

Effect of Mindfulness-Based Intervention on Recent-Onset Psychosis for Patients with Schizophrenia: A Randomized Control Trial

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Abstract

Background: Mindfulness-Based Interventions (MBI) have revealed efficacies in lowering psychological problems including depression and anxiety in a variety of clinical settings, including psychosis. **Aim:** The current study aimed to assess the effect of MBI on recent-onset psychosis for patients with schizophrenia. **Methods:** A randomized control trial research design recruited 69 patients with schizophrenia and randomly assigned them to a MBI group (35 patients) who received seven 90-minutes weekly group sessions and to a treatment-as-usual (TAU) group (34 patients). After informed consent, all patients were assessed using the Positive and Negative Syndrome Scale (PANSS), the Recovery Assessment Scale-Domains and Stages (RAS-DS), and the Five Facet Mindfulness Questionnaire (FFMQ) at baseline and post-intervention. **Results:** No significant difference was found between MBI group and TAU group regarding sociodemographic and clinical characteristics, studied domains and total scores of studied variables before the intervention. After application of the intervention, there was a significant difference between TAU group and MBI group in domains of positive psychosis symptoms, negative psychosis symptoms general psychopathology, PANSS total score ($Z= 2.06, 3.11, 2.16$ and 2.46 respectively). Besides, there was a significant difference between TAU group and MBI group regarding RAS-DS total score and FFMQ total score ($Z= 4.19$ and 4.78 respectively). **Conclusion:** This study preliminarily recognized prompt and transient benefits of MBI as a third-wave intervention on recent-onset psychosis for patients with schizophrenia. These types of intervention are recommended for nurses as a complementary treatment for positive and negative symptoms and enhancing recovery among schizophrenia patients.

Keywords: *Mindfulness-Based Intervention, Psychosis, Schizophrenia & Randomized Control Trial*

Introduction

In global communities, patients with schizophrenia account for more than half of people suffering from serious mental disease (Wang et al., 2016). Psychosis, along with the more specific diagnosis of schizophrenia, is a serious mental condition in which a person's perceptions, thoughts, behavior, and mood alter dramatically (National Institute for Health and Clinical Excellence, 2014). Positive and negative symptoms are present in psychotic symptoms, which are the basic symptoms of schizophrenia (American Psychiatric Association, 2013). Positive symptoms, such as hallucinations and delusions, have an impact on how patients interact with others and go about their daily lives. Negative symptoms such as affect flattening, blunted affect, poor rapport, and social and emotional withdrawal have a strong negative impact on patient functioning (El-Monshed & Amr, 2020; Liu et al., 2021).

Because the first 5 years following beginning are regarded the essential time when biopsychosocial changes are most widespread and the brain demonstrates the most flexibility, early detection and

therapies have been actively advocated (Li et al., 2021). The first five years after diagnosis are classified as a high-risk phase for suicide and relapse, as well as a vital period for developing a solid social identity and relationships (Crespo-Facorro et al., 2016; Mcgorry et al., 2008).

Early intervention also focuses on premorbid states, which are portrayed by subclinical signs and symptoms and particular characteristics, such as bizarre speech, delusions, and attenuated hallucinations with intact reality testing but of adequate frequency and/or severity that it isn't limited or overlooked (Langer et al., 2017). As a result, numerous countries have altered their public policies in attempt to intervene early in the chaos. Evidence suggests a better prognosis, better outcomes and good recovery for patients with a lower duration of untreated psychosis (Boonstra et al., 2012; Iyer et al., 2015; Langer et al., 2017; Skalli & Nicole, 2011; Srihari et al., 2012). A longer period of untreated psychosis, on the other hand, is linked to a worse prognosis and more long-term disability (Chiliza et al., 2012).

Clinical recommendations recommend an integrated treatment, which takes into account both psychosocial and pharmacological factors. For instance, one of the highest successful psychosocial strategies in schizophrenia management on a global scale is cognitive behavioral therapy. In recent times, cognitive behavioral therapy developed some tactics and tools that support mental processes depending on mindfulness and acceptance (Gaudiano, 2015).

The awareness that rises from giving attention to the present moment without judgment is referred to as mindfulness. It's claimed to be a skill that can be learned through meditation and has been proved to boost overall well-being (Tong et al., 2016). After the first (behavioral) and second (cognitive) waves of psychological therapies, Mindfulness-Based Interventions (MBI) have revealed efficacies in lowering psychological problems including depression and anxiety in a variety of clinical settings, including psychosis (Goyal et al., 2014; Hofmann et al., 2010). Furthermore, rather than attempting to remove or change these symptoms or experiences, MBI redefines how individual's thoughts and emotions link to oneself in order to lessen discomfort (Li et al., 2021). In other words, mindfulness is a meditation type aiming at improving many psychological processes by combining emotional and attention regulation and self-awareness in a synergic effort, resulting leading to enhanced psychological resilience and increased self-regulation (Tang et al., 2015).

Mindfulness has been defined as a practice, a theoretical framework, and a psychological process. Mindfulness has been established and promoted from a Western and academic perspective through structured group programs spanning eight to ten weeks, as well as in health and clinical settings (Langer et al., 2017). Furthermore, patients have a better chance of regaining control over their psychotic symptoms such as voices or delusional beliefs by monitoring them with an open, nonjudgmental, and inquiring awareness (Abba et al., 2008; Louise et al., 2018). In a similar vein, mindfulness meditation trains patients to examine their senses and how to react to them without judgment (Chadwick, 2014). Another study discovered that being attentive of hearing voices was linked to voice-related anxiety and decreased response to voices (Stephanie et al., 2018).

