



Investigating the Effectiveness of an Intervention Protocol Based on Grounded Theory on the Quality of Life and Worry of Patients with Irritable Bowel Syndrome

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ABSTRACT

The present study aimed to investigate the effectiveness of an intervention protocol based on grounded theory on the quality of life and worry of patients with irritable bowel syndrome (IBS). The research method of the present study was mixed-methods, implemented in an exploratory design with a two-phase sequential strategy. The qualitative part of the research, considering its grounded theory basis, was phenomenological based on the Strauss and Corbin (1997) theory. The quantitative part employed a quasi-experimental method with a pretest-posttest control group design and a 2-month follow-up phase. The qualitative study population included books, articles, and theses in the field of IBS patients, and IBS patients visiting the Rāh-e Ehyā Psychiatry Clinic, Shahid Tajrish Hospital, and Behboud Gastroenterology Clinic in Tehran during the fall and winter of 2022. The quantitative study population consisted of all IBS patients visiting the Rāh-e Ehyā Psychiatry Clinic, Shahid Tajrish Hospital, and Behboud Gastroenterology Clinic in Tehran during the fall and winter of 2022. In the quantitative part, 28 IBS patients meeting the inclusion criteria were randomly assigned to either the control or experimental groups. Worry was measured using the Penn State Worry Scale. After eight intervention sessions, the research data were analyzed using repeated measures ANOVA and SPSS software, with a significance level of 0.05. The interaction effect of group×time for the components of physical health ($\eta^2 = 0.157$, $P = 0.017$, $F = 4.85$), psychological health ($\eta^2 = 0.302$, $P = 0.001$, $F = 11.27$), social health ($\eta^2 = 0.234$, $P = 0.001$, $F = 7.96$), and total quality of life score ($\eta^2 = 0.362$, $P = 0.001$, $F = 14.72$) was significant. Additionally, the effect of the independent variable on worry ($\eta^2 = 0.352$, $P = 0.001$, $F = 14.15$) was significant. The results indicated that the intervention protocol designed based on grounded theory is effective in improving the quality of life and reducing worry in patients with irritable bowel syndrome.

Keywords: Irritable Bowel Syndrome, Quality of Life, Grounded Theory, Worry

1. Introduction

Functional gastrointestinal disorders are a heterogeneous group of chronic diseases considered major public health issues worldwide due to their significant prevalence and disabling nature (1, 2). Gastrointestinal disorders can be broadly categorized into organic and functional diseases, with functional disorders comprising the majority of patients with chronic gastrointestinal symptoms. The term "functional" is used to describe a disorder that affects function and causes symptoms of an organic disease, but without clear evidence of structural or physiological abnormalities. Thus, treatment for these individuals focuses on symptom management rather than cure (3, 4).

Irritable bowel syndrome (IBS) is the most common disorder within this heterogeneous group, with a high prevalence in the general population worldwide (5) and is the leading cause of referrals to gastroenterology clinics (6). IBS is characterized by chronic and recurrent abdominal pain and bowel movement disturbances. According to the Rome diagnostic criteria, patients must report abdominal pain at least one day per week (on average) associated with changes in stool frequency or form. The etiology of IBS is multifactorial and likely varies from patient to patient (7, 8).

Emphasizing the role of psychological factors, IBS is classified among somatoform disorders, which cannot be explained by structural or biochemical abnormalities. Consequently, over the past three decades, the etiology and treatment of IBS have transitioned from a reductionist biomedical perspective to a biopsychosocial approach. This perspective considers biological factors (genetic predisposition and gastrointestinal physiology), behavioral and cognitive processes, and their interactions (9).

Despite the impacts of IBS on various aspects of mental health, there is no specific treatment protocol that addresses the unique problems of these individuals. Additionally, since IBS is not a life-threatening disorder, does not require hospitalization or surgery, and does not reduce patient survival, its potential impact on daily activities and quality of life may be underestimated (10, 11). This has led to a superficial focus on depression and anxiety when examining the impact of IBS on different life aspects (12). Studies have shown that psychological interventions can have significant operational and functional effects on improving the condition of IBS patients (13-15).

By identifying the factors influencing IBS development and enhancing patient health through grounded theory, the roots of the disease can be understood, and necessary measures to reduce its effects can be taken (16). There is a lack of in-depth information on the significant effects of IBS on various aspects of patients' lives. Given the general concern for psychotherapeutic care of IBS patients, the research problem is identifying procedures and strategies to achieve an effective model for improving the condition of IBS patients (17-19). Therefore, the main objective of the present study is to develop and design an intervention protocol based on cognitive-behavioral therapy and mindfulness treatment principles, consistent with the needs and psychological status of IBS patients, derived from grounded theory and interviews. It seems that not all patients respond equally to treatment, and their needs vary depending on psychological conditions such as high stress levels, depression, worry, and anxiety. Hence, the present study aims to determine the effectiveness of an intervention protocol based on grounded theory on the quality of life and worry of IBS patients.

2. Methods and Materials

2.1. Study Design and Participants

The present study's research method was mixed-methods, implemented in an exploratory design with a two-phase sequential strategy. First, the qualitative method, followed by the quantitative method, where the results of the first phase (qualitative) informed and clarified the second phase (quantitative), shaping the model for tool development (intervention protocol). The qualitative research method, given its grounded theory basis, was phenomenological based on the Strauss and Corbin (1997) theory. The quantitative research method employed a quasi-experimental design with a pretest-posttest control group and a 2-month follow-up phase.

