

Comparing the Effectiveness of Schema Therapy and Emotional Schema Therapy on Emotion Regulation of Individuals with Obsessive Compulsive Symptoms

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Abstract

Introduction: Due to the prevalence of Obsessive Compulsive Symptoms (OCS), it seems that actions should be taken to prevent its recurrence. Therefore, the purpose of the present study was to compare the effectiveness of Schema Therapy (ST) and Emotional Schema Therapy (EST) on the emotion regulation of patients with OCS.

Method: This semi-experimental study was carried out on 24 patients with OSC in three groups of ST (n=8), EST (n=8) and control (n=8) in Mashhad, Iran. The intervention groups received individual EST and ST Sessions. The data were collected by Maudsley Obsessive-Compulsive Scale (MOCAI) and Emotion Regulation Questionnaire (ERQ) in four stages of pre-test, post-test, one and three months follow up. The MANOVA test was utilized to analyze data.

Results: During the above stages, the mean score of expressive suppression and cognitive reappraisal subscales fell and soared significantly in the EST group, respectively ($P < 0.05$). There was a significant difference between the groups of intervention and control in terms of the average total obsessive-compulsive score and its sub-scales except for the slow sub-scales during all three stages after the intervention, one month later and three months later ($P < 0.05$).

Conclusion: Although both ST and EST methods had an effect on the improvement of emotion regulation and OCS, the EST was more effective on improving emotion regulation. Therefore, it is recommended to consider EST with a larger sample size in people with OCS.

Keywords: Obsessive Compulsive Disorder, Emotion Regulation, Schema Therapy, Emotional Schema Therapy

Introduction

Obsessive-Compulsive Disorder (OCD) is a disabling and chronic neuropsychiatric disorder which is associated with significant social damages and burden of illness throughout the world [1]. The prevalence of the mentioned disorder is estimated to be about 1 to 3percent [2]. However, despite the prevalence of this disorder, it is often under-diagnosed and treated which as a result imposes significant costs on both the patient and the health economy[3].

The OCD is a syndrome with two main features of obsession and compulsion that are clinically placed in a permanent uncontrolled cycle [1].The clinical manifestations of OCD are heterogeneous and is associated with a variety of symptoms, as well as, obsession with pollution and aggression, and also force to check out and to clean up [4] are considered as the most common clinical manifestations. The OCS usually occurs severely in a non- clinical,

sub-clinical, and clinical continuum [5] which quantitatively differs in the severity of cognitions and symptoms but they are qualitatively the same in nature [6]. So, most sub-clinical OCS, if left untreated, can progress to Obsessive Compulsive Disorder (OCD) [5]. Therefore, many people may suffer from OCS but only a few number of patients have DSM-5 diagnostic criteria for OCD [7].

It can be stated that OCS may be associated with escalated emotional responses and reduced distress tolerance, which is the result of impaired emotional processing, impaired cognitive control [8] and cognitive-inhibition processes [9]. These symptoms are associated with pathological anxiety, and the adoption of maladaptive strategies to alleviate symptoms may impair the emotion regulation of patients with these symptoms [10, 11]. The emotion regulation disorder is found in other anxiety disorders too, but it is more common among people with OCS [12]. This is due to the fact that OCS distress is linked to a poor understanding of emotions and fear of both negative and positive emotions, which probably leads to emotional avoidance by emotion suppression [13]. Thus, emotion regulation disorder in these patients can amplify the effect of disturbing thoughts on the duration of negative emotions [14].

The cognitive-behavioral model is the dominant psychological model used in the realm of OCD, which demonstrates the role of catastrophic evaluations of disturbing thoughts in the development of the OCD. However, the evidence supporting this model are often contradictory, reporting divergent results regarding the etiology of dysfunctional cognition associated with OCD [15]. However, recent advances in the diagnosis and treatment of OCD suggest that cognitive-behavioral therapy with/without selective serotonin reuptake inhibitors could be the first line of treatment for mitigating the symptoms of the disorder [2].