Moreover, MBI has been demonstrated to be beneficial for negative feeling regulation and has been approved by the American Psychological Association (APA) as a treatment for psychosis, based on growing empirical data (Chambers et al., 2009; Cramer et al., 2016; Khoury et al., 2013; Li et al., 2021). MBI also condensed symptoms of

psychosis and re-hospitalization among individuals with mental illness, according to systematic reviews and meta-analyses (Aust & Bradshaw, 2017; Cramer et al., 2016; Digiaco, 2016; Liu et al., 2021; Potes et al., 2018). These researches, which involved individuals with a range of mental illnesses, can be utilized to reveal the effects of MBI in the subset of schizophrenia patients.

In a meta-analysis of "third-wave or mindfulness- and acceptance-based interventions for psychosis", Louise et al. (2018) showed moderate treatment impacts of group designed as MBI on psychotic symptoms compared to control post-treatment. Despite the fact that there are several randomized control trials (RCTs) of MBI in the literature (Chadwick et al., 2016; Chien et al., 2013; Chien & Thompson, 2014; López-Navarro et al., 2015), only one of these trials looked at consequences on persistent voices and found significant effects on negative voice, such as voice-related distress and perceived control, after a course of person based cognitive therapy, integrating cognitive therapy and mindfulness (Chadwick et al., 2016).

Significance of the Study

Worldwide, estimates of schizophrenia prevalence varies from 0.25-0.75 percent of the population (National Institute of Mental Health, 2021). Furthermore, in schizophrenia spectrum disorders, Persistent positive symptoms like auditory verbal hallucinations (or 'voices') and delusions are the most common, with up to 80% reporting such symptoms (Stephanie et al., 2018). Core therapies for early stage or acute schizophrenia must contain psychosocial interventions, family support, and medication management, according to a published guideline from the National Institute for Health and Clinical Excellence (Wang et al., 2016). As a result, Kim et al. (2021) & Astuti et al. (2020) suggested that nurses can practice mindfulness as one of the nursing interferences to help patients with schizophrenia recover and reduce stress.

Aim

The current study aimed to assess the effect of mindfulness-based intervention (MBI) on recent-onset psychosis for patients with schizophrenia.

Research hypothesis

Our hypotheses were that (1) MBI would be clinically safe for promoting recovery, with no adverse events requiring clinical attention; (2) MBI would be linked with a rise in mindfulness in contributors; and (3) MBI participation would be associated with a reduction in positive and negative symptoms.

Subjects and Method

Study Design

This was a non-blinded randomized controlled trial, evaluating the efficiency of Mindfulness-Based Intervention (MBI) and more treatment as usual (TAU) as opposed to treatment as usual (TAU) alone on recent-onset psychosis for patients with schizophrenia. The study was performed at the psychiatry department of Mansoura University Hospitals. The study adheres to the rules for writing Clinical Trials: “The Consolidated Standards of Reporting Trials” (CONSORT) statement (Eldridge et al., 2016).

Study Setting

The current study was performed at the psychiatric inpatient department in Mansoura University Hospitals.

Study Subjects and Sample size

Participants' recruitment between the beginning of July and the middle of September 2021. Demanded sample size was appraised using G-power software V.3.1.9.7 (Faul et al., 2007). With an effect size $r = 0.80$, which was calculated established on results of Wang et al. (2016). Assuming that a power analysis for the difference between two independent means (two groups) yields 0.95 confidence level, 0.80 statistical power, and fair division, the required sample size was to be 35 patients each group. An additional 4 patients needed to be enrolled to recompense for an probable dropout rate of 10% (Hoerger, 2010). The required sample size is 39 clients each group. All the patients attending the psychiatric inpatient department under study at recruitment were screened for eligibility. All of the patients that were eligible were listed in alphabetical order by surname and the 54 patients of them were randomly nominated from the patient list by “internet based random table technique” with a matched size of six. Cards in chronologically numbered, sealed envelopes kept away from researchers by an independent statistician. Figure 1 presented recruitment, enrollment and allocation process of studied patients.

Participants' criteria of inclusion involved those patients who were 1) aged 18–60, admitted with his/her relatives and diagnosed with schizophrenia following the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5; (American Psychiatric Association, 2013), and this diagnosis was confirmed by a psychiatrist; 2) Less than 5 years had passed from the onset of illness to present at recruitment; and 3) willingness to participate in the study that was scheduled for seven weeks. Patients were excluded if they had a comorbid learning disability or organic brain disorder, were considered mentally unstable or unfit to participate in the study

by their therapist, and/or had newly had (been receiving) psycho-education or somewhat designed psychosocial intervention.

Study Tools

The current study tools were completed during an interview where the first section assessed personal and clinical features in Arabic language included gender, age, residence, marital status, level of education, employment status, duration of illness and previous psychiatry admissions. The following three tools were used in the current study.

The Positive and Negative Syndrome Scale (PANSS); developed by Kay et al., (1987) in English to measure symptom severity of patients with schizophrenia. This is a 30-item instrument. Rating of each item is from (one, no evidence) to (seven, strong evidence) and the total score for overall psychopathology ranges from 30 to 210. Subscales of PANSS yield data on general psychopathology (G1-G16; score range 16–112), positive psychotic symptoms (P1-P7; score range 7–49), and negative psychotic symptoms (N1-N7; score range 7–49). It was reported that the alpha coefficients of reliability for the scores of PANSS are 0.79 for the general psychopathology subscale 0.73 for the positive subscale, and 0.83 for the negative subscale, and. The Arabic version of PANSS was used in the current study. The Cronbach's alpha values were as the following: general psychopathology subscale ($\alpha = 0.901$), positive subscale ($\alpha = 0.823$), and negative subscale ($\alpha = 0.873$); (Hallit et al., 2017). The Reliability of PANSS was tested in the current study by Cronbach's alpha (Cronbach's α) test. Results exhibited excellent scale reliability. Cronbach's α values were 0.87, 0.85, and 0.82 for positive scale, negative scale, and overall psychopathology scale respectively.

