ORIGINAL ARTICLE

Effectiveness of Mindfulness-based Stress Reduction Program in Improving Mental Well-being of Patients with COVID-19: A Randomized Controlled Trial

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Abstract

Aim and objective: Mental well-being is one of the most important aspects of health. Life-threatening situations such as diseases affect mental well-being. Mindfulness-based stress reduction (MBSR) program is an effective program for improving well-being. This study aimed to evaluate the effectiveness of MBSR programs on the mental well-being of patients with coronavirus disease-2019 (COVID-19).

Materials and methods: This randomized controlled trial study was conducted in 2021. We used simple random sampling for recruiting 60 patients with COVID-19 and assigned them to the intervention and control groups. The intervention comprised eight sessions of the MBSR and was performed for the experimental group. The control group received routine postdischarge care. We used a self-report demographic and Ryff's Psychological Well-being Scale to collect data. To analyze the data, descriptive statistics and inferential statistics including Covariance, MANCOVA, and effect coefficient were used. The Significance level was considered lower than 0. 05. We used SPSS version 21 for data management.

Results: The mean score of mental well-being in the intervention group was 56.76 ± 6.88 in the pretest stage and 80.76 ± 7.53 in the posttest stage, and that in the control group was 54.40 ± 10.31 in the pretest stage and 51.23 ± 10.08 in the posttest stage. There was no significant difference between the two groups before the intervention ($p > 0.05$) but there was a significant difference ($p < 0.05$) after the intervention. There was also a significant difference ($p < 0.05$) between the dimensions of mental well-being before and after the intervention.

Conclusion: According to our findings, it is recommend to use MBSR program in line with physical treatment for patients with COVID-19.

Keywords: COVID-19, Mental well-being, Mindfulness, Mindfulness-based stress reduction program, Randomized controlled trial, Stress.

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Introduction

Mental well-being is one of the most important aspects of health[1] and is closely related to physical health. Any disorder in mental well-being causes a disorder in one's health,[2] because health is a complete physical, mental, and social well-being, and absence of disease or organ failure is not considered health.[3] Hence, life-threatening situations, including infectious diseases, endanger people's health, and the more people are able to cope with adverse conditions, the less their mental health changes.[4,5]

Coronavirus disease-2019 (COVID-19), as a contagious and emerging disease, is one of the most threatening conditions for human health. COVID-19 started in Wuhan, China, and spread rapidly to all countries. In addition to physical symptoms, a study by Zhang et al. showed that the immediate effects of COVID-19 pandemic at moderate level include stress, mental health problem, and reduced quality of life.[6] People with suspected COVID-19 have a higher rate of depression, and their quality of life is at an unfavorable level compared to others.[7] The results of a study conducted in Iran showed that people's level of anxiety has increased and their mental health has decreased during COVID-19 pandemic.[8] The study of Vahedian-Azimi et al. showed that the level of anxiety, stress, and depression in Iranian people is high, and in patients with COVID-19, these disorders are more severe and require psychological interventions.[9]

Improving and maintaining health is emphasized by the World Health Organization, and at every opportunity, this organization emphasizes on the responsibility of governments in fighting against current pandemic. In this regard, the World Health Organization has called on governments to take measures to improve the mental health of people during COVID-19 pandemic.[10]

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Since mental well-being refers to all methods and measures that are used to prevent, treat, and rehabilitate mental illnesses,[1] programs that are based on psychological therapies are used to reduce anxiety and pain, relieve fatigue, and reduce depression in patients with physical and mental problems. One of these treatments is a mindfulness-based stress reduction (MBSR) program. Mindfulness is a method of meditation that aims to increase awareness by paying attention to goals at present time without any prejudgment. Mindfulness is a mental capacity that is reinforced by various methods.[11]

The concept of mindfulness was first introduced in Buddhist philosophy, and although modern philosophy was unfamiliar with this concept, it spread rapidly in Western research and psychology. Mindfulness-based interventions include MBSR and mindfulness-based cognitive therapy that combine the nature of Eastern mindfulness practices with Western cognitive-behavioral function.[12] As the mindfulness increases, so does the mood and quality of life.[13] Also, the implementation of mindfulness programs increases the psychological well-being of individuals.[11]

