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



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#### ABSTRACT

Background: 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 thresholds 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 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.

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#### 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 & 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 & Kingdon, 2015; Mueser, Deavers, Penn, & Cassisi, 2013). The concurrent growing realization of the limitations of antipsychotic medication, especially with respect to functional recovery (Jaaskelainen et al., 2013; Leucht, Arbter, Engel, Kissling, & Davis, 2009) and adherence issues (Lieberman et al., 2005) have boosted interest in psychological interventions for the treatment of delusions.

Cognitive-behavioral therapy (CBT) has a leading role in this field. Having provided a wide empirical basis supporting its efficacy in treating delusions (Hutton & Taylor, 2014; Turner, van der Gaag, Karyotaki, & Cuijpers, 2014; Wykes, Steel, Everitt, & Tarrier, 2008), CBT was one of the first psychological interventions to be included in treatment guidelines for psychosis. However, there is still an

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ongoing debate about its efficacy (McKenna & Kingdon, 2014), especially when it comes to disentangling 'true' efficacy from unspecific therapy effects (Jauhar et al., 2014; Lynch, Laws, & McKenna, 2010; Mehl, Werner, & Lincoln, 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, Freeman, Jolley, Dunn, & Garety, 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, Veckenstedt, Bohn, Köther, & Woodward, 2013b, pp. 358–383). MCT builds upon evidence associating delusional beliefs with specific thinking styles that lead to distorted appraisals of events (Garety & 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 & 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, 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, Woodward, & Burlon, 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 & Galletly, 2015; Balzan, Delfabbro, Galletly, & Woodward, 2014; Ross, Freeman, Dunn, & Garety, 2011; So et al., 2015; Waller et al., 2011). In a randomized, controlled, rater-blind trial of group MCT combined with individualized sessions (Moritz, Veckenstedt, Randjbar, Vitzthum, & Woodward, 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, Veckenstedt, Randjbar, & Vitzthum, 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 nonaffective 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 18-65 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, alcohol dependence in the last 6 months, 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 Fig. 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., 2013a, 2014b)] to one of two interventions: MCT+ or CogPack® (Marker, 2003) (see below for details regarding the interventions). Treatment arm allocation was performed observer-blind 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, McCarron, Tarrier, & Faragher, 1999) and the Positive and Negative Syndrome Scale (PANSS) (Kay, Fiszbein, & Opler, 1987). Both instruments have been widely

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