Online Balint Group Work Versus Pharmacotherapy in Treatment of Coronavirus Anxiety in Healthcare Workers in Iran: A Pilot Randomized Controlled Trial

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Research

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Abstract

Background: An increase in symptoms of anxiety is already being reported in relation to the COVID-19 pandemic.

Objectives: We aimed to compare the effectiveness of Balint group work with pharmacotherapy in coronavirus related anxiety among healthcare workers (HCWs) in Iran.

Methods: In This pilot clinical trial, after passing a phone screening procedure by a psychiatrist, subjects were quasi-randomly assigned to Balint (8 sixty-minute online sessions) or pharmacotherapy (Sertraline) groups. Both groups were asked to fill two questionnaires, including the Corona Disease Anxiety Scale (CDAS) and Connor-Davidson resilience scale (CD-RISC), at the beginning and the end of the 4-week intervention period.

Results: A total of 45 HCWs enrolled in this study. The results showed a significant difference between the post-test and pre-test scores of both groups in the total scores of anxiety and its subcomponents ($p \leq 0.001$). There was no significant difference between the effectiveness of the two interventions on anxiety ($p = 0.52$). Both interventions had a significant effect on the subjects' resilience and its subscales ($p \leq 0.05$) except for positive acceptance change. The spiritual influences domain had a significantly higher increase in the pharmacotherapy group ($P = 0.031$).

Conclusions: We showed Balint group work maybe can better to pharmacotherapy with Sertraline in management of COVID-19 related anxiety and boosting resilience in healthcare workers.

Introduction

The coronavirus disease (COVID-19), as a highly contagious infection with a long incubation period, emerged in Wuhan at the end of 2019. It has gained intense attention worldwide and caused huge threats to individuals' mental health (1). Recently, the world health organization (WHO) projected the need for action on mental health and considered the front-line healthcare workers (HCWs) to be at greater risk of psychological problems. During such pandemics, HCWs in the front line have to deal with long work hours, greater risk of infection transmission, social isolation, and getting homesick, all of which can potentially give rise to serious psychiatric problems (1, 2).

The COVID-19 pandemic is a rapidly evolving situation and psychological status of HCWs may be altered in time. Few studies have been done on the probable strategies that could be used to address the psychological needs of front-line HCWs during this pandemic (3).

One of the interventions for reducing anxiety and increasing resilience in the HCWs is Balint group intervention. Balint group is a group of trained and peer therapists and caregivers discussing the difficulties and issues in their relationship with patients in a reflective, insightful, and practical way (4).

The aim of Balint group is changing the uncertainty, confusion, and difficulty of perception, understanding, and meaning in the relationship between the caregiver and patient leading to a stronger therapeutic alliance (5). It also empowers physicians to take the initiative in their profession when there is uncertainty or no clear answer (6) and it helps them to explore their interpersonal abilities and limitations, perceive and strengthen the blind spots in dealing with patients (7).

In one study, the effectiveness of Balint group was evaluated in nurses of intensive care units (ICUs). The results showed a significant effect of Balint group work on reducing burnout and improving the work quality of nurses (8).

To date, more than 1.4 million Iranian COVID-19 cases have been confirmed (9). The number of morbidities, including psychological complications, are higher, especially in vulnerable groups. However, few studies addressed the treatment of anxiety and increasing resilience in the medical staff as one the most at-risk groups. Various pharmacological and non-pharmacological interventions have been effective in increasing resilience and decreasing anxiety caused by COVID-19 (10, 11). Different studies on the effect of the aforementioned treatments have reported contradictory results.

To the best of our knowledge, there is no study comparing the effectiveness of Balint group with pharmacotherapy in the HCWs. Therefore, we aimed to compare the effectiveness of Balint group and pharmacotherapy with selective serotonin reuptake inhibitors (SSRIs) in coronavirus related anxiety and resilience among HCWs.