Querstret et al. (2020) in a systematic review and meta-analysis study examined the implications of MBSR program and mindfulness-based cognitive therapy in mental health and well-being of nonclinical samples. These findings provide evidence that cognitive therapy and stress reduction programs can be effective in increasing mental health of people in the society.[14] Other studies have shown the effectiveness of mindfulness-based cognitive therapy in different groups including patients with MS,[15] healthy people,[16] and athletes.[17]

Due to the emergence of COVID-19 disease, the studies performed on COVID patients are very few, so the present study was conducted with the aim of investigating the effectiveness of MBSR program in improving the mental well-being of patients with COVID-19.

Materials and Methods

This study is a two-arm parallel randomized controlled trial with intervention and control groups that was conducted in 2021 in Zahedan. Zahedan is a city of Sistan and Balochestan, a Province of east-south of Iran.

Study setting was Amir-al-Momenin hospital. All patients with the diagnosis of COVID-19 were referred to this hospital.

Patients who are discharged from hospital received health services including follow-up care in this. The study population included all patients with COVID-19 referred to study setting.

We used G-Power version 3.1 software to calculate the sample size.

We considered the values of test power equal to 80%, confidence coefficient 0.95%, effect size 0.65, and number of samples for the mean difference in two independent groups equal to 60 people in both groups. First, we check the list of the clients of this center. After checking the eligibility criteria, we select our samples by use of random number table. Then, we invited them to participate in our study. After obtaining their first agreement, we explained the aim of the study and intervention and the process of their participation. Again, we obtain written informed consent for entering the study.

We used a quartile block randomization method for randomization. We used a random generation list for this means. We informed the patients about the groups. Data were blind for data analyst totally, and 60 patients (30 patients in experimental group and 30 patients in control group) participated in this study.

Inclusion criteria were as follows: Age of 18–60 years, literacy and ability to communicate verbally, willingness and ability to participate in the intervention, ability to use virtual space and messengers, ability to perform daily individual activities, and having a negative PCR.

Exclusion criteria were as follows: Any changes in the patient's health that prevent him/her from participating in the study, such as readmission in the hospital, loosing ability to do her/his daily activity, hospitalization, nonparticipation in the program and follow-up intervention, and the event of an unintended accident for the person (new physical problem, mental problem, death of a loved one) that affects the mental well-being status.

Our intervention was a MBSR program.

We performed this program in eight individual sessions over 2 months. Table 1 shows the details of MBSR program. We conducted all the sessions by use of virtual space (online and offline).

Table 1: Details of mindfulness-based stress reduction program

Time	*Content of intervention delivered for samples in the intervention group*
Session 1	Introducing and determining the session objectives, examining the expectations, getting acquainted with the physical and psychological symptoms of the disease, a summary of the cognitive training method based on mindfulness, the topic of the session: automatic guidance, raisin eating technique, and then meditating for 30 minutes, then doing body scan exercise and talking about emotions caused by this meditation, determining homework.
Session 2	Focus more on the body, body scan meditation and discuss the experience, discuss homework, discuss the feedback on eating exercise, body scan exercise, give feedback, discuss body scan exercise, start exercising with a focus on short breathing, record pleasant events, homework.
Session 3	Facing obstacles, doing body scan exercises, prioritizing mindfulness and discussing its experience, checking homework, recording unpleasant events, practicing 3 minutes of breathing space including the steps, paying attention to the exercise while doing it, paying attention to breathing and to body, homework, body check.
Session 4	Staying in the present, practicing seeing and hearing, practicing breathing awareness, body, voice, and thoughts and discussing the experience, discussing homework, practicing breathing space, defining homework.
Session 5	Allowing the experience to be present, doing meditation at sitting position and discussing the experience, reviewing homework, discussing thoughts and feelings, practicing breathing space and reviewing it, doing breathing space for 3 minutes while coping with an unpleasant event and reviewing it, defining homework.
Session 6	Doing 40 minutes of meditation at sitting position and reviewing it, discussing homework, discussing the relationship between mood and thoughts, practicing breathing and reviewing it, defining homework.
Session 7	Using meditation exercises when negative thoughts about the disease occur, doing meditation for 40 minutes and reviewing it, discussing homework, doing 3-minute breathing exercises, making a list of enjoyable activities, defining homework.
Session 8	Regular exercise of mindfulness helps maintain balance in life, exercising Persian, reviewing homework, reviewing previous sessions and homework, reviewing the entire program, reviewing and discussing plans, and finding reasons to continue exercising, ending the class.