The Recovery Assessment Scale - Domains and Stages (RAS-DS) that developed by Corrigan et al., (2004) in English to evaluate mental health recovery. The RAS-DS is a 38-item instrument which rated on Four-Liker type scale, “untrue (1)”, “a bit true (2)”, “mostly true (3)”, and “completely true (4)”. This instrument has four recovery subscales: Connecting and Belonging (7 items), Mastering My Illness (7 items), Looking Forward (18 items), and Doing Things I Value (6 items). The total RAS-DS score ranges from 38 to 152. The lower score shows lower recovery levels and vice versa. The RAS-DS subscales have various numbers of items, so each subscale score transformed to a percentage (%) to be best beneficial to evaluate variance across subscales (Hancock et al., 2016). This instrument is accessible in thirteen languages included English (original) and Arabic. Reliability of RAS-DS was tested in the current study using Cronbach's alpha (Cronbach's α)

test. Results exhibited accepted scale reliability. Cronbach's α values were 0.72, 0.81, 0.79, 0.74, and 0.8 for total RAS-DS, Doing Things I Value domain, Looking Forward domain, Mastering My Illness domain, and Connecting and Belonging domain respectively.

The Five Facet Mindfulness Questionnaire (FFMQ) which developed by **Baer et al., (2006)** in English. The FFMQ was handled to evaluate the patients' level of performances made on five domains of mindfulness skills. The five facets are "describing" (8 items), "observing" (8 items), "non-judging of inner experience" (8 items), "acting with awareness" (8 items) and "non-reactivity to inner experience" (7 items). Except for the non-reactive facet, which has a score range of 7 to 35, each facet score runs from 8 to 40. All items were graded on a 5 point Likert scale (1, "very rarely true" to 5, "always true"). Scores of the 19 negative items were reversed, total scores of each domain and total FFMQ were summed. Greater levels of mindfulness represent higher scores. Internal consistency (Cronbach's $\alpha=0.76-0.92$) and predictive power to psychological well-being and symptoms were found in the FFMQ. A coefficient of internal consistency (Cronbach-alpha) was used to determine the reliability of the Arabic version of FFMQ in a previous study (Awamleh, 2014). The reliability values reached significant level (0.699). The Reliability of FFMQ was tested in the current study using Cronbach's alpha (Cronbach's α) test. Results exhibited accepted scale reliability. Cronbach's α values were 0.69, 0.71, 0.8, 0.76, 0.78 and 0.77 for total "FFMQ, observing, describing, acting with awareness, nonjudging of inner experience, and non-reactivity to inner experience" respectively.

Field work

The patients assigned randomly to one of the two arms after completing baseline measurements a set of computerized random numbers created by a statistician using a stochastic minimization technique tool. Matching random sampling, a method of assigning members to groups in which pairs of members are first harmonized on some criteria and then individually allocated to groups at random, was used for randomization (i.e., each subject is chosen and matched with another subject, and then the subjects in each pair are randomly assigned to either the MBI or the TAU group, two samples with clearly paired or matched members. The two groups were harmonized in terms of personal and clinical characteristics, as well as PANSS, FFMQ, and RAS-DS scores. In total, 78 patients were enrolled in the research (39 in the MBI arm and 39 in the TAU arm). Four patients in the MBI arm and five patients in the TAU arm skipped their usual sessions during the research. The total sample included 69 patients (35

MBI arm and 34 TAU arm) who completed the study after dropouts during the study (Figure 1).

Because of the target population's unique characteristics, the self-report tools were conducted with the assistance of one researcher, who used interview to assess the validity of the replies. The rate of improvement of PANSS, RAS-DS, and FFMQ scores were employed as outcome measures. Subjects were assessed twice throughout the study: First when they originally enrolled (baseline scores) and again after the intervention was finished, usually shortly after the final session (end of study scores). To avoid contamination of treatment, the first author instructed the members not to speak to clinic staff or patients about the program they had received. The last author, who was unaware of the sampling/intervention techniques, double-checked all data entries for accuracy.

Pilot Study

A pilot study was conducted on 10 patients to pretest the questionnaire and it revealed that some questions must be explained to them by the researcher. It was done in order to test the clarity, applicability, and feasibility of the used tools and to estimate the time required to fill in the tools. Based on the findings of the pilot study, no modifications were done on the tools, it was simple and clear. Therefore, the patients who shared in the pilot study were not excluded from the main study sample. The pilot study was conducted at May 2021.

Ethical considerations

The research ethics committee at Mansoura University's Faculty of Nursing granted permission to perform the study. For this controlled trial, the relevant approvals from the department of psychiatry were obtained. Before recruiting, each patient and his or her relatives gave their informed written agreement to participate voluntarily. All probable patients were asked if they required any explanations, and their inquiries were answered satisfactorily. Participants' personal identities and data were kept private, and they were given the option to refuse or withdraw from the study at any moment without jeopardizing their treatment plans.

Intervention

Treatment as usual (TAU)

Treatment as usual (TAU) was provided only to the control group (Intervention arm) and entailed of medical and nursing care provided by the psychiatry department. The TAU focused on medication, regular follow ups with the therapist (daily), and daily nursing care.

Mindfulness-based Intervention

The MBI consisted of seven 90-minutes weekly group sessions (13-14 patients per group). In the beginning of each session, participants were asked to

practice 15-minutes breathing practice. Then, it took 15 minutes to review homework of last week. Next the main topic was conducted for 45 minutes. Lastly, sharing feedbacks was for 15 minutes. Three therapists implemented the sessions. Two of the therapists (first and third authors) had mindfulness experience and clinical training with the target group, and they were supervised by a field expert (i.e. second author).

The MBI was developed through a variety of sources were taken as points of departure after reviewing the related literature (Allen et al., 2021; Chiesa & Malinowski, 2011; Martins et al., 2020; Moritz et al., 2015; Proulx, 2003; Shen et al., 2021; Sipe & Eisendrath, 2012; Tong et al., 2016; Wang et al., 2016). The research team tape-recorded all of the group sessions (with participants' consent) and examined them between sessions to monitor the progress and fidelity of the two programs. Then they deliberated and solved the problems that arose during the sessions. An expert panel approved the manual MBI (five professors of psychiatry and two professors of psychiatric and mental health nursing). Each manual was evaluated independently for clarity and suitability of themes, case examples, and methods.

