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Individualized metacognitive therapy for delusions: A randomized controlled rater-blind study

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Abstract

Background & Objectives: Theory-driven interventions targeting specific factors that contribute to delusions are receiving increased interest. The present study aimed to assess the efficacy of individualized metacognitive therapy (MCT+), a short manualized intervention that addresses delusion-associated cognitive biases.

Methods: 92 patients with current or past delusions were randomized to receive 12 twice-weekly sessions of either MCT+ or a control intervention within a randomized controlled rater-blind design. Psychopathology and cognitive biases were assessed at baseline, 6 weeks and 6 months. ANCOVAs adjusted for baseline scores were used to assess differences between groups regarding outcome variables. Both per-protocol and intention-to-treat analyses were conducted.

Results: At 6 weeks, there was a significant difference in favor of MCT+ regarding decrease in delusion severity and improvement of self-reflectiveness (medium effect size), and a trend-wise difference regarding probability threshold to decision. These effects increased, when only patients attending a minimum of 4 therapy sessions were considered. Control group patients subsequently showed further improvement while patients in the MCT+ group remained stable, such that there were no differences between groups at the 6-month follow-up.

Limitations: Lower attendance rates in the control group possibly leading to unequal therapeutic effort; lower baseline delusion severity in the MCT+ group.

Conclusions: The result pattern suggests that MCT+ led to an earlier improvement in delusions and cognitive biases compared to the control intervention. The absence of a long-term effect might reflect floor effects in the MCT+ group, but may also indicate the need for further measures to promote sustainability of MCT+ effects.

Keywords: schizophrenia, metacognition, cognitive biases, jumping-to-conclusions, psychotherapy, cognitive-behavioral therapy.

1. Introduction

Delusions are one of the most common and recognizable symptoms of psychotic disorders. Up until the late 20th century, delusional beliefs were viewed as "non-understandable" (Jaspers, 1913), and biological conceptualizations predominated treatment approaches (Mander and Kingdon, 2015). However, a new picture has gradually emerged. Behavioral, cognitive and social studies but also social influences such as the consumer movement led to an increased awareness of cognitive and psychological factors in the emergence of delusions (Mander and Kingdon, 2015; Mueser et al., 2013). The concurrent growing realization of the limitations of antipsychotic medication, especially with respect to functional recovery (Jaaskelainen et al., 2013; Leucht et al., 2009) and adherence issues (Lieberman et al., 2005) have boosted interest in psychological interventions for the treatment of delusions.

Cognitive-behavioral therapy (CBT) has had a leading role in this field. Having provided a wide empirical basis supporting its efficacy in treating delusions (Hutton and Taylor, 2014; Turner et al., 2014; Wykes et al., 2008), CBT was one of the first psychological interventions to be included in treatment guidelines for psychosis. However, there is still an ongoing debate about its efficacy,(McKenna and Kingdon, 2014) especially when it comes to disentangling 'true' efficacy from unspecific therapy effects (Jauhar et al., 2014; Lynch et al., 2010; Mehl et al., 2015). In an effort to maximize efficacy, recent research has focused on targeted therapies that deal with individual factors thought to contribute to psychotic symptoms, such as worry (Freeman et al., 2015) or reasoning biases (Garety et al., 2015; Moritz et al., 2014a; Waller et al., 2011). It has been suggested that such theory-driven interventions may lead to improved outcomes compared to standard CBT (Mehl et al., 2015).

One of these refined approaches is metacognitive training (MCT), a manualized group intervention (Moritz et al., 2013b). MCT builds upon evidence associating delusional beliefs with specific thinking styles that lead to distorted appraisals of events (Garety and Freeman, 2013). Well-established examples include jumping-to-conclusions, overconfidence in false judgments, and belief inflexibility/incorrigibility. Importantly, these thinking styles, termed 'cognitive biases', are not symptom-specific, but rather an extension of normal thinking styles, appearing also in neutral (i.e. delusion-unrelated) contexts. MCT adopts a hands-on approach, aiming to raise patients' awareness for such cognitive biases. The ultimate goal is to 'plant the seeds of doubt' through entertaining and collaborative exercises that use predominantly non-delusional scenarios.

Several randomized controlled studies (Moritz et al., 2014a) as well as a recent meta-analysis (Eichner and Berna, 2016) have shown promising results regarding the short- and long-term efficacy of group MCT on delusions and/or positive psychotic symptoms in general (although

there have also been negative results (van Oosterhout et al., 2014; van Oosterhout et al., 2016)). This effect appears to be complementary to that of antipsychotic medication, since all the above results were obtained using MCT as adjunctive treatment to patients already receiving antipsychotics. However, the group intervention format may not be suited for some patients, including those with high level of suspiciousness (van Oosterhout et al., 2014), or patients with negative and/or disorganized symptoms that may require more intensive and structured work (Moritz et al., 2005). On the other hand, it has been suggested that the effects of metacognitive interventions on reasoning and delusions might be promoted with use of personalized material and individual therapy sessions (Garety et al., 2015; van Oosterhout et al., 2014).