Every session took 90 minutes. Duration of the session was adjusted to participants willing. The written exercises and audio and video files of each session were delivered to the participants at the end of the session. We had online group meetings via a social network platform. We also reviewed the participants' home works and solved the problems related to them. After training, we reviewed the exercises of all the participants one by one and corrected the possible mistakes. Each session concluded with a review of what happened in the session as well as a summary of the content of the session and assignments. The intervention took 2 months. Two months after the end of the intervention, the tools completed again by both groups. The control group received routine care. After completing the tools by the control group, we delivered the content of the program as a package them.

We asked participants of two groups to complete questionnaires in two times (before the intervention and 2 months after the end of the intervention). Flowchart 1 shows the CONSORT diagram of the study.

We used a self-report demographic and mental health well-being questionnaire to collect data.

A demographic questionnaire including age, gender, marital status, level of education, employment status, place of residence, and income adequacy.

Mental well-being scale: Reef developed this scale in 1989. The short form of this scale has 18 items. The six dimensions of mental well-being include autonomy (three items), personality development (three items), positive relationships with others (three items) purpose in life (three items), self-acceptance (three items), and mastery of the environment (three items). Cronbach's alpha coefficient for this questionnaire was 0.97, which shows that the questionnaire has good reliability. Six-point Likert scoring is reversed from strongly agree (6) to strongly disagree (1) and items 1, 3, 4, 5, 9, 10, 13, and 17 are inverted and completely agree (1), and they are completely opposite (6). We considered the total score of six factors as the overall score of mental well-being. High scores show better mental well-being. The correlation of the short version with the original scale fluctuates from 0.7 to 0.89 and shows an acceptable level of instrument reliability. This questionnaire was translated and validated in Iran by Khanjani et al.[18] In the present study, internal consistency of mental well-being scale using Cronbach's alpha in six factors of self-acceptance, environmental dominance, positive relationship with others, having a purpose in life, personal growth, and independence was 0.51, 0.76, 0.75, 0.52, 0.73, and 0.72, receptively. The internal consistency for the whole scale was 0.71.

To analyze the data, we used descriptive statistics including frequency, mean and standard deviation, and analytical statistics appropriate to the normality of the population to compare the means. First, we used the Kolmogorov–Smirnov test to evaluate the normality of the data.

In order to follow the methods of preventing the spread of COVID-19 disease, we used an electronic questionnaire of a paper questionnaire instead. We provided electronically the intervention to the samples.

Ethical Consideration

We obtained ethical approval (IR.MODARES.REC.1399.099) from the faculty of Medical Sciences at Tarbiat Modares University, receiving permission to enter the research setting, obtaining oral and written informed consent, anonymity, and confidentiality of participants, and an allowance to leave the research freely. Also, we registered this study in Iranian registry of clinical trials (IRCT:20170218032635N3). The control group received the content of the program as a package.