Some studies have shown that maladaptive schemas predict the negative outcomes in OCD patients undergoing cognitive behavioral therapy, which are associated with reduced treatment effectiveness [16]. Hence, the severity of OCS is often influenced by early maladaptive schemas such as punishment, failure, social isolation, and subjugation [17], as well as more specific schemas such as abuse/mistrust, vulnerability to harm, and high standards [18]. This leads to problem solving of self-worth in these people by developing moral and social beliefs and ideals [19]. Also, emotion regulation disorder may be rooted in interpretations of childhood traumatic events and maladaptive schemas. Therefore, it seems that ST strategies and techniques can successfully enhance emotion regulation in mental health disorders [20]. Jeffrey Young (1990) was the first to suggest ST, which was initially used to treat personality disorders and patients with chronic cognitive-behavioral refractory chronic mental disorders [21]. Nowadays, ST is used to reduce maladaptive schemas and improve symptoms of mental health disorders [22]. Studies have shown the effectiveness of ST in enhancing exposure and response prevention in OCD patients [21]. Moreover, theoretical integration of cognitive modeling and schema therapy

can reduce obsessive-compulsive beliefs in these patients [23]. On the other hand, in recent years, emotion and emotion regulation have been at the heart of cognitive-behavioral therapy. Although emotions are often ignored in cognitive-behavioral therapy, a number of emotional schema models have been developed. According to these models, emotions can be extracted from cognition or derived as a consequence or outcome of cognition [24]. Therefore, Leahy presented EST, which directly addresses emotion regulation strategies, emotional processes and their effects on experiences [24]. From Leahy's stance, emotional schemas form the basis of a spectrum of psychological disorders processes, affecting the severity of symptoms [25]. Thus, EST has been shown to affect clinical symptoms and emotional schema in people with OCD [26], and to improve emotion regulation, and social anxiety symptoms [25].

Despite the importance of diagnosing OCS in patients in order to prevent the development of symptoms into OCD, and the fact that emotion regulation disorder is one of major obstacles in controlling OCS, scant scholarly attention has been paid to this subject. Thus, in light of the advancement in the third wave of cognitive-behavioral therapies, no study has compared these therapies. Given that emotion regulation disorder could be rooted in the interpretation of childhood traumatic events and maladaptive schemas, ST can help enhance emotion regulation in mental health disorders. The importance of EST, which deals directly with emotion regulation, lies in emotional regulation processes. Therefore, this study was undertaken to compare the effect of ST and EST on emotion regulation in people with OCS. The research hypotheses of this study are as follows:

The ST and EST have varying effects on improving emotion regulation in people OCS varies. Also, since EST directly deals with how one's emotion regulation strategies and processes are affected and or influence experiences, it may be more effective than ST.

Method

This study was a semi-experimental research with a pre-test, post-test and follow-up design and a control group. The study population consisted of 24 patients with OCS who had referred to Mehregan Center in Mashhad in 2019. The sample size ($n=27$) was estimated based on the Cochran's formula and the number of clients with OCS who had referred to the counseling center over the past year. However, only 24 people, who were selected using available sampling through clinical interview based on DSM-5, agreed to participate in the study. The inclusion criteria consisted of willingness to participate, 18-40 years of age, and a minimum of a high school diploma degree. The exclusion criteria included physical illness or other psychiatric disorders, unwillingness to attend the study, and missing more than two sessions in the intervention groups. Participants were randomly divided into three groups, ST, EST, and control groups. The main data collection tools in this study were as follows:

Maudsley Obsessive Compulsive Inventory (MOCI):

This questionnaire was developed by Hudgson and

Rachman in 1977 to identify various types of OCS [27]. It is also used as a screening tool for the nonclinical population [28]. The questionnaire contains 30 true/false close-ended questions in four subscales of checking (items 2, 6, 8, 14, 15, 20, 22, 26, 28), cleaning (1, 4, 5, 9, 13, 17, 19, 21, 24, 26, 27), slowness-repetition (2, 4, 8, 16, 23, 25, 29) and doubting (3, 7, 10, 11, 12, 18, 30). Each item is assigned to a score of 0 or 1. The highest scores of the four subscales were 9, 11, 7, 7, respectively, and the total score is between 0 and 30 with higher scores indicating a higher level of obsession [27]. According to Rachman and Hodgson (1980), the convergent validity and reliability of this questionnaire were satisfactory [29]. The content validity of the Persian version of this questionnaire was confirmed by Ghasemzadeh et al. [30]. The internal consistency of the questionnaire and the subscales of checking, cleaning, slowness, repetition, and doubting were evaluated and a Cronbach's alpha of 0.78, 0.93, 0.99, 0.85, and 0.89 was obtained for these subscales, respectively.