Materials And Methods

Study Design

This pilot quasi-randomized controlled study performed over four weeks in Gorgan, Iran from March 2020 to May 2020. After completing the written informed consent, patients were quasi-randomly assigned into parallel intervention groups, namely Balint group work or pharmacotherapy. We performed an alternate allocation method according to the order of enrollment. The first participant to fulfill the inclusion criteria was assigned to Balint group work, the second participant was assigned to the pharmacotherapy group, and the allocation continued in this alternating way. The pilot trial protocol was registered at irct.ir (Registration code: IRCT20200411047023N1, registration date: 26/01/2021, available at: <https://www.irct.ir/trial/53441>).

Participants

A total of 60 individuals were assessed for eligibility criteria, from which 15 cases were excluded. The remaining participants were divided into two groups, including 17 participants in pharmacotherapy group and 28 participants in the Balint group (Fig. 1). We included cases with 18–59 years of age with illness anxiety who had been diagnosed by two psychiatrists, according to the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5). Participants were excluded from the study if they had

psychiatric disorders other than illness anxiety, were treated with psychiatric drugs or were pregnant. A blinded psychiatric coordinator screened the HCWs for eligibility criteria via a phone call interview.

Intervention

Participants in the Balint group attended eight sessions in four weeks. Participants in the pharmacotherapy group received 4-week of oral Sertraline tablets (starting with 50 mg/day and increased if needed according to the patient's symptoms and tolerance). Due to the high rates of coronavirus transmission, it was not possible to hold face-to-face groups, and Balint groups were held virtually via Skype video calls with nine members, one leader and one assistant leader for 60 minutes per session, two times a week. An additional 15 minutes could be added. To collect data at the beginning and end of the 4-week intervention period, individuals in each group answered demographic and research questionnaires. All participants were evaluated at the beginning and the end of the study (pre-and post-test).

Sample size:

To achieve the appropriate number of research samples, G-power version 3.1.9.2 (17) software was used, considering the significance level of 0.05 and beta of 0.8 and the effect size of 0.5 according to a related study (12). The appropriate sample size was 16 people and considering the possible drop-out rate, 20 participants were considered as the appropriate number of cases in each group.

Data collection

The study questionnaire, which included *Corona Disease Anxiety Scale* and *Connor-Davidson resilience scale*, was prepared online in the Google Forms platform (available at [https](https://forms.gle/QWmXdBEFKs2FXEy27)

[//forms.gle/QWmXdBEFKs2FXEy27](https://forms.gle/QWmXdBEFKs2FXEy27)) and distributed in social networks. In this format, a brief statement about the purpose of the research and the principal investigator was included to introduce the survey. Participants' demographic data (such as age, sex, educational status, and marital status) was also collected.

Ethical considerations

The study design was approved by Golestan University of Medical Sciences (ethical code: IR.GOUMS.REC.1399.023). All participants were informed that participation is voluntary and reassured that their records would remain confidential.

Research tools

Corona Disease Anxiety Scale (CDAS)

This instrument has been developed and validated in the Iranian population to measure anxiety caused by coronavirus outbreak. This instrument consists of 18 items in two subscales of psychological (items 1 to 9) and physical (items 10 to 18) symptoms. This tool is rated on a 4-point Likert scale (never = 0,

sometimes = 1, most of the time = 2, and always = 3), so respondents' scores range from 0 to 54. Higher scores indicate higher levels of anxiety. The reliability of this tool was obtained using Cronbach's alpha method for the first factor ($\alpha = 0.879$) and the second factor ($\alpha = 0.861$) and the whole questionnaire as ($\alpha = 0.919$) (13).

CD-RISC resilience scale (Connor-Davidson resilience scale)

This tool is measured by Connor and Davidson and consists of 25 items on a five-choice Likert scale (completely incorrect = 0, rarely true = 1, sometimes true = 2, often true = 3, and always true = 4), and its overall score ranges from 0-100. The score of each subject is equal to the sum of the scores of all 25 questions. Higher scores represent higher resilience in the respondent and vice versa. The cut-off point is set on 50, which means scores higher than 50 will indicate resilience, and the higher the score, the higher the resilience, and vice versa (14).