Previous studies have shown that use of MCT material in an individual treatment format can have beneficial effects on cognitive biases and/or delusions after very few sessions (Balzan et al., 2014; Balzan and Galletly, 2015; Ross et al., 2011; So et al., 2015; Waller et al., 2011). In a randomized, controlled, rater-blind trial of group MCT combined with individualized sessions (Moritz et al., 2011), patients in the MCT arm showed significantly greater improvement in delusion severity and conviction, as well as in jumping-to-conclusions, relative to the active control group. Interestingly, effect sizes were quite large ($d>0.6$) for delusions in that study despite the short duration of the intervention and follow-up (4 weeks). The authors concluded that the application of MCT material to individual delusional beliefs might provide additional benefits compared to the group MCT; however, the sample size was too small to draw conclusive inferences.

Based on these findings, our group developed a fully individualized version of MCT. Metacognitive therapy (MCT+)(Moritz et al., 2012b) is a manualized intervention that, similar to MCT, targets common reasoning biases encountered in patients with delusions. However, MCT addresses the 'metacognitive infrastructure' of delusions solely with use of neutral exercises. In contrast, individualized MCT+ follows up on this initial step by applying the learned material (using techniques adopted from CBT) to challenge the content of individual delusional beliefs.

So far, there have been no randomized clinical studies on MCT+. Therefore, the present study aimed to assess the efficacy of this intervention in patients with delusions compared to an active control condition, consisting in a cognitive training intervention. We designed the study as a randomized controlled, rater-blinded trial, while at the same time including as many 'pragmatic' aspects as possible (such as broad inclusion criteria and flexibility in intervention delivery) to ensure generalizability of results and inform planning of larger, multicenter trials on MCT+. We hypothesized that MCT+ would lead to significantly greater decline in delusion severity and dysfunctional reasoning compared to the control condition.

2. Materials and methods

The study was conducted at the Department of Psychiatry and Psychotherapy of the University Medical Center Hamburg-Eppendorf (Germany). Participants were 92 patients with non-affective psychotic disorders and current or past delusions, recruited among in- and outpatients treated at the Psychosis Center of the Department from January 2013 through July 2015 and judged by their attending psychiatrist to qualify for study participation. Inclusion criteria were age 18 to 65 years, a DSM-IV diagnosis of a schizophrenia spectrum disorder confirmed with the Mini Neuropsychiatric Interview (Sheehan et al., 1998), and a present or prior delusional episode. Exclusion criteria were kept to a minimum in order to ensure generalizability of findings, and included a primary diagnosis of substance use disorder, IQ<70, severe organic brain disorders, previous experience with group MCT or any of the experimental interventions, and any ongoing CBT-oriented psychotherapy. The trial was approved by the ethics committee of the German Psychology Association, and all patients gave their written informed consent before entering the study. A CONSORT diagram is provided in Figure 1.

Patients were randomized according to a computerized randomization plan [pseudorandom fixed procedure, analogous to a previous group MTC trial by our group (Moritz et al., 2014b; Moritz et al., 2013a)] to one of two interventions: MCT+ or CogPack® (Marker, 2003) (see below for details regarding the interventions). Treatment arm allocation was performed observer-blind and communicated to patients by a person who was neither involved in the assessments nor in intervention delivery. All patients continued to receive their usual treatment throughout study participation. Importantly, as group MCT is a standard part of treatment in our department, patients from both groups were allowed to take part in MCT groups during study participation. However, this information was documented and considered in analyses.

Assessments were carried out at baseline, at 6 weeks (T1, corresponding to completion of 12 intervention sessions) and 6 months later (T2). All assessments were carried out by raters blind to treatment allocation. Rater training was performed according to the same procedure used in our recent group MCT study (Moritz et al., 2013a). In order to further enhance reliability, assessments for each individual patient were carried out by the same rater throughout the trial period.

2.1 Outcomes

Psychopathology was assessed with the Psychotic Symptom Rating Scales (PSYRATS) (Haddock et al., 1999) and the Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987). Both instruments have been widely used in intervention studies and have good psychometric properties (Drake et al., 2007; Peralta and Cuesta, 1994). The main outcome of interest was

delusion severity at T1 as reflected in the delusion subscale total score of the PSYRATS. Secondary outcomes included PSYRATS delusion score at T2, PANSS P1 item (Delusions) at T1 and T2, and psychopathology according to the 5-factor model of the PANSS (Wallwork et al., 2012), at T1 and T2.