Results

Totally, 60 patients participated in this study. Table 2 shows participants' sociodemographic characteristics. There was no significant difference between the two groups before the intervention in terms of mental well-being ($p > 0.05$). There was a

Flowchart 1: CONSORT 2010 flow diagram

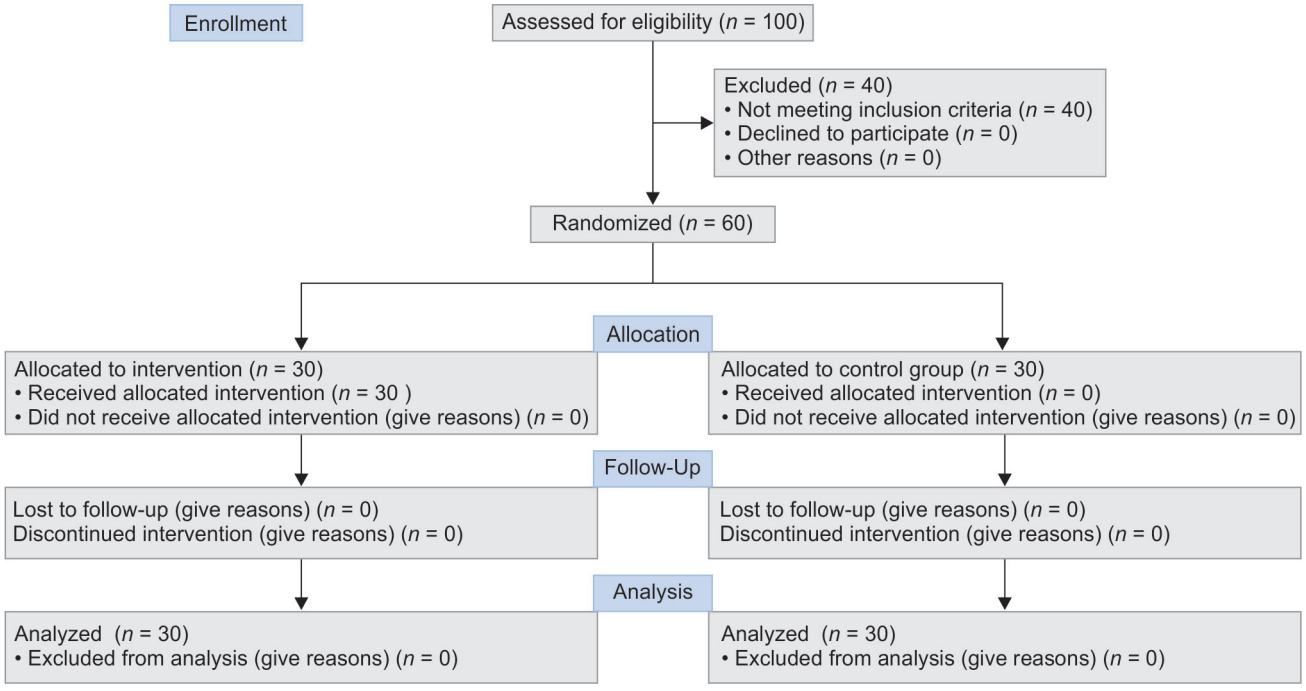

Table 2: Sociodemographic characteristics of participants

Variable		*Control group (%)*	*Intervention group (%)*
Gender	Female	14 (46.70)	18 (60.00)
	Male	16 (53.30)	12 (40.00)
Marital status	Single	8 (26.70)	5 (16.70)
	Married	22 (73.30)	25 (83.30)
Level of education	Less than diploma	6 (20.00)	4 (13.30)
	Diploma	6 (20.00)	6 (20.00)
	Bachelor	15 (50.00)	14 (46.70)
	Master	3 (10.00)	6 (20.00)
Occupation	Unemployed	5 (16.70)	6 (20.00)
	Self-employee	12 (40.00)	9 (30.00)
	Housekeeper	3 (10.00)	4 (13.30)
	Employee	10 (33.30)	11 (36.70)
Living place	Own house	17 (56.70)	19 (63.30)
	Rental house	13 (43.30)	11 (36.70)
Adequacy income	Adequate	27 (90.00)	23 (76.70)
	Partly adequate	3 (10.00)	5 (16.70)
	Nonadequate	0 (0.00)	2 (6.70)

Table 3: Mean and standard deviation of mental well-being scores and its subscales in the study groups

