

RESEARCH ARTICLE

Assessing the Feasibility of Metacognitive Training for Patients with Schizophrenia in Pakistan: A Randomized Controlled Trial

Parsa Waqar Abbasi & Muhammad Aqeel

Abstract

Background: Schizophrenia is a grave and incapacitating global mental health challenge. Prior research has proposed various psychological interventions aimed at alleviating the severity of schizophrenia symptoms in developing nations. Notably, in Pakistan, there exists a notable dearth of research efforts directed at tackling this issue and implementing strategies to bridge this gap. This study endeavors to create a distinctive intervention tailored to enhance the severity of symptoms experienced by individuals grappling with schizophrenia in Pakistan.

Methods: This study used a pre-post design with a double-blinded, two-arm, randomized controlled trial. Sixty participants were recruited from psychiatric departments in hospitals in Rawalpindi and Islamabad from August to November 2022. They were divided into two groups: an experimental group (30 participants) and a control group (30 participants). To assess the impact of an intervention, four measurement tools were used to gauge symptom severity, cognitive insight, disability, and quality of life in individuals with schizophrenia. The study employed a two-way factorial analysis of variance (ANOVA) to evaluate the effectiveness of metacognitive therapy (MCT) in reducing symptoms, improving cognitive insight, reducing disability, and enhancing quality of life.

Results: The study's outcomes revealed that, when compared to the standard treatment, metacognitive therapy (MCT) yielded positive effects in ameliorating both symptom severity and cognitive insight among individuals diagnosed with schizophrenia. Conversely, the results indicated that MCT did not yield statistically significant improvements in the domains of quality of life and disability in this cohort of schizophrenia patients.

Conclusions: The findings of this study hold promise for enhancing the treatment of schizophrenia in Pakistan and providing valuable insights for policymakers to consider the integration of this therapy into multiple healthcare facilities nationwide.

Keywords: Metacognitive Training, schizophrenia, randomized controlled trial, feasibility study.

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Background

Schizophrenia represents a significant persistent global mental health problem that exerts a profound negative influence on an individual's quality of life, resulting in impairments across multiple domains, including self-care, occupational performance, family relationships, and general social interactions (Guilera et al., 2012; Nowak et al., 2016; Sagayadevan et al., 2019). According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5, text revision), schizophrenia is characterized by the presence of a minimum of two of the following symptoms: delusions, hallucinations. disorganized speech, grossly disorganized or catatonic behavior, and negative symptoms. Additionally, among these symptoms, at least one should be from the first three categories listed (American Psychiatric Association, 2022; De-Pinho et al., 2021).

Schizophrenia affects more than 20 million people around the world (Magwai et al., 2021; Nowak et al., 2016; Wahbeh & Avramopoulos, 2021; World Health Organization, 2022). It is fourth leading causes of disability worldwide and a condition that shortens the lifespan (Beyene et al., 2021; Mathew, 2022). Moreover, mental health issues are a major concern in low- and middle-income countries (LMIC), and conflicts, hunger, poverty, trauma, social inequity, and limited access to healthcare all contribute to the rise in mental health conditions like schizophrenia (Alloh et al., 2018; Mackenzie & Kesner, 2016; Rathod et al., 2017). Approximately 90% of all patients with schizophrenia are living in LMIC (Charlson et al., 2018; Nawaz et al., 2020). Among the people of Pakistan, almost 1.5% of the entire population is affected by schizophrenia (Nawaz et al., 2020). There is a shortage of psychiatric and specialist clinics for the identification and management of schizophrenia in Pakistani patients, and mental health treatment mostly focuses on the use of antipsychotic medications, and medical and physical therapies, such as electro-convulsive therapy (Gadit, 2007; Nawaz et al., 2020). Similarly, non-compliance is another common problem in Pakistan when it comes to taking medication for mental health conditions such as schizophrenia. Many of the reasons for non-compliance cited include a lack of awareness of the benefits of treatment, difficulty paying for medications, physical side effects, lack of knowledge among clinicians, and stigma associated with mental health issues and treatment. This has led to a high rate of relapse for schizophrenia patients in Pakistan, and adherence to psychotherapy is even worse (Ali et al., 2006; Nawaz et al., 2020; Taj & Khan, 2005).