Further secondary outcomes of interest (assessed both at T1 and T2) included the following:

- The Fish Task (Moritz et al., 2012a), a computerized variant of the Beads Task, was used to assess jumping-to-conclusions, a prototypical cognitive bias. In the task, participants are presented with two lakes containing fish in opposite color ratios (80:20 orange:gray or vice-versa). Ten fish are successively presented in a predetermined sequence to the participant. After each draw, the participant is required to estimate the probability that fish originated from lake A, and to indicate whether they have made a decision regarding the origin of the fish. All fish drawn remain visible throughout the task in order to minimize working memory demands. Parallel versions were used across the testing sessions to reduce practice effects. The variables of interest were the number of draws to decision, as well as the probability threshold at decision (i.e., the minimum probability estimate, at which a decision was made in favor of the respective lake; a higher probability threshold indicates more cautious inference making).
- The World Health Organization Quality of Life - BREF (WHOQOL-BREF) (Murphy et al., 2000) was used as a measure of overall life satisfaction. This self-report scale assesses quality of life in four domains: physical, psychological, social and environment. Moreover, two global items assess overall quality of life and general health satisfaction.
- The Rosenberg Self-Esteem Scale (von Collani and Herzberg, 2003), a widely used 10-item self-report measure, was administered to assess self-esteem.
- The Beck Cognitive Insight Scale (BCIS) (Beck et al., 2004) measures the ability to distance oneself from one's own ideas and reflect upon their possible fallibility. The 15-item self-report measure yields two scores reflecting self-reflectiveness and self-certainty. It has been suggested (Beck and Warman, 2004) and confirmed in patient studies (Riggs et al., 2012) that these cognitive insight indices are related to delusional thinking in particular among psychotic symptoms, as they reflect inflexible reasoning styles that support delusional beliefs.

2.2 Interventions

2.2.1 Experimental intervention

MCT+ is a manualized intervention that comprises 12 twice-weekly individual therapy sessions. Its main goal is to highlight the fallibility of cognition in general and encourage patients to reflect on their own thinking styles in relation to symptoms, but also to everyday life. MCT+ has a

modular structure. Three introductory modules focus on history taking, introduction to the intervention rationale and development of a personal illness model. The major cognitive biases described above are each introduced in separate modules, and this knowledge is used in later modules to discuss broader topics such as social interaction, mood and stress coping. Other than the three introductory modules, presentation of individual modules was not fixed in the present study, but rather tailored to the individual needs and metacognitive abilities of the patient as judged by the therapist. Thus, it was possible to spend more time on a module, revisit some and skip other modules. Sessions lasted approximately 45-60 min. Most sessions included homework tasks according to the principles of CBT.

Therapy was delivered by psychologists with variable expertise (and mostly in various stages of their training in psychotherapy) in order to best reflect standard conditions in patient care. All therapists received group supervision by a certified psychotherapist.

2.2.2 Control intervention

In order to match the two patient groups on therapeutic effort, an active control condition was used. The latter consisted in CogPack® (Marker, 2003), a computerized cognitive training program that targets cognitive dysfunctions commonly encountered in patients with psychosis. Treatment was administered individually on personal computers and covered a wide range of neuropsychological exercises involving memory, reasoning, selective attention and psychomotor speed. Each session lasted approximately 45-60 min. Similarly to MCT+, patients could receive a maximum of 12 consecutive sessions.

2.3 Statistical analyses

Differences between groups in gender, age, premorbid IQ, baseline symptom severity and antipsychotic dose, as well as mean antipsychotic medication dose over the whole study were assessed by means of t-tests.

Both intention-to-treat (ITT) and per protocol (PP) analyses were conducted. For PP analyses, participants were required to participate in post-treatment and follow-up assessments, respectively. ITT analysis considered data from all participants with available baseline data. Multiple imputation was adopted to estimate post-treatment and follow-up scores for non-completers. Both types of analyses used ANCOVAs to assess differences regarding outcome variables between groups at T1 and T2. In each of these ANCOVAS, change score of the respective variable (e.g. PSYRATS delusions change score for the primary outcome) was the dependent variable. Independent variable was group allocation (MCT+ vs. CogPack®). The baseline score of the outcome variable was included as a covariate in the model. The reported

results include also gender and IQ as predictors, although conducting analyses without these variables led to no changes at all regarding the direction of differences and significance levels. Significant results are reported at $p<0.05$ (two-sided), and statistical trends at $p<0.1$. Effect sizes are expressed using $\eta^2_{partial}$, whereby .01 is equivalent to a small effect, .06 is equivalent to a medium effect and .14 is equivalent to a strong effect (Kinnear and Gray, 2009).