		Pretest	*Posttest*
Variable	*Group*	*Mean ± standard deviation*	*Mean ± standard deviation*
Well-being total score	Intervention	56.76 ± 6.88	80.76 ± 7.53
	Control	54.40 ± 10.31	51.23 ± 10.08
Autonomy	Intervention	8.06 ± 1.94	11.26 ± 2.13
	Control	7.30 ± 2.30	6.90 ± 2.21
Mastery of the environment	Intervention	8.20 ± 1.66	11.53 ± 1.81
	Control	7.56 ± 2.29	6.96 ± 2.31
Personality development	Intervention	9.06 ± 1.87	12.90 ± 2.38
	Control	9.36 ± 2.02	9 ± 1.85
Positive relationships with others	Intervention	10.06 ± 2.39	14.7 ± 2.49
	Control	10 ± 3.05	9 ± 1.85
Purpose in life	Intervention	10.86 ± 1.87	15.26 ± 2.06
	Control	10.26 ± 2.42	9.66 ± 2.53
Self-acceptance	Intervention	10.50 ± 1.97	15.06 ± 1.72
	Control	9.90 ± 2.66	9.33 ± 2.53

significant difference ($p \leq 0.05$) after the intervention between two groups. The mean score of mental well-being in the intervention group was 56.76 in the pretest stage and 80.76 in the posttest stage, and that in the control group was 54.40 in the pretest stage and 51.23 in the posttest stage Tables 3 and 4. There was also a significant difference ($p \leq 0.05$) between the dimensions of mental well-being before and after the intervention Tables 5 and 6.

Discussion

The aim of this study was to evaluate the effectiveness of MBSR program in improving the mental well-being of patients with COVID-19. Findings of this study showed that MBSR program improved the overall score of mental well-being in the intervention group. The intervention also had positive effect on mental well-being subscales including autonomy, mastery of the environment, personality development, positive relationships with others, purpose in life, and self-acceptance compared to the pretest period. Also, the results showed a statistically significant difference in the mean scores of mental well-being before and after the intervention in both intervention and control groups.

The result of present study that shows improvement in mental well-being of intervention group is consistent with the results of Rahmani Fard et al. study, as they also found that cognitive therapy

Table 4: Covariance test results of the difference between control and intervention groups in the mental well-being variable

Source	*Type III sum of squares*	*df*	*Mean square*	*F*	*Sig*	*Partial eta squared*
Group	151.763	1	151.763	44.351	0.000	0.442
Premental well-being	3870.612	1	3870.612	1131.133	0.000	0.953
Error	191.626	56	3.422			
Total	279038.000	60				

Significant difference between two groups in term of mental well-being scores after intervention (significance level <0.05). Participants of the intervention have better mental well-being than control group. In general, data analysis indicates that MBSR program is effective in promoting the mental well-being of individuals with effect size (442)

Table 5: Significant difference between the intervention and control groups in the terms of mental well-being subscales

Test	*Value*	*F*	*Hypothesis df*	*Error df*	*Sig*	*Partial eta squared*
Pillai's trace	0.950	147.992	6.000	47.000	0.000	0.950
Wilks' lambda	0.050	147.992	6.000	47.000	0.000	0.950
Hotelling's trace	18.893	147.992	6.000	47.000	0.000	0.950
Roy's largest root	18.893	147.992	6.000	47.000	0.000	0.950

Significance level <0.05

Table 6: Summary of MANCOVA results of subscales of mental well-being

Source	*Type III sum of squares*	*df*	*Mean square*	*F*	*Sig*	*Partial eta squared*
Autonomy	44.575	1	44.575	166.587	0.000	0.762
Mastery of the environment	53.184	1	53.184	157.109	0.000	0.751
Personality development	44.947	1	44.947	86.548	0.000	0.625
Positive relationships with others	79.990	1	79.990	145.264	0.000	0.736
Purpose in life	77.009	1	77.009	301.475	0.000	0.853
Self-acceptance	88.676	1	88.676	88.502	0.000	0.630