The MBI's mindfulness theory aimed to improve patients' acceptance, insight into the illness/treatment and to enhance their awareness and illness management, as well as their ability to resolve poor functioning and problems arisen from illness, to care for themselves, and to seek help. The MBI had seven components: 1) Intervention overview and commitment; 2) awareness increasing and understanding of feeling, body sensations, and thoughts related to symptoms or illness experience and; 3) mindful training and homework exercises; 4) illness (schizophrenia) management psychoeducation session; 5) controlling and confronting negative perceptions and thoughts and perceptions, as well as daily life problems arisen by symptoms, and committing the most effective problem-solving techniques; 6) behavioral rehearsals of relapse prevention strategies; and 7) community support resources, effective mindfulness practices, and making realistic future plans. The authors can give details about the MBI upon request.

Data Analysis

Data was sorted, organized, coded, and categorized before being moved into custom-made formats. The IBM Corporation's Statistical Package for the Social Sciences (SPSS) version 24 was used to conduct the analyses. The data was first examined for normalcy using the "one-sample Kolmogorov–Smirnov test", which revealed that the data had an irregular distribution. Non-parametric tests were utilized as a

result. Numbers and percentages were used to present categorical variables. For nonparametric data, continuous variables were displayed using medians and ranges. For paired (pre–post) comparisons of the different scores, the Wilcoxon signed-rank (Z) test was used., while the Mann-Whitney U Test (Z) test was utilized for independent two groups (TAU group and MBI group). The effect size was estimated using the formulation $r = (Z / \sqrt{N})$, where r represents the effect size, Z represents the Wilcoxon signed-rank rate, and N represents the size of sample (Rosenthal, 1994). The interpretation values for r were calculated using Cohen (2013) method. When the probability of error is less than 5% (p.05), the results are considered significant.

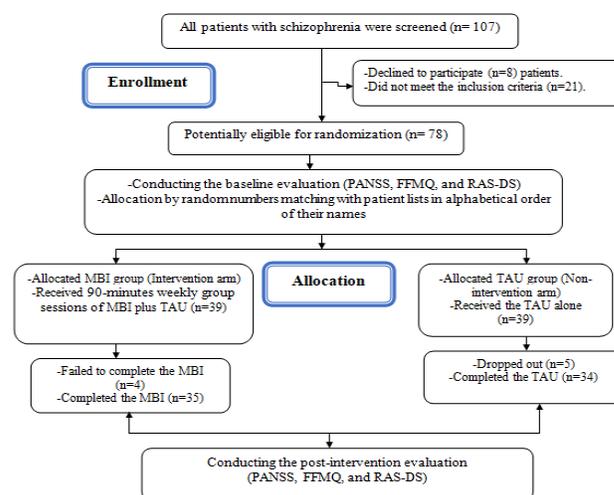


Figure (1): Flow diagram describing the procedure of the current controlled trial

Results

Table (1): Distribution of the studied patients according to personal and clinical characteristics between mindfulness-based intervention (MBI) group and treatment as usual (TAU) group.

Variables	MBI group Frequencies n=35		TAU group Frequencies n=34		X ²
	No	%	No	%	
Gender					
Male	23	65.7	20	58.8	.349
Female	12	34.3	14	41.2	
Age					
From 20 to < 30 years	16	45.7	21	61.8	1.944
From 30 to 40 years	15	42.9	11	32.4	
More than 40 years	4	11.4	2	5.9	
Residence					
Rural	18	51.4	15	44.1	.369
Urban	17	48.6	19	55.9	
Marital status					
Single	25	71.4	22	64.7	.359
Married	10	28.6	12	35.3	
Education					
Basic education	5	14.3	3	8.8	.514
Secondary	17	48.6	18	52.9	
University	13	37.1	13	38.2	
Employment Status					
Employed	16	45.7	11	32.4	1.293
Unemployed	19	54.3	23	67.4	
Disease duration					
One year or less	13	37.1	9	26.5	3.657
> one year to < three years	17	48.6	15	44.1	
From three to five years	5	14.3	10	28.6	
Previous admission					
No	30	85.7	22	64.7	4.099
Yes	5	14.3	12	35.3	

Table (2): Correlation between studied patients before application of the intervention (n=69)

PANSS total score	Correlation Coefficient	FFMQ total score	RAS-DS total score
		Sig. (2-tailed)	<.001

**Significant at level less than 1% (p<.01), PANSS (positive and negative syndrome scale), FFMQ (five facet mindfulness questionnaire), RAS-DS (recovery assessment scale).

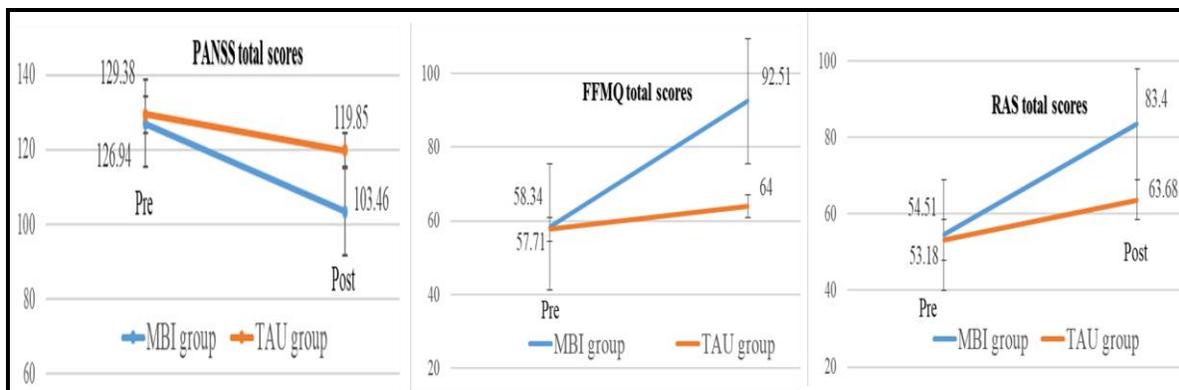


Fig 2: Means of PANSS total scores, FFMQ total scores and RAS-DS total scores pre and post intervention showing difference between MBI group and TAU group.