Sample size calculations performed with Gpower (Erdfelder et al., 1996) indicated that a total sample size of 90 would be sufficient to detect an effect in the medium range for the primary outcome ($\eta^2_{partial}=0.08$), for $a=0.05$ and $\beta=0.20$.

3. Results

3.1 Sample characteristics

The two groups did not significantly differ in gender, age, premorbid IQ (as assessed with a German vocabulary test (Schmidt and Metzler, 1992)) and years of education (Table 1). About one third of patients concurrently participated in the MCT group program (a standard part of treatment in our department, see Section 2), and there were no differences between the two treatment groups in this regard (MCT+ n=15; CogPack® n=20; $\chi^2(1)=1.35$, $p=0.25$). There were also no differences in antipsychotic medication dose either at baseline or in average over the whole study period (Table 1).

There were some baseline differences in symptoms between the two intervention groups, with CogPack® patients scoring significantly higher on delusional severity and positive symptoms, while patients in the MCT+ group had significantly more negative symptoms (Table 1).

Assessment data were available for approximately 86% of patients at T1 and 80% at T2 and did not significantly differ between the two groups. Attendance rates were significantly different between the two groups, which was due to higher early drop-out rates in the CogPack® group. Patients who dropped out of treatment early (before the 4th session) had significantly lower premorbid IQ ($t=1.95$, $p=0.05$), requested less draws to reach a decision in the Fish Task ($t=3.57$, $p=0.001$), and had higher BCIS self-certainty scores ($t=2.04$, $p=0.04$), as well as higher baseline disorganization ($t=2.01$, $p=0.05$) and excitement scores ($t=2.66$, $p=0.009$).

3.2 Intervention effects

Changes in outcome variables over time are presented in Table 2. Both ITT and PP analyses yielded similar results. There was a significant difference in favor of MCT+ with respect to the primary outcome variable, PSYRATS delusion score, at T1 [ITT: $p=0.03$; PP: $F(1,72)=5.89$,

p=0.02, η^2_p=0.08]. The same was the case for PANSS item P1 at T1 [ITT: p=0.04; PP: F(1,72)=5.19, p=0.03, η^2_p=0.07].

Regarding reasoning, there were no differences in draws to conclusion change scores between the two groups (p>0.80). However, patients in the MCT+ group demonstrated a trend towards greater increase in their probability threshold to decision between baseline and T1 (ITT: p=0.07; PP: F(1,68)=3.38, p=0.07, η^2_p=0.05). Moreover, there was a significant difference in favor of MCT+ regarding BCIS self-reflectiveness increase at T1 [ITT: p=0.02; PP: F(1,72)=6.16, p=0.02, η^2_p=0.08].

Regarding all other outcome variables, there were no significant differences between the two groups at T1, although there was a numerical advantage for MCT+ in most cases. The highest effect sizes, which bordered a statistical trend in the ITT analyses, were noted for WHOQOL-BREF environment [ITT: p=0.08; F(1,70)=2.60, p=0.11, η^2_p=0.04], and for self-esteem as assessed with the Rosenberg scale [ITT: p=0.10; F(1,72)=2.50, p=0.12, η^2_p=0.03].

At T2, there were no significant differences between the two groups in any of the psychopathology, reasoning or other variables (all p>0.30). In many cases, this was due to the fact that patients in the CogPack® group, but not in the MCT+ group, showed further improvement between T1 and T2 (see Table 2).

3.3 Additional analyses

In order to assess whether concurrent group MCT affected results, we repeated all analyses using group MCT participation and its interaction with intervention group as additional predictors. The main effect of intervention group (MCT+ vs CogPack®) at T1 remained significant for PANSS P1 [ITT: p=0.02; PP: F(1,68)=6.40, p=0.01, η^2_p=0.09], BCIS self-reflectiveness score [ITT: p=0.005, PP: F(1,68)=8.56, p=0.005, η^2_p=0.11], and for PSYRATS delusion score [ITT: p=0.04; PP: F(1,68)=7.18, p=0.009, η^2_p=0.10]. Regarding decision thresholds at T1, group MCT participation showed a trend-wise effect [ITT: p=0.07; PP: F(1,68)=3.10, p=0.08, η^2_p=0.05]; the main effect of intervention group was no longer significant. At T2, these additional analyses led to no differences compared to the original results.