Significant difference between the intervention and control groups in terms of six subscales of mental well-being. All subscales significantly increased after intervention in intervention group

based on mindfulness improved psychological well-being and its subscales including self-acceptance, positive relationships with others, autonomy, mastery of the environment, purpose in life, and personality development in infertile women. They argued that this method is an effective way to improve the psychological well-being of infertile women.[19] Norouzi et al.[20] also found that mindfulness-based therapy can play an effective role in reducing and controlling patients' psychological symptoms and promoting them. Ahmadi et al. argued that mindfulness-based cognitive therapy is effective in promoting patients' mental well-being.[21] The results of Brown et al. study showed that mindfulness through vitality and clear perception of experiences can make positive changes in happiness and psychological well-being of people.[22] This study also showed the positive effect of mindfulness-based cognitive therapy on improving self-acceptance of patients with COVID-19. This is consistent with the results of Thompson et al.'s study that examined the relationship between mindfulness, self-esteem, and unconditional self-acceptance. They concluded that there is a positive correlation between mindfulness, self-esteem, and unconditional self-acceptance, and also mindfulness skills may be a tool for improving unconditional self-acceptance.[23] The results of present study also showed the effect of mindfulness-based cognitive therapy on improving the autonomy of patients with COVID-19, which is consistent with the results of Astin's study that showed mindfulness meditation can increase the sense of control. According to our hypothesis, the intervention group obtained better score than the control group in terms of the subscale of mastery of the environment.[24] Spence in a study stated that mindfulness-based cognitive therapy for 8 weeks increased the participants' mastery of environment. Cognitive therapy has made changes in the life purpose of patients with COVID-19.[25] In addition, we observed a significant effect of cognitive therapy on the personality development of patients with COVID-19. A study by Garland et al. compared the effectiveness of MBSR program and art therapy program in facilitating posttraumatic growth and spirituality in cancer patients and concluded that both programs may facilitate posttraumatic growth. However, it seems that mindfulness-based cognitive therapy can be more useful in strengthening spirituality and reducing stress, depression, and anger compared to art therapy.[26] Considering the findings of present study, it can be argued that psychological trauma is often continued by biased and extreme thoughts and exacerbated through distortion of data processing, which can lead to reduced mental health and well-being of patients.[27] Emotional stress can affect a person's behavior in a way that the person is unable to control it. Recognizing these problems and eliminating or reducing them, along with providing training such as mindfulness interventions, are important parts of treatment to improve psychological well-being.[28,29] Mindfulness

training, by increasing people's awareness about present, affects cognitive and information processing systems through techniques such as paying attention to breathing and body and focusing the mind on present and here, which lead to reduced rumination and dysfunctional attitudes. It also helps people to pay attention to their ruminating thoughts and diverts their mind to other issues, such as present time, breathing, walking, and environmental noises, and this way reduces the rumination. These positive changes in people increase their mental well-being.[30] Another reason for the effectiveness of mindfulness training is that mindfulness training leads to cognitive change in attitude. In this way, the patients try to find themselves in order to reach the next step, and this tendency toward reaching the next step continuously improves their mental well-being and solves their shortcomings and problems.[31]

Conclusion

The results of present study showed that the MBSR program was effective in improving the mental well-being of patients with COVID-19. These results can be used by nurses in various fields including education, research, clinical practice, management, and policy-making. The findings of present study provide a basis for designing other studies with similar target groups and communities. Also, the program used in this study can be used in nursing care, especially community health nursing and after hospital discharge. The use of virtual version of questionnaire was a new innovative method that showed in situations where the presence and physical contact of participants are not possible, the use of cyberspace can be a good solution. Also, more attention should be paid to the development of training and care packages at the ministry level and its dissemination among people. The mindfulness-based psychological interventions can play an important role in the design of educational program by nurses for groups that need them.

Study Limitation

One of the limitations of this study was that it was done only in the urban environment of Zahedan, so it is suggested that similar studies should be designed and implemented in rural areas. Also, the questionnaires in this study were completed by self-reporting method, which can affect the accuracy and precision of the results.

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