Table (3): Score differences between studied domains and total scores of studied variables

	Pre			Post			Effect size (r)	Difference in TAU group (Z^2)	Difference in MBI group (Z^3)
	Median (range)		Z^1	Median (range)		Z^1			
	MBI group	TAU group		MBI group	TAU group				
Positive psychosis symptoms	28 (19-47)	29 (17-47)	0.26	20 (13-41)	23 (18-42)	2.06*	.248 (small)	4.89**	5.18**
Negative psychosis symptoms	29 (18-40)	32 (20-44)	1.23	25 (12-39)	30 (20-42)	3.11**	.374 (Medium)	4.35**	4.89**
General psychopathology	66 (47-103)	66.5 (49-96)	0.05	53 (31-93)	62 (46-91)	2.16*	.259 (small)	4.89**	4.80**
PANSS total score	126 (93-190)	128 (93-183)	0.60	96 (64-173)	116.5 (86-171)	2.46*	.296 (small)	5.0**	5.16**
Observing	11 (8-17)	11 (8-17)	0.29	18 (8-25)	119 (9-17)	4.23**	.509 (large)	.578	4.65**
Describing	13 (10-21)	13 (10-21)	0.05	23 (12-31)	16 (11-24)	3.79**	.457 (Medium)	5.29**	5.03**
Aware acting	11 (8-17)	10 (8-17)	0.59	21 (11-27)	14 (11-19)	5.52**	.664 (large)	5.14**	5.19**
Non-judging of inner experience	11 (8-16)	11 (8-16)	0.53	18 (9-24)	12 (9-16)	5.45**	.656 (large)	2.92**	5.03**
Non-reactivity to inner experience	9 (7-13)	9 (7-14)	0.43	16 (9-20)	9 (7-14)	5.74**	.691 (large)	.001	4.90**
FFMQ total score	54 (46-80)	53.5 (47-82)	0.27	97 (51-122)	61 (52-86)	4.78**	.575 (large)	5.10**	5.01**
Doing Things	8 (6-15)	8 (6-13)	0.81	14 (9-19)	10.5 (8-15)	4.65**	.559 (large)	5.20**	5.19**
Looking Forward	23 (18-38)	23.5 (19-36)	0.33	41 (20-55)	27 (21-38)	4.20**	.506 (large)	4.64**	5.05**
Mastering My Illness	10 (8-17)	10 (7-17)	1.51	16 (9-23)	11 (8-17)	4.04**	.487 (Medium)	4.94**	5.10**
Connecting and Belonging	9 (7-15)	9 (7-15)	1.09	16 (10-21)	13 (10-20)	3.67**	.441 (Medium)	5.07**	5.10**
RAS-DS total score	50 (39-77)	50.5 (40-79)	0.30	91 (49-113)	61.5 (49-82)	4.19**	.505 (large)	5.08**	5.16**

Z^1 = Mann-Whitney U Test, difference between cases and control (between groups), Z^2 = Wilcoxon Signed Ranks Test, difference between pre and post intervention (in TAU group), Z^3 = Wilcoxon Signed Ranks Test, difference between pre and post intervention (in MBI group), PANSS (positive and negative syndrome scale), FFMQ (five facet mindfulness questionnaire), RAS-DS (recovery assessment scale). *Significant at level less than 5% ($p < .05$), **Significant at level less than 1% ($p < .01$).

Table (4): Variance of total scores of PANSS, FFMQ and RAS-DS according to patients' personal and clinical characteristics post intervention.

	PANSS			FFMQ			RAS-DS		
	Median (range)		Z	Median (range)		Z	Median (range)		Z
	MBI Case	TAU		MBI Case	TAU		MBI Case	TAU	
Gender									
Male	94(64-166)	117(86-170)	2.57*	97(52-122)	62(52-86)	4.18**	91(49-113)	61(49-82)	3.53**
Female	121.5(67-173)	113(90-171)	.592	96.5(51-120)	58.5(54-84)	1.22*	90.5(49-110)	61.5(54-81)	2.01*
Age									
From 20 to < 30 years	104(72-155)	116(86-170)	1.365	90(51-122)	61(52-86)	3.07**	80.5(49-113)	61(49-82)	2.62**
From 30 to 40 years	92(64-173)	110(90-171)	1.662	97(55-120)	61(55-79)	3.15**	92(56-110)	63(52-82)	2.78**
More than 40 years	98.5(67-135)	128.5(128-129)	.926	106.5(55-119)	55(54-56)	1.39	93(49-100)	57(54-60)	.939
Residence									
Rural	99.5(70-166)	118(86-148)	1.429	95(55-121)	61(54-79)	3.42**	87(49-110)	62(50-82)	2.95**
Urban	96(64-173)	113(88-171)	1.823	98(51-122)	61(52-86)	3.28**	92(49-113)	61(49-82)	2.3**
Marital status									
Single	93(64-173)	117.5(86-170)	2.60*	97(51-121)	61(52-86)	4.23**	91(50-110)	60.5(49-82)	3.72**
Married	108.5(67-166)	110.5(90-171)	.561	97(52-122)	58.5(55-75)	1.66	91(49-113)	62.5(56-82)	1.62
Education									
Basic education	104(67-166)	128(92-170)	1.043	83(55-121)	54(53-86)	1.34	73(56-109)	54(49-76)	1.34
Secondary	92(64-148)	116.5(86-171)	2.49*	105(51-122)	61(55-80)	3.85**	93(49-113)	60.5(50-82)	3.72**
University	121(67-173)	113(88-170)	.513	84(52-119)	61(52-84)	2.57*	73(49-102)	62(52-82)	2.00*
Occupation									
Employee	84.5(67-148)	116(93-129)	2.22*	100(51-122)	59(56-79)	3.76**	93(50-113)	62(56-79)	3.71**
Unemployed	114(64-173)	117(86-171)	1.11	84(52-121)	61(52-86)	2.92**	73(49-109)	60(49-82)	2.05*
Disease duration									
One year or less	121(67-173)	113(86-171)	.167	94(52-120)	62(54-84)	1.91	86(49-98)	61(55-82)	1.84
> one year to < 3 years	96(64-155)	13(88-170)	1.568	97(51-122)	61(52-86)	3.33**	93(49-113)	61(49-82)	2.70**
From 3 to 5 years	72(67-104)	123(103-148)	2.95**	106(83-121)	59(54-80)	3.07**	97(73-109)	63(52-82)	2.82**
Previous admission									
No	100(64-173)	114.5(88-170)	1.593	96.5(51-122)	59(52-86)	4.24**	90(49-113)	61(49-82)	3.62**
Yes	92(70-166)	122.5(86-171)	1.689	109(55-111)	61(55-80)	1.961	97(56-99)	62(50-82)	1.797