We also repeated analyses including only patients who completed at least 4 sessions of either intervention. The cut-off of 4 sessions was selected to ensure that patients in the MCT+ group would have received at least one session dealing with cognitive biases. This change generally led to an increase of effect sizes in favor of MCT+ at T1: PSYRATS delusions [ITT: p=0.002; PP: F(1,59)=12.26, p=0.001, η^2_p=0.17]; P1 [ITT: p=0.003; PP: F(1,59)=10.92, p=0.002, η^2_p=0.16]; BCIS self-reflectiveness [ITT: p=0.002; PP: F(1,59)=13.1, p=0.001, η^2_p=0.18]. Moreover, significance was achieved at T1 for group differences in PANSS positive symptom improvement

[ITT: p=0.02; PP: F(1,59)=6.00, p=0.02, η^2_p=0.09)], PANSS total score improvement [ITT: p=0.02, PP: F(1,59)=6.69, p=0.01, η^2_p=0.10] and decision threshold increase [at a trend level for ITT: p=0.07; PP: F(1,57)=5.33, p=0.03, η^2_p=0.09]. Results at T2 did not change substantially.

4. Discussion

The present study assessed the efficacy of an individualized metacognitive intervention (MCT+) compared to an active control, using a randomized controlled rater-blind design. MCT+ led to greater improvement regarding delusions and some aspects of cognitive bias in the short term (6-week follow-up). At the long-term follow-up 6 months later, there were no differences between the two intervention groups.

The beneficial effects of MCT+ on delusions and (partly) cognitive biases are consistent with previous studies on group MCT in a purely group format (Moritz et al., 2014a) and accompanied by individual therapy sessions (Moritz et al., 2011). This effect was more pronounced in the subset of patients who attended a minimum of 4 sessions of either intervention (although this finding should be interpreted with caution, because it resulted from additional analyses that did not consider the original randomized patient sample). Importantly, the intervention was delivered by therapists who did not always have long experience; five of six therapists were still in psychotherapy training. It is possible that, due to its highly structured and manualized format, MCT+ might be suitable for low-threshold administration without extensive therapist training. This increased applicability might, in turn, improve dissemination in clinical practice, which is unfortunately still very low for evidence-based therapies such as CBT in patients with psychosis (Haddock et al., 2014).

The observed effects of MCT+ were only observable at the 6-week follow-up. The pattern of results suggests that, although MCT+ led to improvement of delusions and reasoning quite early on (6 weeks), patients in the CogPack® group eventually attained the same improvement levels. This absence of longer-term effects is not consistent with previous studies on group MCT (Moritz et al., 2014a). It is probable that this inconsistency is due to selective floor effects in the MCT+ group: As shown in Tables 1 and 2, the randomization process resulted in differences between the two groups regarding baseline symptoms, which were lower in MCT+ patients -and, in fact, lower than in previous studies by our group (Moritz et al., 2013a; Moritz et al., 2011) and others (Favrod et al., 2014; So et al., 2015). This, in combination with the rapid improvement, led to very low symptom levels in these patients post-intervention, while the control group may have benefited from greater margins for change. Alternatively, it may be that further measures are needed to promote sustainability of MCT+ effects, especially in patients with psychosis who are known to have impaired memory capacity. The CBT concept of 'booster sessions' might be

applicable here. Other, more low-threshold, possibilities include online or mobile-phone based exercises; our group is currently working on the development of respective applications.

Surprisingly, we did not observe a significant effect on the number of draws to decision in the Fish Task, inconsistent with our previous findings regarding group MCT (Moritz et al., 2013a). Table 1 indicates a possible reason for this negative finding: The number of draws to decision in the present patient sample was much higher at baseline compared to previous studies by our group and others (Moritz et al., 2013a; Moritz et al., 2011; So et al., 2015) on MCT. The Fish task is widely used in patient studies in our research center, and group MCT is an integral part of standard patient care in our department. Hence, most patients would have had at least some superficial contact with the concept of "hasty decisions", which may have biased findings. This is only a tentative explanation, since Garety et al. (2015) noted a significant effect of their own individualized metacognitive intervention on the number of draws to decision despite a similarly high baseline value as in the present study. In any event, MCT+ did have beneficial effects on other indices of cognitive bias (decision threshold and BCIS self-reflectiveness). However, these too were short-lived suggesting a possible need for 'reminders' in the forms discussed above. Interestingly, group differences between groups disappeared when concurrent participation in group MCT was considered in analyses, while a trend for the group intervention emerged. This may indicate a stronger effect for the group intervention, which focuses more explicitly on ‘formal’ aspects of cognitive biases rather than individual delusional content. However, this hypothesis needs to be assessed in future studies, as group MCT participation was not randomized.