There is limited evidence to suggest that psychotherapy is an effective stand-alone therapy or in combination with standard pharmacological therapy for people with psychosis. While some studies have found that CBT can be helpful, more research is needed to determine its full effectiveness (Naeem et al., 2015; Nawaz et al., 2020).

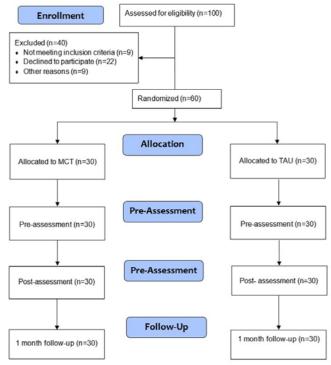
The present study examined the efficacy of adapted MCT in combination with the treatment as usual, as compared to the treatment as usual as a standalone, in individuals with schizophrenia. It examined the effect of MCT on symptom severity, as well as cognitive insight, functioning, and quality of life. While cognitive insight and quality of life have been previously associated with MCT, very little research has been done to find the effect of MCT

on disability and functioning. Thus, the current research also focused on bridging this gap.

Method

Research design

This study was a pre-post design, parallel two arm, double blinded, feasibility, randomized controlled trial. The Consolidated Standards of Reporting Trials (CONSORT) was used to report this study (Eldridge et al., 2016). The trial was registered at American Economic Association's registry for randomized controlled trials. ID AEARCTR-0009510.



Research objectives

This study aimed to develop a unique intervention to improve the severity of symptoms in individuals with schizophrenia in Pakistan.

Participants

A purposive sampling technique was done to recruit sixty participants (Male=22, female=38) with an age range of 20 to 60 years (M=31.4, SD=7.99) from the department of psychiatry of various hospitals across Rawalpindi and Islamabad. They were divided into two groups: experimental group (n=30) and control group (n=30).

Eligibility

Inclusion Criteria. Included participants had to be between 18 and 65 years of age, with a diagnosis of schizophrenia as evaluated by a psychiatrist. Patients also had to have a PANSS score of 58-116 (mildly to markedly ill) to be included in the study (Leucht et al., 2005).

Exclusion Criteria. Patients with very severe psychotic symptoms that could hinder their understanding of the objectives of the sessions were excluded, particularly based on PANSS score of 116 (severely ill) (Leucht et al., 2005). Additionally, patients with any psychiatric comorbidities were also excluded from the study via a consultant psychiatrist's assessment.

Randomization and masking

Participants were randomly assigned (1:1) to receive treatment with MCT or standard treatment using a

computer-generated randomization schedule. This was supervised by an external independent statistician with rigid concealment of allocation. The assessment was done at pre and post-intervention levels and was conducted by the same investigator who was blinded and did not know to which group the participants belonged. Both the participants and clinicians were masked to treatment allocation throughout the intervention.

Interventions

Metacognitive Training for Psychosis.

Metacognitive Training for Psychosis was created in 2005 by Steffen Moritz and Todd S. Woodward. Currently available in 37 languages, it is a group training program that focuses on cognitive biases that are thought to contribute to the development and maintenance of psychotic symptoms such as attributional biases, jumping to conclusions, overconfidence in errors, and maintaining beliefs despite compelling contrary evidence, as well as negative cognitive schemata and dysfunctional coping mechanisms that promote depression and impaired social functioning (Moritz et al., 2021; Penney et al., 2022).

The main goals of MCT are to educate patients about the basics of cognitive distortions and to help them become more aware of the dysfunctionality of these biases. The exercises in the program aim to deliver corrective experiences to patients, teach them alternate information-processing techniques, and normalize the fact that cognitive biases are normal to some degree. The MCT program consists of two cycles, each of which contains eight core modules and two additional modules. The modules include attribution, jumping to conclusions, changing beliefs, empathy, memory, mood, self-esteem, and dealing with stigma. Participants should complete two sessions per week, with one module covered in each session. This way, one full cycle of the program can be completed in one month (Moritz et al., 2014, 2021).