The results of factor analysis indicate that this test has five factors: the perception of personal competence, trust in individual instincts, tolerance of negative emotions, positive acceptance of change and safe relationships, control, and spiritual effects (14). Cronbach's alpha coefficient for the total resilience score was 0.93 in the Iranian version of the questionnaire (15).

Statistical analysis:

The data were analyzed using SPSS software (Version 16, Chicago, IL, USA), and the significance level was set at $P < 0.05$. Data were shown as mean $\pm$ SD or frequency (%). Homogeneity of demographic variables was checked by Chi-square test, Fisher's exact test where applicable or t-test. The normality of continuous variables was checked using the Shapiro-Wilk test. Since variables were not normally distributed, comparison between the two groups was made using Wilcoxon signed-ranked test. The difference between quantitative variables after the intervention was studied using the analysis of covariance (ANCOVA) while considering baseline and those confounding variables as confounders. The correlation between CDAS and its subscale differences (after–before) and CD-RISC and its subscale differences (after–before) were evaluated using Spearman's correlation coefficient.

Results

In this study, 45 eligible subjects were randomized in Balint ($n = 28$) and pharmacotherapy ($n = 17$) groups (Fig. 1). Five cases dropped due to non-adherence, and 40 could finish the study intervention after four weeks. No harm, unintended or critical side effects were observed during the intervention period. The female-to-male ratio was 21/4 and 12/3 in Balint and pharmacotherapy groups, respectively. The mean age of the individuals was 34.0 ± 5.5 years in the Balint group and 31.8 ± 3.9 years in the pharmacotherapy group ($P = 0.18$). Furthermore, most participants were married and had children. The percentage of individuals with Ph.D. degrees was 68.0% in the Balint group, while most people in the pharmacotherapy had a bachelor's or master's degree. Moreover, all the people in the pharmacotherapy

group were in contact with suspicious patients with COVID-19, but there were some people in the Balint group who had no history of close contact with COVID-19 patients in their workplace (Table 1.)

Table 1
Comparison of demographic variables between Balint and pharmacotherapy groups.

	Balint (n = 25)	Pharmacotherapy (n = 15)	p-value*
Sex			
Male	4(16.0%)	3 (20.0%)	> 0.99
Female	21(84.0%)	12(80.0%)	
Age (years)	34.0 ± 5.5	31.8 ± 3.9	0.184
Marital status			
Single	9(36.0%)	3(20.0%)	0.477
Married	16(64.0%)	12(80.0%)	
Education level			
MD	5(20.0%)	6(40.0%)	< 0.001
BSC or MSC	3(12.0%)	9(60.0%)	
PhD	17(68.0%)	0	
Having children			0.622
Yes	13(52.0%)	9(60.0%)	
No	12(48.0%)	6(40.0%)	
Contact with COVID-19 patients in workplace			0.002
Close contact with COVID-19 patients	11(44.0%)	0	
Contact with suspicious COVID-19 patients	11(44.0%)	15(100.0%)	
No contact with COVID-19 patients	3(12.0%)	0	
Data were presented as Mean ± SD, frequency (%).			
* Based on Fisher's exact test, Chi-square test or t-test.			

The mean level of CDAS score in the Balint group was 12.3 ± 12.7 comparing to 12.7 ± 8.4 in pharmacotherapy group, which was not significantly different ($P \geq 0.52$). Since the workplace, level of education, and total score of CDAS was significantly different between the two groups, ANCOVA was done. As shown in Table 2, after adjusting for confounders, the score of CDAS was not significantly different between the two groups ($P = 0.53$). The mean decline of psychological and physical symptoms

was higher in the pharmacotherapy group and Balint group, respectively. Nonetheless, none of the mentioned differences were statistically significant ($P > 0.05$). Also, a significant improvement was seen in CDAS scores and its subscales in both groups after the intervention ($P < 0.01$, Table 2.).