Apart from a transient effect on WHOQOL-BREF environment factor at T1, we did not note any significant effects on quality of life and self-esteem, which may be due to the short follow-up period: in a previous trial by our group on group MCT (Moritz et al., 2014b), positive effects of MCT on quality of life and self-esteem were visible only at the 3-year follow-up.

A strength of the present study was that it used a randomized controlled rater-blind design while simulating conditions of standard care as well as possible through non-restrictive inclusion criteria, a wide range of patient baseline symptom severity and therapist experience, and flexibility regarding therapy content. However, there are also limitations that should be considered. (1) One limitation results from the significantly lower psychopathology scores of the MCT+ group at baseline. This difference between the two intervention groups can be attributed to chance, since our randomization plan was analogous to the one successfully implemented in a previous clinical trial by our group (Moritz et al., 2014b; Moritz et al., 2013a). Still, and although all analyses of clinical variables were adjusted for baseline symptom severity, it complicates interpretation of results: apart from issues associated with possible floor effects in the MCT+ group or larger regression to the mean in control group that may have confounded between-

group differences, it is not possible to exclude subtle indirect effects of baseline psychopathology on outcomes, e.g. by affecting motivation for treatment, or the establishment of a therapeutic relationship. (2) There were significantly lower attendance rates in the CogPack® than in the MCT+ group. This is in itself a positive finding, as it reflects better acceptance rates of MCT+, confirming findings of previous studies on group MCT (Eichner and Berna, 2016). Moreover, attendance rates did not affect re-assessment rates, which were comparable in the two intervention groups, such that the validity of statistical analyses was not compromised. However, the two intervention groups cannot be considered to be similar regarding therapeutic effort. This is not a trivial matter, given the results of a recent meta-analysis on CBT for psychosis (Mehl et al., 2015) suggesting that effect sizes in favor of CBT diminish significantly when the intervention is not compared against treatment-as-usual, but rather against an active control intervention. Thus, this point should be considered when designing future efficacy studies for any psychotherapy approach. (3) A final limitation of the present study was that it did not include a group MCT arm. Although MCT group participation was considered in analyses, it will be an interesting aim for future studies to directly compare the two interventions, in order to assess whether the individualized format of MCT+ provides further advantages compared to the group training.

In summary, a short course of individualized metacognitive therapy (MCT+) led to faster improvement in delusions and cognitive biases compared to a control intervention. The benefit associated with MCT+ disappeared in the long term, which may have been due to floor effects but may also indicate the need for regular reviews of therapeutic material after completion of the intervention.

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Figure legends

Figure 1: CONSORT flow diagram

Tables

Table 1: Sample description and treatment characteristics

	MCT+			CogPack				
	n	*mean*	*SD*	*n*	*mean*	*SD*	t/χ^2	*p*
Gender (m/f)	21 / 25			30 / 16			3.56	0.09
Age (years)		36.91	12.5		35.59	13.1	0.50	0.62
Years of education		11.65	1.7		11.27	2.1	0.94	0.35
IQ		105.42	12.2		100.91	11.5	1.78	0.08
Symptoms								
PSYRATS delusions		5.74	5.9		8.50	7.3	2.01	0.05
PANSS								
P1 (delusions)		2.59	1.3		3.24	1.7	2.05	0.04
total score		49.78	13.0		49.35	12.8	0.16	0.87
positive		7.37	3.1		9.33	4.4	2.46	0.02
negative		10.83	4.8		8.30	2.9	3.06	0.003
disorganization		5.30	2.2		5.76	2.5	0.92	0.36
excitement		4.74	1.3		5.17	1.5	1.48	0.14
depression		6.85	3.1		5.74	2.7	1.83	0.07
Reasoning style								
Fish Task - draws to decision		4.02	2.8		3.44	2.6	1.02	0.31
Fish Task - decision threshold		79.22	19.3		78.47	22.5	0.17	0.87
BCIS self-certainty		13.84	2.8		14.74	2.9	1.48	0.14
BCIS self-reflectiveness		23.89	4.1		24.29	5.0	0.12	0.68
Quality of Life & self-esteem								
Rosenberg self-esteem scale		16.82	8.3		19.82	8.2	1.72	0.89
WHOQOL-BREF								
physical		57.48	20.8		61.43	17.5	0.97	0.36
psychological		49.29	20.9		56.53	19.3	1.69	0.10
relations		54.89	21.1		57.27	21.8	0.52	0.60
environment		66.24	16.7		62.97	19.1	0.86	0.39
Antipsychotic medication								
CPZ dose at T0		344.56	424.0		305.49	393.5	0.85	0.40
mean CPZ dose T0-T2		343.39	310.2		282.83	374.2	0.85	0.40
Attendance & study adherence								
number of sessions		8.28	3.5		5.59	4.3	3.28	0.001
participation at >=4 sessions (y/n)	41/5			29/17			8.60	0.006
data available at T1 (y/n)*	42 / 4			40 / 9			2.24	0.23
data available at T2 (y/n)**	39 / 7			35 / 11			1.11	0.43

* for all variables, with the following exceptions: Fish Task based outcomes (n=40 and n=36 cases for MCT+ and CogPack®, respectively); WHOQOL-BREF (n=42 and n=35 cases for MCT+ and CogPack®, respectively).