Each module starts with educational elements on normalizing cognitive biases. The different domains of cognition are introduced with a variety of examples and activities, and the fallibility of human cognition is discussed and illustrated. The pathological extremes of each cognitive bias are emphasized in the next step. Patients are made aware of how exaggerations of (typical) thinking biases can cause issues in daily life and occasionally even result in delusions or other symptoms. This is demonstrated through real-life examples of persons who have psychosis, giving group members the chance to relate their own experiences if they so choose. Patients gain the ability to recognize and defuse "cognitive traps" in this way (Moritz et al., 2021).

The intervention was delivered to participants in groups of 3-5 people. Eight sessions were delivered biweekly. Data was collected at pre and post-intervention delivery. Sessions were not repeated and missed sessions could not be made up since all sessions are independent of each other. New participants could enter at any session. The participants continued their psychopharmacological treatment and regular psychiatric care throughout the program.

Treatment as Usual. The control group received treatment as usual (TAU). This included psychopharmacological treatment as well as routine psychiatric care. However, due to ethical concerns, all

individuals were given the option of participating in the MCT program once the trial was completed.

Outcome Measures

Primary outcomes.

Positive and Negative Syndrome Scale

(PANSS). The Positive and Negative Syndrome Scale (PANSS; (Kay et al., 1967) is used to determine a patient's current severity level of schizophrenia symptoms. The items are evaluated from 1 to 7, with responses ranging from absent to minimal, mild, moderate, moderately severe, and extreme. PANSS is divided into three subscales: positive, negative, and general psychopathology. The positive scale evaluates positive symptoms of schizophrenia, whereas the negative scale evaluates negative symptoms. The general psychopathology scale provides a distinct parallel measurement of schizophrenia illness severity that can be utilized to interpret syndromal scores as a point of comparison or a control measure. The positive and negative scales each have seven items, while the overall psychopathology scale contains sixteen. For the purpose of this study, we used the scoring method proposed by Leucht et al. (2005) which provided a cutoff score for PANSS as mildly ill (58-74), moderately ill (75-94), markedly ill (PANSS score 95-115) and severely ill (PANSS score 116-210).

Secondary outcomes.

WHO Quality of Life scale (WHOQOL-

BREF). WHO Quality of Life scale (WHOQOL-BREF; Lodhi et al., 2017; World Health Organization, 1996) assesses an individual's perception of their health and wellbeing over the course of their illness. Items are rated 1 to 5 with possible responses being not at all, not much, moderately, a great deal, or completely. WHOQOL-BREF covers four dimensions of quality of life: psychological wellbeing, physical health, social relationships, and environment. Two further items assess the overall quality of life and health.

WHO Disability Assessment Scale (WHODAS 2.0). WHO Disability Assessment Scale (WHODAS 2.0; Üstün et al., 2010) assesses the health and disability level of an individual as well as the impact of a health-related intervention. The WHODAS 2.0 has three versions, each with three different modes of application. These are the 36-item version, the 12-item version, and the 12+24-item version. Each version can be administered via self, interview, or proxy. For the purpose of this study, the 12-item version administered either via self or interview was used. Possible responses include none (1), mild (2), moderate (3), severe (4), and extreme or cannot do (5). WHODAS 2.0 comprises 6 main domains: cognition, mobility, self-care, getting along, life activities, and participation.

Beck Cognitive Insight Scale (BCIS). Beck Cognitive Insight Scale (BCIS; Beck et al., 2004) assesses an individual's self-reflectiveness and their overconfidence in their interpretations of their experiences. Items are rated on a 4-point scale with the possible response being do not agree at all (0), agree slightly (1), agree a lot (2), and agree completely (3). BCIS is composed of two subscales: self-reflectiveness, containing items measuring objectivity, reflectiveness, and openness to feedback, and self-certainty, which measures certainty about one's own beliefs and judgments.