Emotion Regulation Questionnaire (ERQ): This questionnaire was developed by Gross and John (2003) [31] to measure how people respond to emotion regulations. It contains 10 items in two subscales of expressive suppression (items 2, 4, 6, 9) and cognitive reappraisal (items 1, 3, 5, 7, 8, 10), which are scored on a 7-point Likert scale (completely disagree =1 to completely agree =7). The total score is in the range of 10 to 70 with higher scores indicating the greater adoption of emotion regulation strategies. The validity of this questionnaire has been demonstrated and its reliability has been estimated at 0.79 for cognitive reappraisal and 0.73 for expressive suppression subscales [31]. The content validity of the Persian version of this questionnaire was evaluated by Lotfi et al. for Iranian children and adolescents [32]. The internal consistency of expressive suppression and cognitive reappraisal subscales were assessed and a Cronbach's alpha of 0.93 and 0.89 were obtained, respectively.

Schema Therapy: Schema therapy based on Young's (2003) model [33] was performed in the present study on 20 individuals in 45-min sessions (once a week). The schema therapy group focused on creating a mutual and cooperative relationship, training the schema therapy procedure, assessing patient's problems, regulating

patient's problem from a schema-based approach, adopting cognitive and experimental techniques, encouraging patients to discard incompatible coping styles and ultimately convening patients to provide a list of learned skills for treatment to prevent recurrence.

Emotional Scheme Therapy: Emotional Scheme Therapy was executed based on Leahy's Model (2015) [34] on 15 individuals in 45-min sessions (once a week) in Mehregan Consulting Center in Mashhad in 2019. In this group, the emphasis was on creating a mutual and cooperative relationship, describing obsession based on emotional schema pattern, conceptualizing emotional schemas, labeling and differentiating emotions, recording the merits and drawbacks, distinguishing between emotions and actions, increasing the power of accepting feelings, performing a behavioral experiment to test misguided emotional beliefs, strengthening emotional awareness, training comprehensive review by continuities techniques, adopting dual criteria, looking at the problem from a balcony, summarizing contents, and running the post-test.

The details of schema therapy and emotional schema therapy sessions are presented in Tables 1 and 2, respectively.

The control group was in the waiting list until the end of the data collection period. At the end of the study, EST was performed for the control group. Data was collected in four stages: pre-intervention, post-intervention, one-month, and three-month follow-ups. Data analysis was carried out using SPSS-22 and MANOVA test with a confidence interval of 95% and $\alpha = 0.05$.

Results

The present study was conducted on 24 individuals with OCS in three groups of schema therapy (n=8), emotional schema therapy (n = 8), and control (n = 8). Regarding gender, 70.8% (n = 17) of the participants were female and 29.2% (n = 7) were male and the mean age of participants was 25.9 ±5.3 years old. There was no significant difference between three groups in terms of demographic information (P>0.05) (table 3). Table (4) presents the mean and standard deviation of the three groups in the four stages of pre-test, post-test and follow-up after one month and after three months.

Table 1. Content of Schema Therapy (ST) Sessions

Sessions 1 to 2	Creating a mutual and cooperative relationship, training the schema therapy procedure, obtaining informed consent, presenting the research tests
Sessions 3 to 6	Assessing patient's problems, evaluating the coping styles, regulating patient's problem due to schema based approach and filling conceptualization form of meetings
Sessions 7 to 10	Using cognitive techniques in order to doubt and discredit the dominant schemas of the patient (evidence assessment, coping evaluation, conversation between schema aspect and normal aspect, and training cards)
Sessions 11 to 15	Using experimental techniques toward patient in order to introduce the developmental roots of schemas and understand incompatible strategies to satisfy emotional needs (starting mental imagery, imaginary conversation, limited re-parenting)
Sessions 16 to 20	Encouraging patient to give up incompatible coping styles and to practice compatible coping behaviors in order to satisfy the main emotional needs and convince the patient to provide a list of learned skills for treatment and preventing from recurrence