Table 2
Comparison of Corona Disease Anxiety Scale and its subscales' scores between Balint and pharmacotherapy groups.

Variable	Timepoint	Group		Adjusted p-value
		Balint (n = 25)	Pharmacotherapy (n = 15)	
Score in the psychological symptoms subscale of CDAS	Before	13.7 ± 5.9	19.7 ± 4.7	0.888 [‡]
	After	7.2 ± 3.6	12.3 ± 5.7	
	Difference	-6.5 ± 6.0	-7.4 ± 5.5	
	p-value	< 0.001 [†]	0.002 [†]	
Score in the physical symptoms subscale of CDAS	Before	9.0 ± 7.5	15.8 ± 5.3	0.164 [‡]
	After	3.2 ± 2.6	10.5 ± 6.1	
	Difference	-5.8 ± 7.2	-5.3 ± 4.1	
	p-value	0.001 [†]	0.002 [†]	
Total CDAS score	Before	22.7 ± 12.6	35.5 ± 9.5	0.527 [‡]
	After	10.4 ± 5.3	22.9 ± 11.3	
	Difference	-12.3 ± 12.7	-12.7 ± 8.4	
	p-value	< 0.001 [†]	0.001 [†]	
Data presented as Mean ± SD.				
†Based on Wilcoxon signed rank test.				
‡Based on ANCOVA adjusted for measurements before intervention, education level and workplace.				

Based on CDAS scores, before the intervention, 20.0% and 36.0% of individuals in the Balint group had moderate and severe corona disease anxiety, respectively, both of which reduced to 4.0% after the intervention. Besides, in the pharmacotherapy group, the frequency of mild anxiety increased from 0.0–20.0%, and the frequency of severe corona-related anxiety decreased from 73.3–20.0% after the intervention (Fig. 2).

There was a significant improvement in CD-RISC subscale scores including personal competence, trust in one's instincts, tolerance, and spiritual influences after the intervention in both groups, however, positive acceptance of change subscale scores had a significant decrease ($P < 0.05$). Comparison of total scores of CD-RISC and its domains after the intervention while adjusting for mentioned covariates indicated no significant difference between the two groups except for the spiritual influences domain, which had a significantly higher increase in the pharmacotherapy group ($P = 0.03$, Table 3.).

Table 3

Comparison of Connor-Davidson Resilience Scale between Balint and pharmacotherapy groups.

Variable	Timepoint	Group		Adjusted p-value
		Balint (n = 25)	Pharmacotherapy (n = 15)	
Personal competence	Before	19.4 ± 11.1	16.3 ± 2.5	0.696 [‡]
	After	26.9 ± 4.4	25.9 ± 5.5	
	Difference	7.6 ± 9.7	9.7 ± 5.0	
	p-value	0.003 [†]	0.001 [†]	
Trust in one's instincts	Before	16.1 ± 8.7	13.9 ± 2.5	0.364 [‡]
	After	22.5 ± 3.5	22.2 ± 5.1	
	Difference	6.4 ± 8.4	8.3 ± 4.5	
	p-value	0.001 [†]	0.001 [†]	
Positive acceptance of change	Before	13.6 ± 7.4	10.0 ± 1.8	0.111 [‡]
	After	3.7 ± 2.0	7.1 ± 4.3	
	Difference	-9.9 ± 7.1	-2.9 ± 4.4	
	p-value	< 0.001 [†]	0.018 [†]	
Control	Before	7.9 ± 4.1	6.2 ± 0.9	0.790 [‡]
	After	10.0 ± 1.9	9.5 ± 2.1	
	Difference	2.2 ± 3.5	3.3 ± 1.9	
	p-value	0.007 [†]	0.001 [†]	
Spiritual influences	Before	4.2 ± 2.9	3.9 ± 0.9	0.031 [‡]
	After	5.4 ± 1.7	6.3 ± 1.3	
	Difference	1.2 ± 2.8	2.4 ± 1.3	
	p-value	0.059 [†]	0.001 [†]	
Total CD-RISC score	Before	61.2 ± 33.3	50.3 ± 7.7	0.527 [‡]
Data presented as Mean ± SD.				
[†] Based on Wilcoxon signed rank test.				
[‡] Based on ANCOVA adjusted for measurements before intervention, education level and workplace.				