Ethical Considerations

Approval was obtained from the Ethical Review Board (IRB) of Foundation University Islamabad and permission was granted to carry it out. Targeted hospitals were approached and informed about the study details. Written informed consent was obtained from them regarding voluntarily permitting to carry out the study trial on their premises. Before the trial began written informed consent was obtained from the participants, and it was ensured that their participation was voluntary. All ethical standards and confidentiality were maintained.

Data analysis

For the present study, the data were evaluated by using SPSS version 20. A two-way factorial ANOVA was employed for the primary endpoint analysis. The mean difference between two treatment arms, three-time points, together with its 95% confidence interval (CI), was derived from the multivariate analysis. Effect sizes were estimated using the partial eta squared (η^2_p), the cut-off points of which were: small = 0.01, medium = 0.0588, and large = 0.14 (Cohen, 1988). Significance was assessed using the p-value, and p < 0.05 was considered statistically significant.

Results

In Table 1, the current study sought to determine whether treatment as usual or treatment with MCT was more effective in lowering psychotic symptoms in people with schizophrenia. The trial was divided into two treatment groups: treatment as usual and treatment with MCT. The assessment took place across three distinct time periods: pre, post, and follow-up.

Primary outcome

Schizophrenia Symptom severity. Application of a two-way factorial ANOVA revealed a significant effect for the treatment condition in the group $(F=59.35, p=.00, \eta^2_p=.25), \text{ time } (F=89.48, p=.00, \eta^2_p=.51),$ and interaction effect (F=9.4, p=.00, η^2_p =.10). Control group did not exhibit any appreciable improvement in pre (M=89.6, SD=6.93) to post-treatment (M=80.97, SD=6.12), and follow-up (M=77.87, SD=6.24) settings, whereas the experimental group's subjects significantly reduced their symptom severity in the post-condition (M=70.4, SD=8.57) in comparison to the precondition (M=87.73, SD=7.21). There was a minor improvement in follow-up condition (M=64.93, SD=9.09) because while MCT was not provided, the patients continued with their treatment as usual.

Secondary outcome

Three outcome measures were considered to be secondary: cognitive insight, disability, and quality of life. All are outcomes that relate to the long-term adjustment of the schizophrenia population.

Cognitive insight. The analysis showed a highly significant effect for treatment condition in the group (F=24.72, p=.00, η^2_p =.12) and time (F=12.39, p=.00, η^2_p =.13), and a low effect for treatment condition in the interaction of group and time (F=4.32, p=.01, η^2_p =.05). Participants who were exposed to the MCT condition significantly improved from pre (M=30.1, SD=4.15) to post-treatment (M=33.7, SD=3.36), but a slight decline in the follow-up period (M=32.13, SD=2.73). The control group showed a very small improvement from the pre (M=28.17, SD=3.37) to post-treatment (M=29.47, SD=2.81), and

continued improvement in the follow-up period (M=31.23, SD=2.32).

Functioning. The analysis showed a low effect for treatment condition in the group (F=8.16, p=.01, η^2_p =.05) and time (F=4.4, p=.01, η^2_p =.05), while a non-significant effect for treatment condition in the interaction of group and time (F=1.13, p=.32, η^2_p =.01). Participants who were exposed to the MCT condition significantly improved from pre (M=20.43, SD=5.94) to post-treatment (M=16.2, SD=3.87), but a very slight increase in the follow-up period (M=16.6, SD=3.82). The control group showed a very small improvement from the pre (M=21.33, SD=8.19) to post-treatment (M=20.4, SD=6.9), and more improvement in the follow-up period (M=19.17, SD=6.16).

Quality of life. The analysis showed a low effect for treatment condition in the group (F=4.03, p=.04, η^2_p =.02) and a medium effect in time (F=9.17, p=.00, η^2_p =.09), while a non-significant effect for treatment condition was found in the interaction of group and time (F=.34, p=.71, η^2_p =.01). Participants in the test group showed a noticeable improvement from pre (M=71.83, SD=11.91) to post-treatment (M=80.87, SD=15.56), but showed a slight decline in the follow-up period (M=78.8, SD=13.6). The control group also showed noticeable improvement from pre (M=67.37, SD=9.51) to post-treatment (M=75.67, SD=12.46), while displaying a small improvement in the follow-up period (M=77.17, SD=11.7).

