrap simulations were located in the northwest quadrant, indicating that TAU dominated MCT + TAU. Various sensitivity analyses were conducted to assess the robustness of the current results. These analyses examined completers only, leaving out 'other informal care', and adding 'time costs' for the MCT + TAU group. The impact of these sensitivity analyses on the overall economic outcomes was very small and did not change any of the results. This provides additional support for the conclusion that MCT + TAU was not cost-effective. An additional cost-effectiveness analysis focusing on the balance between costs and paranoid symptoms (GPTS) showed similar results.

Discussion

In the present study, although both groups generally showed a decrease of symptoms, improvement in the experimental group could not be attributed to MCT. Moreover, MCT did not affect subjective experience of cognitive biases, dysfunctional metacognitive beliefs and cognitive insight. As a result, MCT did not prove to be cost-effective.

Similar to other uncontrolled findings (Favrod et al., 2011; Ferwerda et al., 2010) we found small-to-medium within-subject effect sizes on symptom reduction in the experimental group (Cohen's d ranging from .29 to .64). The control group improved even further, reflecting a strong time effect.

In the pilot study (Ferwerda et al., 2010) participants with florid psychosis were included and delusions and self-reflectiveness improved after MCT, but the pilot also found that the beads task improved only partially: there was only an effect on the easy version and not on the more difficult version. There were no effects on the Hinting Task, not on memory corruption and not on self-esteem. Regression to the mean may explain the symptom reduction in MCT and TAU in this trial and in the pilot study, while the other measures showed no effect.

Another explanation for the current lack of effect of MCT might be that MCT just utilizes education and does sufficiently personalize the information to arouse emotion and shape the conditions for emotional learning. As Beck stated that it is absolute necessary to arouse personal emotional meaning, because otherwise the cognitive constellations underlying affect do not become accessible and modifiable (Beck & Weishaar, 1989). Awareness about a disorder such as psychosis does not necessarily lead to a decrease of symptoms (Cunningham Owens et al., 2001) or reduction of relapse (Bechdolf et al., 2004). In the British Guidelines, there is no evidence for the efficacy of psychoeducation in the treatment and management of schizophrenia in primary and secondary care (NICE, 2009), although these recommendations are partially refuted in later research (Xia, Merinder, & Belgamwar, 2011). Furthermore, homework assignments to improve generalization to daily life were lacking.

A third reason might be that MCT does not affect patients with moderate to severe delusions. The inclusion of these deluded cases did not have a negative influence on the group cohesion, but no effects were found. Encouraged by our pilot findings (Ferwerda et al., 2010) only participants with at least moderate delusional symptoms were included (PSYRATS-DRS M_{exp} = 13.5). Other studies included only mild delusions (Moritz, Veckenstedt et al. (2011): M_{exp} = 8.71 & Moritz, Kerstan et al. (2011): M_{exp} = 5.50). Also, Ross et al. (2011) found that the effect of training on biases was limited to patients with low baseline scores and that more deluded cases did not benefit. Ross and colleagues suggested that a lengthier training package (focusing on generalizing to delusional thinking, which proceeds from the engaging materials to stimuli related to interpersonal judgments and then to materials more directly relevant to the content of delusions – such as interpersonal threat), may have a greater impact on the more extreme JTC reasoning bias, and on belief flexibility and delusional conviction. Moritz and Woodward have recently recommended a combination of MCT and CBT to meet these goals, and they developed an individualized MCT program (Moritz, Veckenstedt, Randjbar, & Vitzthum, 2011; Moritz, Veckenstedt, Randjbar, Vitzthum, et al., 2011). A pilot trial on this matter was found to be partially successful (Moritz, Veckenstedt, Randjbar, Vitzthum, et al., 2011). Positive symptom scores on the PANSS improved, but not on the PSYRATS.

The present study has some limitations and strengths that need to be addressed.

A limitation is that only the PSYRATS is a rated measure, while other measures are self-rated. Yet, Liraud and colleagues found that ratings and self-rating of symptoms were highly correlated independent of insight (Liraud, Droulout, Parrot, & Verdoux, 2004).

A second limitation is that no pre-, post- and follow-up measurements of cognitive biases, depression, anxiety or self-esteem were included. Future research should include measures of cognitive biases as these are the focus of MCT and symptom changes are assumed to be secondary to changes in cognitive biases.

A third limitation was the number of patients lost to follow-up. At the end of treatment the drop-out rate was 11%, which is common in psychosocial treatment (Villeneuve, Potvin, Lesage, & Nicole, 2010). But at follow-up another 17% was lost to follow-up. These findings could not be attributed to the study condition or research site and it is unclear what caused dropout other than participants withdrawing consent.

A fourth limitation concerns the blinding procedure in which assistants were asked to report unblinding during assessment. Even though no unblindings were reported a more assertive check on unblinding would have been appropriate. Because self-report and interview-obtained assessments of delusion were quite alike, we cautiously assume that unblinding did not affect the results in a dramatic way.

Finally, this trial was based on the original MCT Manual dating from 2007 without the combination with CBT. Whether this addition of CBT will exceed the effects of CBT alone, still needs to be established.

The strengths of the study include a randomized design, rigorous randomization procedures, generously formulated inclusion criteria, intention-to-treat analysis, assessment of comprehensive primary and secondary outcomes, well-trained and motivated trainers, and outcomes assessed by researchers blinded to treatment allocation.

The conclusion is that this study does not demonstrate the efficacy of MCT on researcher rated delusions and self-reported symptoms, subjective experience of cognitive biases and metacognitive beliefs in at least moderately deluded patients. MCT did not prove to be cost-effective.

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