Note. Z= Mann-Whitney U Test, difference between cases and control (between groups), PANSS (positive and negative syndrome scale), FFMQ (five facet mindfulness questionnaire), RAS-DS (recovery assessment scale). *Significant at level less than 5% ($p < .05$). **Significant at level less than 1% ($p < .01$)

Table (1): Showed that there was no significant difference between MBI group and TAU group regarding sociodemographic and clinical characteristics of studied patients. Moreover, table showed a predominance to patients who were male, aged from 20 to less than 30 years, secondary educated, unemployed, with disease duration more than one year to less than three years and who did not admit to psychiatric hospital previously.

Table (2): Revealed that total positive and negative symptoms score correlated significantly and negatively to five total facet mindfulness score and total recovery assessment score ($r = -.433$ and $-.565$ respectively) before application of the intervention.

Figure (2): Showed means of studied variables pre and post the intervention. PANSS total mean of score decreased from 129.3 to 119.85 among TAU group while among MBI group, it decreased from 126.94 to 103.64. FFMQ total score increased 57.71 to 64 among TAU group while among MBI group, it increased from 58.34 to 92.51. RAS-DS total score increased 53.18 to 63.68 among TAU group while among MBI group, it increased from 54.51 to 83.4. Figure revealed that improvements in MBI group was higher than TAU group in all studied variables.

Table (3): According to, Mann-Whitney U Test (Z^1) showed that there was no significant difference between TAU group and MBI group regarding studied domains and total scores of studied variables before intervention. After application of the intervention, there was a significant difference between TAU group and MBI group in domains of positive psychosis symptoms, negative psychosis symptoms general psychopathology, PANSS total score ($Z = 2.06, 3.11, 2.16$ and 2.46 respectively). Table revealed a small effect size for domains of positive psychosis symptoms, general psychopathology and PANSS total score, while negative psychosis symptoms showed medium effect size.

Difference varied significantly in observing, describing, aware acting, non-judging of inner experience, non-reactivity to inner experience and FFMQ total score ($Z = 4.23, 3.79, 5.52, 5.45, 5.74,$ and 4.78 respectively), effect size was large for all domains and total FFMQ except describing domain that revealed a medium effect size. Moreover, table 3 revealed a significant difference between TAU group and MBI group regarding domains of doing things, looking forward, mastering my illness, connecting and belonging, and RAS-DS total score ($Z = 4.65, 4.20, 4.04, 3.67,$ and 4.19 respectively), additionally, table revealed medium effect size in domains of mastering my illness, connecting and belonging while it revealed a large size in domains of doing things, looking forward, and RAS-DS total score.

By comparison of differences before and after application of the intervention in TAU group and MBI group, Wilcoxon Signed Ranks Test ($Z^{2\&3}$), showed a significant difference between all studied domains and total scores of studied variables except domain of observing and domain of non-reactivity to inner experience in TAU group. $Z^{2\&3}$ values showed that improvements in MBI group were higher than TAU group in all studied domains and total scores of studied variables.

Table (4): Showed that differences of studied variables were better among patients who were male, aged from 30 to 40 years, single, secondary educated, employed, with disease duration from three to five years and who did not admit to psychiatric hospital previously.

Discussion

This RCT was one of the few conducted to evaluate the effectiveness of MBI on recent-onset psychosis for patients with schizophrenia and its comparative effectiveness with TAU. Overall results support the feasibility of the MBI as evidenced by high attendance, and low drop-out rates, supporting the three hypotheses of the current study.

The current study results claimed that after seven sessions MBI, there was a significant difference between TAU group and MBI group in domains of positive psychosis symptoms, negative psychosis symptoms general psychopathology. Possible explanations could be that MBI sessions encouraging schizophrenia patients to actively be aware of life experiences. Mindful exercises and homework activities could help reduce positive and negative symptoms by awareness increasing and knowledge of thoughts, physical sensations, and feelings related to sickness symptoms or even experiences. As a result, patients have to refocus on and reengage with their daily activities in order to be aware of and communicate them.

Besides, the MBI group in this study was urged to read thoughtfully and to practice breathing and meditation for the benefit of others as well as for themselves. These techniques not only taught patients how to relax, but also how to be more aware of and control their feelings. Furthermore, lessening distress might help to reduce positive and negative symptoms. According to the model of delusion, they found that persecutory delusion was formed via interactions among psychotic process, beliefs (of self, other and the world), emotion and environment. Distress (especially anxiety) may be a trigger and consequence of delusions and form a feedback loop with delusions. Hence, they asserted that it is better to improve distressing emotion prior to treatment for positive symptoms. Furthermore, patients were taught to be

attentive of the current moment in their daily lives and through current intervention, they were able to let go of ruminating of distress symptoms and control the undesired voices and then embrace experience of psychosis.