** for all variables, with the following exceptions: Fish Task based outcomes (n=37 and n=35 cases for MCT+ and CogPack®, respectively); BCIS, WHOQOL-BREF and Rosenberg (n=40 and n=34 cases for MCT+ and CogPack®, respectively).

Table 2: Outcomes per intervention group and time point. Means and standard deviations (in brackets). Symbols indicate the significance levels for the comparison T0-T1 and T1-T2 in each group separately. For between-group comparisons, please refer to the Results section.

	MCT+			CogPack		
	T0	**T1** *(within-subject change from T0)*	**T2** *(within-subject change from T1)*	**T0**	**T1** *(within-subject change from T0)*	**T2** *(within-subject change from T1)*
Symptoms						
PSYRATS delusions	5.74 (5.9)	3.48** (5.1)**	5.05 (6.6)	8.50 (7.3)	7.43 (7.1)§	5.60 (7.0)*
PANSS						
P1 (delusions)	2.59 (1.3)	1.88 (1.0)***	2.10 (1.4)	3.24 (1.7)	2.68 (1.5)**	2.34 (1.6)*
total score	49.78 (13.0)	43.31 (9.2)***	43.85 (12.8)	49.35 (12.8)	45.43 (11.0)**	45.00 (12.1)
positive	7.37 (3.1)	6.00 (2.6)***	6.23 (3.1)	9.33 (4.4)	7.70 (3.5)**	7.66 (3.4)
negative	10.83 (4.8)	9.64 (4.7)*	9.35 (3.9)	8.30 (2.9)	8.24 (3.3)*	8.37 (3.0)
disorganization	5.30 (2.2)	4.50 (1.7)**	4.58 (2.0)	5.76 (2.5)	4.84 (1.9)	4.91 (2.6)
excitement	4.74 (1.3)	4.45 (0.9)	4.38 (0.8)	5.17 (1.5)	4.92 (1.6)	4.94 (1.7)
depression	6.85 (3.1)	5.76 (2.6)*	5.85 (3.3)	5.74 (2.7)	5.49 (2.5)	5.23 (3.0)
Reasoning Style						
Fish Task - draws to decision	4.02 (2.8)	4.10 (2.3)	4.19 (2.4)	3.44 (2.6)	4.22 (2.9)	4.49 (2.9)
Fish Task - decision threshold	79.22 (19.3)	83.69 (18.3)§	82.81 (18.8)	78.47 (22.5)	74.08 (28.0)	84.31 (19.6)
BCIS self-certainty	13.84 (2.8)	13.98 (2.5)	14.14 (2.8)	14.74 (2.9)	14.08 (2.8)	13.96 (2.4)
BCIS self-reflectiveness	23.89 (4.1)	24.76 (4.4)*	23.28 (4.6)*	24.29 (5.0)	23.04 (4.5)	22.80 (4.9)
Quality of Life & self-esteem						
Rosenberg self-esteem scale	16.82 (8.3)	20.17 (8.2)***	20.65 (7.7)	19.82 (8.2)	20.59 (7.4)	21.79 (7.9)*
WHOQOL-BREF						
physical	57.48 (20.8)	63.48 (18.5)*	66.52 (18.1)	61.43 (17.5)	64.59 (18.3)	64.18 (19.3)
psychological	49.29 (20.9)	56.57 (20.3)*	60.52 (19.0)§	56.53 (19.3)	61.31 (17.8)	61.11 (17.4)
relations	54.89 (21.1)	59.03 (22.3)	63.13 (19.2)	57.27 (21.8)	57.14 (20.4)	61.74 (17.3)
environment	66.24 (16.7)	71.00 (13.3)*	72.47 (15.9)	62.97 (19.1)	65.92 (15.5)	67.55 (13.9)