Discussion

The present study examined the efficacy of adapted Metacognitive Training for psychosis in combination with the treatment as usual, as compared to the treatment as usual as a standalone, in individuals with schizophrenia in Pakistan by means of a randomized controlled trial. This was the first such study that examined the effect of MCT on symptom severity, as well as cognitive insight, disability, and quality of life. Results indicated that the severity of schizophrenia decreased over the one-month period of MCT given over eight sessions. The patients given TAU only also improved but considerably less than the MCT group. At the one-month follow-up, both groups displayed the same amount of improvement in symptoms. These results were in line with prior RCTs that used PANSS as an assessment tool (Briki et al., 2014; Chen et al., 2021; Favrod et al., 2008; Fekete et al., 2022; Ishikawa et al., 2020; Kuokkanen et al., 2014; Moritz, Veckenstedt, et al., 2011; Ussorio et al., 2016).

The MCT program was also effective in improving cognitive insight in schizophrenia patients. Significant improvements were observed in the MCT group relative to the control group. These results were similar to other studies that used BCIS as a measure of cognitive insight (Birulés et al., 2020; de Pinho et al., 2021; Lam et al., 2015; Ochoa et al., 2017; Ussorio et al., 2016). Improvement in cognitive insight has been linked to improved treatment compliance, metacognition, and decreased symptoms in people with schizophrenia (Lysaker et al., 2015; Vohs et al., 2015).

For functioning, while MCT did appear to have an impact on the WHODAS scores when compared with TAU, the results were found to be non-significant. This corroborated with the only study found testing the effects of MCT on WHODAS where the results were also non-significant (de Pinho et al., 2021).

Table 1Mean Differences between Treatment as Usual and Metacognitive Training for Psychosis on Measures of Symptom Severity, Cognitive Insight, Disability, and Ouality of Life (N=60).

		TAU (n=30)		MCT (n=30)		Group	Time			Group*time		Mean difference (95% CI)	
	α	M	SD	M	SD	F	η^2_p	F	η^2_p	F	η^2_p	UL	LL
PANSS													
Pre	.70	89.6	6.93	87.73	7.21	59.35***	.25	89.48***	.51	9.40***	.10	86.42	90.91
Post		80.97	6.12	70.4	8.57							73.44	77.92
FU		77.87	6.24	64.93	9.09							69.16	73.64
BCIS													
Pre	.71	28.17	3.37	30.1	4.15	24.72***	.12	12.39***	.13	4.32**	.05	28.26	30.01
Post		29.47	2.81	33.7	3.36							30.71	32.46
FU		31.23	2.32	32.13	2.73							30.81	32.56
WHOD	AS												
Pre	.92	21.33	8.19	20.43	5.94	8.16**	.05	4.40**	.05	1.13	.01	19.32	22.44
Post		20.4	6.9	16.2	3.87							16.74	19.86
FU		19.17	6.16	16.6	3.82							16.32	19.44
WHOQ	OL												
Pre	.85	67.37	9.51	71.83	11.91	4.03*	.02	9.17***	.09	.34	.01	66.38	72.82
Post		75.67	12.46	80.87	15.56							75.04	81.49
FU		77.17	11.7	78.8	13.6							74.76	81.21

Note. TAU = treatment as usual; MCT = Metacognitive Training for psychosis; PANSS = Positive and Negative Syndrome Scale; BCIS = Beck Cognitive Insight Scale; WHODAS = World Health Organization Disability Assessment Schedule; WHOQOL = World Health Organization Quality of Life scale; * p < .05; *** p < .01; *** p < .001.