Theoretically, people with schizophrenia who embrace MBI may be able to control their brain circuits pathways, particularly the amygdala and other emotional load pathways (Dudley et al., 2018). The interventional effects of MBI on hallucination and delusion could be mediated by a number of pathways. First, mindfulness meditation alters brain oscillations and improves brain network integration, both of which may contribute to reduced abnormal brain activity and delusion/ hallucination (van Lutterveld et al., 2017). Second, mindfulness training improves acceptance and reduces anxiety/distress feeling, leading to a decrease in symptoms of psychosis (Sheng et al., 2019).

The findings of this study are in line with those of a comprehensive review, which proposed four hypothesized mechanisms: (a) mindful observation and decentered awareness may decrease the influence of self-beliefs on distress and negative voice-content; (b) reducing control behaviors like worry and rumination; and (c) acceptance offers an alternative to experiential suppression or avoidance (Strauss et al., 2015). Besides, prior studies demonstrated that mindfulness practice helped schizophrenia and explained the mechanisms of MBI improving the positive symptoms (delusion and hallucination (Chadwick et al., 2009; Chien et al., 2013; Chien & Thompson, 2014; Shen et al., 2021). Other studies found that a 24-week MBI (2-hour program guided by therapists biweekly) reduced both negative and positive symptoms in outpatients with schizophrenia (Chien et al., 2017 & Chien et al., 2019).

According to the current study results, the MBI had a small effect size for domains of positive psychosis symptoms, while negative psychosis symptoms showed medium effect size. Namely, mindfulness interventions were more effective against negative than positive symptoms. These results should be interpreted with caution, it might be because the attenuation of positive symptoms is largely dependent upon cognitive changes and reappraisals which might not be easily achievable, especially for patients with early onset schizophrenia in the current study.

These study findings are consistent with a randomized controlled trials meta-analysis on effectiveness of MBI on psychotic symptoms among people with schizophrenia. This meta-analysis reported small immediate post-MBI effect on positive symptoms and moderate effects in decreasing negative symptoms both immediately post-MBI and at short-term follow-up (Liu et al., 2021). Similarly,

Wang et al. (2016) & Usher et al. (2019) found a significant reduction in positive symptoms in the group that received MBI.

In contrast, another meta-analysis found that MBI failed to reduce the positive symptoms (Cramer et al., 2016). Moreover, a previous RCT reported that the PANSS negative symptoms subscale in the MBI group was significantly lower post course, but there was no significant difference in positive symptoms between the groups post course or after follow-up by 3-month (Lee, 2019). Besides, a pilot study conducted on patients with first psychotic episode found that there were no significant variances after MBI in scores of PANSS positive symptoms in patients with first psychotic episode (van der Valk et al., 2013). A more recent systematic review and meta-analysis of MBI for individuals with schizophrenia spectrum disorder showed effects on negative symptoms, nevertheless no significant impacts for positive symptoms (Jansen et al., 2020).

The results of this study displayed that there is a significant variance between TAU group and MBI group regarding domains of looking forward, doing things, mastering my illness, connecting and belonging, and RAS-DS total score after MBI. This means that MBI enhances recovery from illness among people with schizophrenia. Plausible explanations could be given by that the studies patients with recent onset of schizophrenia may have high levels of motivation to enhance their illness management and heavily participated in any type of interventions that could be beneficial to the illness. Furthermore, patients can learn to accept their ideas and feelings while letting go of their dysfunctional symptoms of thoughts, emotions, and behaviors through training on mindfulness exercises (Strauss et al., 2015). This has been proven in the current study findings, which was mentioned above, that the MBI has helped in reducing positive and negative symptoms among the studied patients.

Another explanation could be given by that psychoeducation incorporated with mindfulness training may play an important role in enhancing recovery among the studied patients. Three sessions of the MBI, from the fourth to the sixth MBI sessions, the patients were given an education workshop on illness management, which included encountering and controlling negative thoughts and perceptions, practicing effective problem-solving strategies, and being trained on behavioral rehearsals of relapse prevention methods. People with schizophrenia may benefit from a more complete MBI program with some surprising therapeutic results. Previous research has found that mindfulness alone engages individuals in perceiving and accepting internal experiences without expressly concentrating on and reinforcing

behavioral change and illness management skills and techniques. The concepts of 'theoretical integration,' which integrate different principles of psychosocial interventions or psychoeducation from two or more approaches to synergize or amplify the therapeutic objectives and purposes of MBI, is involved when mindfulness is added to psychoeducation sessions or other psychological therapies (Cayoun, 2011; Hassed et al., 2009; Lam et al., 2020).

Unfortunately, only two studies have documented the effects of MBI on recovery from illness in people with schizophrenia, so the current study cannot determine the optimum amount of mindfulness performs to achieve the best patient results in trials and thus offer regulation to therapists in determining the best proper form of home exercises for users. The first study, which looked at the effects of mindfulness on hope and recovery in patients with schizophrenia, discovered that the intervention group had a higher mean score recovery following mindfulness therapy than the control group (Astuti et al., 2020). The second study used a pretest/posttest design with two groups (training and control) to examine the efficacy of MBI training on increasing functional recovery and insight in schizophrenia patients. After training, the educated group recorded much greater in insight levels and functional recovery than the control group, according to this study (Yilmaz & Okanlı, 2018).