Table 2. Content of Emotional Schema Therapy (EST) Sessions

Sessions 1 to 3	Creating a mutual and cooperative relationship, describing obsession based on emotional schema pattern, conceptualizing emotional schemas, Leahy emotional schema questionnaire, grading the wrong emotional beliefs, exposing with wrong emotional beliefs, presenting a pattern of emotion
Sessions 4 to 6	Labeling and differentiating emotions from each other, normalizing emotional experience, increasing the tolerance of mixed emotions, recording the advantages and disadvantages of the schema that "are my emotions abnormal?" or "do other people experience that emotion, too?" , increasing the power of accepting feelings, training that emotions are transient, distinguishing between emotion and action, experiencing emotion as a wave, behavioral experiment of emotional prediction, fundamental acceptance of feelings, overwhelming replication with thoughts, introducing compassionate writing
Sessions 7 to 9	Increasing the power of accepting feelings, contrasting action, adopting a position far from judgment for emotion, doing a behavioral experiment in order to test wrong emotional beliefs, investigating the resistance against identifying different origins of emotional schemas, identifying problematic responses to validation, innovating strategies and adaptive measures to compromise with discrediting, training the ways to receive social support, historical assessment of discrediting
Sessions 10 to 12	Strengthening emotional awareness, induction of emotion, emotional atmosphere, studying motion as an aim, practicing detachable mindfulness toward emotions and thoughts, practicing detachable mindfulness, going to high levels of concepts, defect of success, identifying automatic thoughts, distinguishing thoughts from feelings, vertical descent, de-disaster, using the word definition techniques, evidence assessment, playing the role of both aspects of thoughts, distinguishing behavior from personality
Sessions 13 to 15	Training comprehensive review by continuities techniques, dual criteria, looking at problem from balcony, summarizing contents, executing post-test

Table 3. Demographic Characteristics of Individuals with Obsessive-Compulsive Symptoms

Variable	Schema Therapy (ST)			Emotional Schema Therapy (EST)			control			Chi-square test result	
	n=8			n=8			n=8				
	n(%)			n(%)			n(%)				
Gender	Female	6 (75.0)			5(62.5)			6(75.0)			P=0.82
	Male	2(25.0)			3(37.5)			2(25.0)			
Education	Diploma	2(25.0)			4(50.0)			5(62.5)			P=0.42
	Associate Degree	1(12.5)			1(12.5)			0(0.0)			
	Bachelor	4(50.0)			3(37.5)			1(12.5)			
	Master's Degree	1(12.5)			0(0.0)			2(25.0)			
Age	Mean ± sd			Mean ± sd			Mean ± sd			ANOVA test result	
	24.7 ± 4.5			27.0 ± 6.0			25.9 ± 5.6			F=0.34 P=0.71	

Table 4. Mean and standard deviation of obsessive-compulsive and emotion regulation variables in individuals with obsessive-compulsive symptoms.

Variable	ST group				EST group				Control group			
	T1	T2	T3	T4	T1	T2	T3	T4	T1	T2	T3	T4
	m (sd)	m (sd)	m (sd)	m (sd)	m (sd)	m (sd)	m (sd)	m (sd)	m (sd)	m (sd)	m (sd)	m (sd)
Checking subscale	7.0 (0.9)	3.1 (1.7)	2.6 (1.4)	2.5 (1.3)	7.1 (1.1)	4.6 (1.3)	4.1 (1.9)	4.1 (1.7)	7.9 (0.3)	7.8 (0.3)	7.7 (0.4)	7.8 (0.3)
Cleaning subscale	8.0 (0.9)	3.0 (1.3)	2.6 (0.9)	2.5 (0.9)	7.9 (1.0)	5.4 (2.4)	4.5 (2.4)	4.2 (2.4)	7.6 (0.5)	7.9 (0.3)	8.0 (0.1)	8.0 (0.2)
Slowness subscale	3.8 (1.8)	3.2 (0.9)	2.6 (1.3)	2.4 (1.4)	3.1 (0.8)	2.4 (1.6)	2.1 (1.7)	2.0 (1.8)	3.1 (0.3)	3.4 (0.7)	3.5 (0.7)	3.5 (0.6)
Doubting subscale	5.2 (2.0)	2.2 (0.7)	2.0 (0.9)	1.9 (0.8)	5.7 (0.9)	3.7 (1.6)	3.5 (1.8)	3.6 (1.6)	6.2 (1.2)	6.6 (0.7)	6.6 (0.8)	6.5 (0.7)
** Total scale	25.5 (1.1)	11.2 (2.1)	9.5 (2.4)	9.2 (2.5)	24.7 (1.2)	16.0 (5.4)	14.2 (6.4)	13.9 (6.4)	24.9 (1.4)	25.6 (1.5)	26.2 (1.3)	26.2 (1.3)
Cognitive Reappraisal	17.9 (0.6)	26.7 (0.7)	27.1 (0.8)	27.0 (0.9)	18.7 (0.5)	29.6 (1.2)	30.1 (1.2)	30.2 (1.3)	19.1 (6.4)	18.9 (0.6)	19.1 (0.5)	18.9 (0.6)
expressive suppression	20.0 (0.5)	14.6 (0.9)	13.7 (0.9)	13.3 (0.8)	20.0 (1.1)	11.2 (1.3)	10.6 (1.1)	10.5 (0.9)	18.2 (0.7)	18.1 (0.6)	18.2 (0.7)	18.1 (1.0)
*** Total scale	37.9 (1.0)	41.4 (0.7)	40.9 (1.2)	40.7 (1.3)	38.7 (1.0)	40.9 (1.8)	40.7 (1.7)	40.7 (1.6)	37.4 (0.9)	37.0 (1.0)	37.4 (0.9)	37.0 (1.2)