§ p<0.1, * p<0.05, ** p<0.01 *** P<0.001

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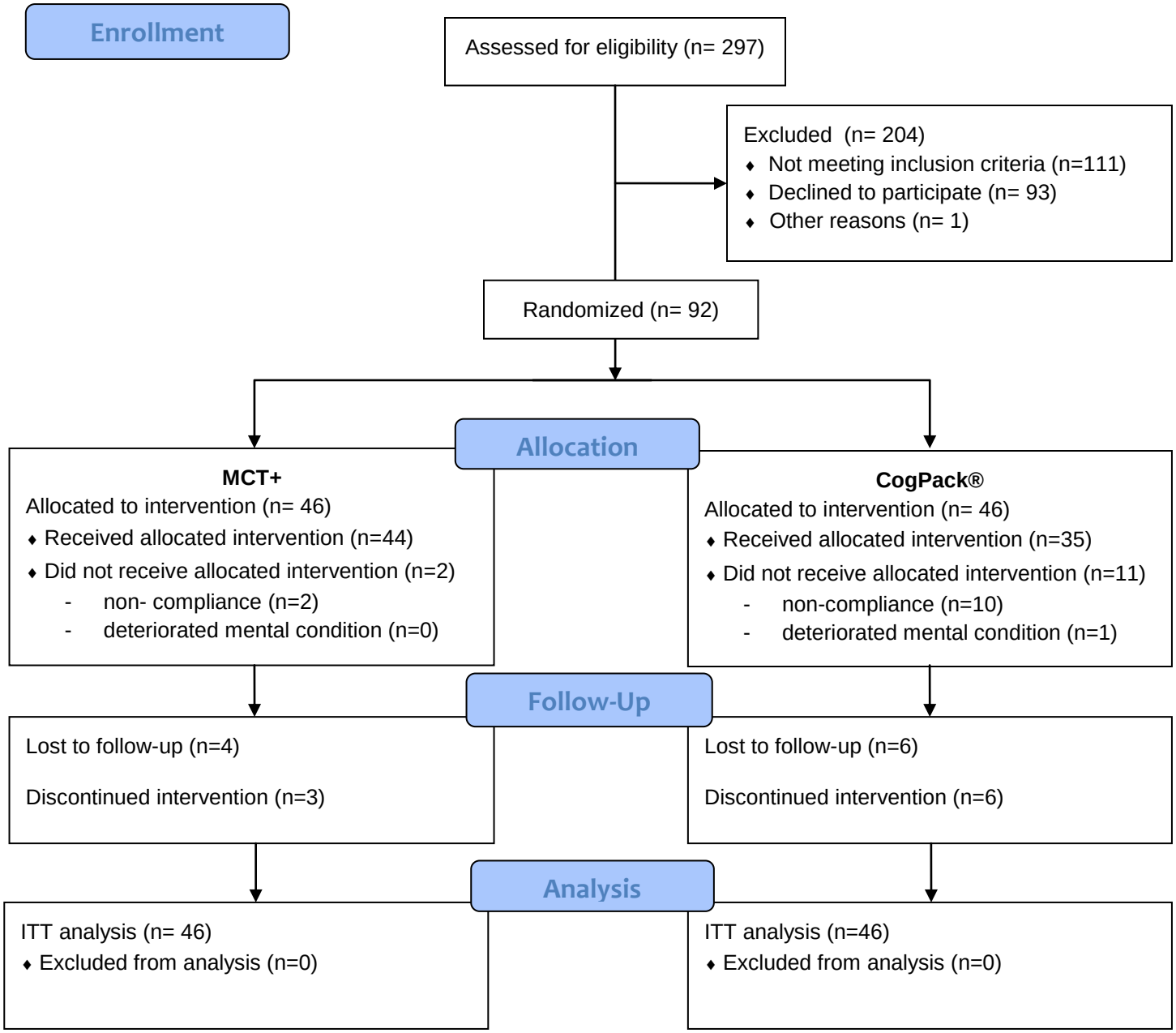
Enrollment
Assessed for eligibility (n= 297)
Excluded (n= 204)
♦ Not meeting inclusion criteria (n=111)
♦ Declined to participate (n= 93)
♦ Other reasons (n= 1)
Randomized (n= 92)
Allocation
MCT+
Allocated to intervention (n= 46)
♦ Received allocated intervention (n=44)
♦ Did not receive allocated intervention (n=2)
- non- compliance (n=2)
- deteriorated mental condition (n=0)
CogPack®
Allocated to intervention (n= 46)
♦ Received allocated intervention (n=35)
♦ Did not receive allocated intervention (n=11)
- non-compliance (n=10)
- deteriorated mental condition (n=1)
Follow-Up
Lost to follow-up (n=4)
Discontinued intervention (n=3)
Lost to follow-up (n=6)
Discontinued intervention (n=6)
Analysis
ITT analysis (n= 46)
♦ Excluded from analysis (n=0)
ITT analysis (n=46)
♦ Excluded from analysis (n=0)