However, there have been semi-similar studies that have examined the effect of the MBI on patients' psychotic symptoms, functioning, insight into their illness, and relapse prevention. For instance, studies by Chien et al. (2013); Chien & Thompson (2014) examined illness recurrence or relapse, focusing solely on patients' stay and length of re-hospitalizations, and found that MBI could help reduce re-hospitalization duration (or number). Besides, Davis et al. (2015) found that BMI can improve patients' job performance and professional functioning in a study of schizophrenia patients. Mindfulness encourages people with mental illnesses to accept themselves as fallible and unconditionally accept themselves. As a result, it improves patients' social interaction, allowing them to be less anxiety and feel more at ease in their interpersonal relations. Moreover, Khoury et al. (2013) discovered that mindfulness techniques enhanced emotional regulation (a reduction in anxiety and depression), boosted patients' self-care abilities, and enhanced treatment commitment as well as everyday functioning in psychotic patients.

The findings of the intervention effect of developing mindfulness skills among the examined patients, as measured by the FFMQ, backed up the effect of MBI on reducing positive and negative symptoms and enhancing recovery. After the seven sessions, the

patients in the intervention group had a substantial increase in self-reported mindfulness, showing that the intervention increased participants' awareness of mindfulness, which was consistent with prior MBI studies (Tabak et al., 2015 & Tang et al., 2021). Fortunately, the results of the current study are closely interrelated, and this has been shown in the positive impact of the program on the three variables measured by the study, as the results of the study proved that total positive and negative symptoms score correlated significantly and negatively to five total facet mindfulness score and total recovery assessment score. These results indicated that when the mindfulness skills increase, the positive and the negative symptoms of schizophrenia decrease with it, and thus the degree of recovery improves to a high degree.

An explanation for this result could be that the patients were taught to be aware of their emotions, cognitions, and bodily sensations by first teaching them about their own "automatic navigation mode" (for instance, during body scanning, many thoughts come and go, attentions always run away, and so on) and then teaching them to be aware of their emotions, cognitions, and bodily sensations. These patients may eventually be able to recognize their own avoidance thoughts in this way. It's worth noting that teaching awareness is a big aspect of MBI. It's also difficult to gauge a patient's level of awareness when they have schizophrenia. The awareness training began with the most basic breathing awareness and progressed to include bodily sensations, emotions, and thoughts. This may make it easier for patients to comprehend the FFMQ. Furthermore, each patient's movement and inner state of mind were paired with mindfulness breath, body feeling, and awareness. Patients were instructed to notice all forms of body feelings subconsciously, immediately, and objectively while in a clear and peaceful state.

Similar results were reported by Chien et al. (2020) & Wang et al. (2016) who indicated that the performance levels in mindfulness practice in the MBI contributors have been significantly increased after the intervention. In a similar vein, a study conducted 8-week mindfulness-based psychoeducation, concluded that mindfulness-based psychoeducation lead to significantly higher improvement in some processes of mindfulness ability and emotion regulation and decrease the depressive symptoms and the perceived disturbance of hallucinations (Lam et al., 2020). Likewise, another study showed that a brief online MBI can increase mindfulness skills, specifically the Observe, Describe and Non-react subscales of the FFMQ (Shore et al., 2017).

Schizophrenia is commonly treated with antipsychotic medications and therapy. The drugs aren't always successful, and they can have unfavorable side effects. As a result, safe and effective complementary therapy for schizophrenia patients, such as MBI, is required. As a result, the current study discovered that MBI may be beneficial in the holistic management of schizophrenia.

Limitations

This study has a few limitations. Firstly, the studied patients were not blinded to the intervention assignment, which could lead to desired reaction bias and probably inflate the treatment effects. Secondly, this study conducted only on patients recent-onset psychosis (less than 5 years) and patients were excluded from the current study if they were found mentally unfit or unstable to participate by their psychiatrist, if they had comorbidity of learning disability and organic brain disorder, or/and had newly established (been getting) any regulated psychosocial interventions or psychoeducation. These exclusions might reduce the generalizability and clinical efficacy of the findings. Thirdly, there were some difficulties to extend this RCT and to estimate the long-term benefits of MBI. The researchers were unable to conduct a follow-up measurement, due to time constraints, and also the difficulty of coordinating between patients after their discharge from the hospital, especially patients who live in far areas from the hospital and require travel from their place of residence. Fourthly, other issues that may affect expressive communication throughout the interview include psychotic symptoms that cause poor insight and communication. Furthermore, antipsychotic medication adverse effects such as drowsiness cannot be ruled out. Fifth, the results of this study are measured using self-reported data, which may lead to self-reported/response bias and learning effects. Finally, despite the fact that this was an RCT, the findings did not fully confirm MBI's efficacy because it was not compared to another type of active schizophrenia intervention.

Conclusion

This study preliminarily recognized prompt and transient benefits of MBI as a third-wave intervention on recent-onset psychosis for patients with schizophrenia. The results demonstrated that MBI can be acceptable, efficacious, and feasible for nurses as a complementary treatment for positive and negative symptoms and enhancing recovery among schizophrenia patients.

Recommendations

Firstly, the current study created a new brief clinical intervention that is simple to administer and appears

to be adaptable to a variety of contexts. The MBI may be effective as a preliminary intervention for individuals who decline to involve in longer therapy protocols because it is brief and not extremely demanding (e.g., in terms of homework tasks, number of sessions, etc.). In addition, the MBI can produce results without increasing demand for community mental health services or prescription use. Second, advanced practice nurses are encouraged to use MBI as a supplemental therapy for treating psychotic symptoms and improving recovery in patients with schizophrenia. Thirdly, further research, particularly double-blind studies, is needed to evaluate the impact of MBI on individuals with psychotic disorders in populations and settings with larger samples and more socio-demographic and clinical features. Fourthly, follow-up measurements are required to determine the MBI's long-term benefits. After the trial is completed, follow-up can be used to investigate the patterns and consequences of treatment modifications and co-interventions. Finally, future research should compare MBI to other forms of schizophrenia treatment.

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Conflict of interest

The authors declare that they have no conflict of interest.

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