*T1= Pre-test, T2= Post-test, T3=one-month Follow-up, T4= three- month Follow-up

** maudslay obsessive compulsive inventory (MOCAI)

*** Emotion Regulation Questionnaire (ERQ)

The level of significance in MANOVA test was determined using Pillai's trace (due to the small sample size). The direction of covariance equality of dependent variables was to use box test for all independent variables ($P > 0.05$). Pre-test scores were considered as covariate variables. The results of MANOVA showed a significant difference between the intervention and control groups in terms of OCD mean score and its subscales except for the slowness in the post-test, one-

month follow-up and three-month follow-up (Table 5).

Also, a significant difference was observed between three intervention groups and the control group in the mean score of emotion regulation scale and its subscales in the three stages of post-test, one-month follow-up and three-months follow-up (table 5). Table 6 shows the results of Bonferroni follow-up test that draws a comparison between the two groups.

Table 5. Results of MANOVA Test Analysis between Three Groups

Dependent Variable	T2				T3				T4			
	f	df	p	Parital eta	f	df	p	Parital eta	f	df	p	Parital eta
Checking subscale	24.1	2	0.001	0.7	25.1	2	0.001	0.7	26.5	2	0.001	0.7
Cleaning subscale	16.5	2	0.001	0.62	25.6	2	0.001	0.7	28.5	2	0.001	0.7
Slowness subscale	1.8	2	0.20	0.51	2.4	2	0.11	0.2	5.5	2	0.08	0.2
Doubting subscale	29.3	2	0.001	0.7	25.1	2	0.001	0.7	31.3	2	0.001	0.7
**Total scale	35.5	2	0.001	0.8	34.4	2	0.001	0.8	35.1	2	0.001	0.8
Cognitive Reappraisal	297.6	2	0.001	1.0	290.9	2	0.001	1.0	288.3	2	0.001	1.0
expressive suppression	58.0	2	0.001	0.8	88.6	2	0.001	0.9	88.5	2	0.001	0.9
***Total scale	23.0	2	0.001	0.7	13.5	2	0.001	0.6	15.5	2	0.001	0.6

Table 6. The results of post-hoc test for paired comparison with Bonferroni correction for OCD and ERQ total scale mean and their subscales in three groups of intervention and control.

Dependent Variable	ST group with EST group			ST group with Control group			EST group with Control group		
	T2	T3	T4	T2	T3	T4	T2	T3	T4
	P value	P value	P value	P value	P value	P value	P value	P value	P value
Checking subscale	0.09	0.14	0.09	0.001	0.001	0.001	0.001	0.001	0.001
Cleaning subscale	0.03	0.06	0.08	0.001	0.001	0.001	0.02	0.001	0.001
Slowness subscale	0.93	1.00	1.00	1.00	0.38	0.21	0.22	0.15	0.13
Doubting subscale	0.05	0.11	0.02	0.001	0.001	0.001	0.001	0.001	0.001
**Total scale	0.04	0.10	0.12	0.001	0.001	0.001	0.001	0.001	0.001
Cognitive Reappraisal	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
expressive suppression	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
***Total scale	0.89	1.00	1.00	0.001	0.001	0.001	0.001	0.004	0.2