	After	82.6 ± 11.9	80.0 ± 16.4
	Difference	21.4 ± 29.0	29.7 ± 14.5
	p-value	0.004 [†]	0.001 [†]
Data presented as Mean ± SD.			
[†] Based on Wilcoxon signed rank test.			
[‡] Based on ANCOVA adjusted for measurements before intervention, education level and workplace.			

There was a significant negative correlation between CDAS and CD-RISC difference scores (after–before) in Balint groups. We also investigated the correlation between subscales of two studied questionnaires. As shown in Table 4, there was a significant correlation between all subscales of CDAS and CD-RISC in the Balint group. In contrast to the Balint group, the correlation between positive acceptance of change and CDAS, psychological symptoms scores were positive and significant (Table 4).

Table 4
Correlation of Corona Disease Anxiety and Connor-Davidson Resilience Scale in Balint and pharmacotherapy groups.

		CDAS		psychological symptoms		physical symptom	
		r	P-VALUE*	r	P-VALUE*	r	P-VALUE*
Balint group	CD-RISC	-0.742	< 0.001	-0.791	< 0.001	-0.728	< 0.001
	Personal competence	-0.772	< 0.001	-0.841	< 0.001	-0.731	< 0.001
	Trust in one's instincts	-0.737	< 0.001	-0.798	< 0.001	-0.747	< 0.001
	Positive acceptance of change	-0.751	< 0.001	-0.825	< 0.001	-0.694	< 0.001
	control	-0.781	< 0.001	-0.782	< 0.001	-0.790	< 0.001
	Spiritual influences	-0.787	< 0.001	-0.726	< 0.001	-0.806	< 0.001
Pharmacotherapy group	CD-RISC	-0.336	0.221	-0.448	0.094	-0.087	0.757
	Personal competence	-0.334	0.223	-0.456	0.088	-0.105	0.711
	Trust in one's instincts	-0.459	0.085	-0.477	0.072	-0.258	0.353
	Positive acceptance of change	0.649	0.009	0.654	0.008	0.395	0.146
	control	-0.435	0.105	-0.502	0.056	-0.269	0.333
	Spiritual influences	-0.011	0.968	-0.246	0.376	0.255	0.358
r = Spearman correlation coefficient							

Discussion

Anxiety is now a common psychological complication among HCWs during the COVID-19 pandemic (16). However, few studies addressed the coping strategies and treatments to mitigate this complication. We aimed to compare the effectiveness of Balint group therapy with pharmacotherapy in decreasing coronavirus anxiety and increasing resilience in health care workers dealing with COVID-19.

During a critical situation like the COVID-19 pandemic, one of the major problems of HCWs is increased anxiety. Anxiety is the result of suppressing emotions and feelings which were not expressed (17). Moreover, job stress occurs when job requirements are not matched with worker's authorities and abilities (18). Several factors are important in creating and permanence of anxiety including traumatic experiences of health care providers in hospitals, especially those who deal with patients. They usually suppress negative emotions and do not express their experiences, blame themselves for failure and tragic events, and have a high expectation of their abilities (18).

Our study showed that there is no significant difference between the effectiveness of Balint group therapy and pharmacotherapy in decreasing anxiety and increasing resilience. Regarding the effectiveness of Balint group therapy on anxiety and resilience, we found a notable decrease in anxiety and increase in resilience among HCWs. This result is consistent with the result of previous studies (19, 20).

Furthermore, the ability to empathize is in having the right relationship with the patient, to follow the treatment, and to help in the prediction of clinical consequences (12). Balint groups are designed to assist health professionals and medical students in developing their empathy skills and reducing interpersonal problems (21). So, Balint group can result in the reduction of anxiety in health care providers.