WHODAS assesses functioning in all areas of life, not just social functioning. Thus the lack of good results could be related to the fact that people with schizophrenia typically have severely reduced Social and occupational performance while other areas of functioning can remain unchanged. This study also utilized the 12-item version of WHODAS 2.0, rather than the 32-items version, which could be a reason for the non-significant results, despite the fact that the 12-item version accounts for approximately 85% of the variance of the full version (Üstün et al., 2010).

Finally, the effect of MCT on quality of life was found to be non-significant as well. Other studies have found that the quality of life among patients with schizophrenia does not improve immediately after MCT, but rather improves over time (Moritz et al., 2014; Moritz, Kerstan, et al., 2011). This lack of significant results could be because WHOQOL-BREF aims to measure four dimensions of quality of life: psychological well-being, physical health, social relationships, and environment, while people with schizophrenia usually face problems in the social and psychological domain. The results of this study were encouraging and suggested that this type of intervention could be employed as a preventative and early technique for reducing psychotic symptoms in people with schizophrenia. The MCT program in Urdu makes it accessible to the majority of people living in Pakistan, as it is the national language and is spoken by almost 164 million people across the country (Eberhard et al., 2022). Psychotherapeutic treatments for schizophrenia are scarcely used in Pakistan and research on such treatments is minimal. Thus, the study also implied that it might be beneficial to look into the potential of group-based psychological interventions for patients with schizophrenia in Pakistan. MCT is a groupbased, short-term therapy which is standardized in the form of PowerPoint slides freely accessible to everyone. As a result, the treatment method is feasible, easy to implement, and cost-effective. The therapy can be given between 2 to 4 weeks or longer, which makes it much easy for patients to adhere. The training may also inspire new ideas and knowledge for researchers and other professionals working with individuals with schizophrenia. The current findings may also assist group clinicians in changing their attitudes toward group therapies by bolstering the effectiveness of group treatment protocols. At the same time, they may aid researchers in better addressing the challenges of group facilitation, which are typically under-examined in RCTs with this challenging patient population.

Limitations

This study had several limitations. First, it was difficult to recruit patients with schizophrenia, so the sample size was small. Nonetheless, based on the computation of sample size stated earlier, the sample size was large enough to detect a significant effect. Future research should use a more extensive sample that includes participants from diverse demographics. Finally, effects of various demographic variables on the impact of MCT on patients with schizophrenia should also be tested in future studies. The follow-up interval was short, so it's not clear if the intervention had an effect on the study participants. Studies that have followed participants for a longer period of time have shown that the intervention has a significant effect

(Moritz et al., 2014; Moritz, Kerstan, et al., 2011). More longitudinal research should be done with an extended follow-up period to understand the impact of MCT over a longer period of time. Third, the TAU in the control group can also limit the effectiveness of the treatment. To get better results, an active control intervention might have been more effective. The current study also has the limitation of being an add-on study because all the participants continued their regular antipsychotic meditation throughout the process. However, a future study should be designed to test the impact of MCT on patients with schizophrenia when compared with an active control intervention or a placebo.

Conclusions

Metacognitive Training for psychosis is a cognitive therapy designed to alleviate psychotic symptoms in individuals with schizophrenia. It has been proven effective by numerous clinical trials across the world. It has been translated in 37 languages, but to date, the therapy has never been implemented in Pakistan. The current research was a unique feasibility study that tested the efficacy of MCT in patients with schizophrenia in Pakistan. This is the first such study to be conducted in the country. The results proved that MCT is an effective treatment for individuals with schizophrenia in Pakistan. This could serve as a model for designing future studies based on MCT for a more diverse sample representing the whole population.

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Ethical Consideration

The study was approved by Department of Psychology, Foundation University School of Science and Technology, Pakistan. Consent Form was taken before taking data and participants were asked to take voluntary participation.

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Availability of data and materials

The data sets used and analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions/Author details

Parsa Waqar Abbasi performed this study under the supervision of Muhammad Ageel.

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Ethics declarations

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of Department of Psychology, Foundation University School of Science and Technology, Pakistan. A written informed consent was obtained from all participants.

Consent for publication

Not applicable.

Competing interests

The authors declare to have no competing interests.

Additional Information

Not applicable.

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