Discussion

The goal of the present study was to compare the effect of ST and EST on emotion regulation in patients with OCS. The results revealed that both ST and EST methods could be effective in improving emotion regulation and OCS clinical syndromes in participants, but no treatment had a positive impact on the slowness subscale. On the other hand, the results showed that ST was more effective than EST in reducing OCD mean score and cleaning subscale in the post-test, but no significant difference was observed in the follow-up stages, suggesting that both approaches were equally effective in long term. However, both treatments were effective in reducing the mean score of doubting subscale in posttest and one-month follow-up but ST had a greater effect on reducing this subscale at the follow-up, which may indicate the sustained impact of schema therapy on this subscale. On the other hand, the results showed that EST had a greater effect than ST on decreasing the mean score of expressive suppression and increasing the mean cognitive reappraisal score, which was consistent with follow-up stages.

The present study was the first attempt to compare both ST and EST therapeutic approaches in patients with OCS. The results, in line with previous studies, illustrate the effect of EST on improving emotion regulation and

symptoms of social anxiety [25], OCD [26], depression, anxiety symptoms associated with traumatic stress disorder [35], and excitement adjustment in individuals with irritable bowel syndrome [36]. Also, the findings of a pilot study [21] regarding the effect of ST on improving emotion regulation in personality disorders [20] and reducing OCS in people with OCD are aligned with the results of the present study.

People with OCS often utilize intra-psycho-avoidance coping styles as well as early maladaptive schemas, which have a bearing on the severity of symptoms and provoke chronic symptoms [18]. One of the pillars of ST is establishing therapeutic communications by adopting empathic exposure techniques [37]. It mitigates psychological problems by focusing on early maladaptive schemas as the main cause of symptoms. Also, the distress of mental health disorders appears as dysfunctional patterns of thinking, feeling and behavior [22]. OCSs are repetitive, maladaptive and inflexible behavioral and cognitive patterns [38], which are probably influenced by parenting styles as early childhood maladaptive schemas [18]. Therefore, based on the results of the present study, it seems that ST can effectively reduce OCS by modifying these early maladaptive schemas. On the other hand, poor emotion awareness in people with OCS is a reflection of

emotional ambiguity, which results in escalated emotional distress and immediate relief of negative emotions, thereby contributing to maladaptive preventive behaviors for emotion regulation [14]. Hence, emotion rejection, impulse control disorder and impaired use of emotion regulation strategies at the time of experiencing negative emotions are common emotion regulation problems [11]. The purpose of EST is to normalize painful and difficult emotional experiences and to link emotions with personal needs and interpersonal relationships, which improve one's ability to tolerate and accept emotions [24]. A major problem in people with OCS is avoidance of negative emotions. The results of the present study suggest that although both treatments are effective in reducing OCS, EST is more effective than ST in improving emotion regulation. However, no treatment was found to influence the slowness subscale. The slowness subscale manifests the clinical experience of OCD progress due to the repetitive behaviors associated with OCS [27]. Therefore, since this slowness is a behavioral outcome of obsessive symptoms over time, it seems to provide more psychological benefits for patients and are more resistant to changes from ST and EST.

This study had a number of limitations including the small sample size, which was inevitable due to individual sessions and time constraints. Therefore, future studies are recommended to adopt a larger sample size. The ST and EST techniques can be implemented alongside other psychological and medical treatments to boost psychological well-being and enhance the functioning of people with OCS.

Conclusion

Given the high prevalence of OCS, it is essential to take measures that hamper its relapse into OCD. According to the findings, both ST and EST approaches are effective in improving OCS and emotion regulation in patients with OCS, but EST is more effective in reinforcing emotion regulation. The results of this study are particularly useful for people with OCD, as learning ST and EST techniques can help improve their emotional regulation.

Conflicts of Interest

Authors declare no conflict of interests.

Ethical Approval

All ethical principles were considered in this article. The participants were informed about the purpose of the research and its implementation stages. They were also assured about the confidentiality of their information. Moreover, they were allowed to leave the study whenever they wish, and if desired, the results of the research would be available to them.

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