Resilience is the capacity to respond to stress in a healthy way to achieve goals at minimum physical and psychological costs. Persons with this ability facing challenges without bouncing back, so they become stronger than ever. Resilience is key to enhance the quality of care and sustainability of workers in healthcare. In the literature review, we noticed that Balint group improves the wellbeing and empathy of healthcare providers through narrative interactions and appreciative inquiry-based dialogues and increases resilience, and helps them to apply more proper methods to deal with stress (22). In another study, self-awareness and self-monitoring were introduced as effective methods in increasing resilience in healthcare providers (23).

Therefore, these results confirm that Balint group increases resilience in healthcare workers by 1. Dealing with different aspects of the patient-therapist relationship (24), 2. creating opportunities to express experiences, feelings, and self-reflections to other members (25), 3. informing the individual of their power and abilities and helping them understand and analyze (25), 4. Enhancing their empathy and interaction with the patient (12), 5. Helping caregivers express their suppressed negative emotion, 6. Helping them to develop their mutual understanding, 7. Helping them to change their misperceptions about unpleasant experiences and not to feel alone, 9. Reducing the rate of anxiety in health caregivers, 10. Helping them to increase their capacity responding anxiety through reviewing their past experiences and challenges (26, 27).

The other intervention that was used in this study was pharmacotherapy with a significant effect on the reduction of anxiety and increasing resilience. These results are consistent with results of other studies (28, 29).

SSRIs are the first line pharmacological treatment for anxiety disorders (28). The serotonin system plays an important role in the neural processing of anxiety and the involvement of serotonin reuptake receptors in the dysfunctionality of anxiety has a wide research background (29). Serotonin reuptake receptors increase neurotransmitters which result in the reduction of anxiety in people. In a study on the effect of serotonin on the resilience of civilians suffering from post-traumatic stress disorder, the results showed that serotonin works as a protective factor against stress and increases the resistance to stress and helps people be more flexible to anxious situations and results in an increase resilience (30).

Although drug interventions have essential and rapid effects, they have many side effects with a reduction in therapeutic effects after finishing their use. On the contrary, psychological interventions have no side effect and can keep their therapeutic effect, however, they are too time-consuming (31).

Declarations

Ethics approval and consent to participate:

The study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee at Golestan University of Medical Sciences (IR.GOUMS.REC.1399.023). All participants were informed that participation is voluntary and reassured that responses would remain confidential. Informed written consent was also obtained from all participants filling in the questionnaires. Participants may withdraw from the trial at any point without any penalty and will not receive compensation for taking part.

In the study personal information about participants collected during the consent/data collection processes are stored securely

Consent for publication: not applicable.

Availability of data and materials:

The data for the current study will not be shared publicly as participants were informed at the time of providing consent that only researchers involved in the project would have access to the information they provided. Researchers and scientific institutions can access the anonymous results by sending their request to the corresponding author.

Competing interests:

The authors declare that they have no competing interests.

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The study was funded by Golestan University of Medical Sciences, Gogan, Iran. (Investigators including two psychiatrists who voluntarily do the screening and follow-up visits and prescriptions, also Balint group leader, co-leader, and other investigators did not charge participants or funding organization for

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Authors' contributions

Najmeh Shahini: data collection, writing the article, and final approval of the article; Shakiba Gholamzad and Mansoureh Kiani Dehkordi: study concept and design, and Administrative support; Zanjireh Salimi: writing the article, data collection, and literature review, Reza Rahimzadeh Oskoei: critical revision of the article, provision of the materials, patients, and resources; Saeedeh Hajebi Khaniki: statistical analysis; and Hossein Mohaddes Ardabili: literature review, critical revision of the article, drafting the manuscript. All the mentioned authors critically reviewed the manuscript for key intellectual content and approved the final version of the manuscript.

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Figures

Figure 1

Quasi-experimental diagram showing the disposition of all subjects screened for the study.

Figure 2

Frequency of Corona Disease Anxiety in Balint and pharmacotherapy groups.

Supplementary Files

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