The qualitative study population included books, articles, and theses in the field of IBS patients, which were reviewed. It also included psychology and counseling specialists who evaluated the validity of the developed intervention protocol. Additionally, IBS patients visiting the Rāh-e Ehyā Psychiatry Clinic, Shahid Tajrish Hospital, and Behboud Gastroenterology Clinic in Tehran during the fall and winter

of 2022 were interviewed. The quantitative study population consisted of all IBS patients visiting the Rāh-e Ehyā Psychiatry Clinic, Shahid Tajrish Hospital, and Behboud Gastroenterology Clinic in Tehran during the fall and winter of 2022.

The sample size for the qualitative part included IBS patients who underwent in-depth interviews. The sampling process continued until data saturation was achieved. Thus, the qualitative sample size was determined to be 12 individuals after data saturation. In the quantitative part, based on Cohen's table, with 1 group ($u = 1$), a 95% confidence level, 0.8 test power, and an effect size of 0.4, the sample size was calculated to be 12 individuals per group. Considering overestimation, 28 IBS patients meeting the inclusion criteria were randomly assigned to either the control or experimental groups. The accessible sampling method was used in this study, identifying IBS patients visiting the Rāh-e Ehyā Psychiatry Clinic, Shahid Tajrish Hospital, and Behboud Gastroenterology Clinic in Tehran. Of these, 28 patients willing to participate were randomly assigned to experimental and control groups (14 patients in the experimental group and 14 patients in the control group). The experimental group received the developed intervention protocol in eight 60-minute sessions over eight weeks, while the control group did not receive the mentioned interventions during the study.

Inclusion criteria were informed consent to participate in the study, IBS diagnosis based on medical records, a minimum disease duration of one year, no acute or chronic physical and psychological diseases (based on health and consultation records), no concurrent psychological intervention, an age range of 25 to 45 years, ability to read and write in Persian, and no chronic illness. Exclusion criteria were more than two session absences, lack of cooperation, failure to complete assigned tasks, unwillingness to continue participation, and failure to respond to questionnaires at any post-test or follow-up stages.

To conduct the research, necessary coordination was made with the officials of Shahid Tajrish Hospital and Behboud Gastroenterology Clinic in Tehran, and permission to be present at the mentioned locations was obtained. IBS patients willing to participate in the study were identified. Written consent was obtained, and accessible sampling and

random assignment to experimental and control groups (15 patients in each group) were employed, and research questionnaires were administered. The experimental group received the developed intervention protocol in eight 60-minute sessions over eight weeks, while the control group did not receive the mentioned interventions. A two-month follow-up phase was conducted. To ensure research ethics, patient consent for intervention participation was obtained, and all intervention stages were informed. The control group was assured that they would receive the developed intervention protocol for free after the research process. Both groups were assured of the confidentiality of their information and anonymity. The intervention protocol for IBS patients in this study was developed using qualitative analysis and with guidance from supervising and consulting professors. The intervention was implemented by the researcher.

2.2. Measures

2.2.1. Quality of Life

The Quality of Life Questionnaire, developed by the World Health Organization in 1994, includes 26 items that assess four subscales: physical health, psychological health, social relationships, and environmental health, on a 5-point Likert scale from 1 = not at all to 5 = extremely. The first two items do not belong to any domain. Najat et al. (2006) reported Cronbach's alpha coefficients ranging from 0.52 to 0.84 for this tool, with significant differences between patient and healthy groups in the four domains, indicating its discriminant validity. The questionnaire's reliability was found to be 0.82 using Cronbach's alpha coefficient (11, 20).

2.2.2. Worry

The Penn State Worry Questionnaire, developed by Meyer et al. (1990), includes 16 items scored on a six-point Likert scale from 1 = not at all true to 6 = very true. Dehshiri et al. (2009) reported a Cronbach's alpha coefficient of 0.88 for this tool, with a correlation of 0.68 with trait worry. Aftab and Shams (2020) reported confirmatory factor analysis indices of 2.44 for chi-square adjusted, 0.67 for root mean square error of approximation, 0.954 for incremental fit index, and 0.954 for comparative fit index, supporting the one-factor structure and construct validity of this tool. The

reliability was found to be 0.88 using Cronbach's alpha coefficient (21, 22).

2.3. Intervention

The intervention protocol comprises eight sessions designed to address the psychological and social aspects of Irritable Bowel Syndrome (IBS) and to improve patients' quality of life and reduce worry. Each session focuses on specific themes and utilizes cognitive-behavioral therapy and mindfulness techniques. The sessions include educational content, practical exercises, and homework assignments to reinforce learning and encourage the application of skills in daily life.

Session 1: Introduction and Orientation

The first session introduces the intervention, explaining the schedule and rules of the sessions. Participants get to know each other and discuss general information about IBS, including its biological, psychological, and social effects. The session emphasizes how IBS impacts physical, psychological, and social health and provides an overview of the treatment process. Homework: Participants are asked to prepare a list of psychological factors that trigger or worsen their symptoms.

Session 2: The Impact of Stress on IBS

This session focuses on the effects of stress on IBS. It covers the causes, mechanisms, and signals involved in IBS, sources of stress (daily stressors and major life events), the role of personality in stress, belief systems, and introduces the A-B-C model. Participants learn problem-solving techniques to reduce daily stress. Homework: Participants are to record daily events using the A-B-C method and apply problem-solving skills to weekly issues.

Session 3: Cognitive Techniques for Thought Restructuring

In this session, participants learn cognitive interventions to reduce stress, such as selective awareness, self-talk, the pause and question method, and positive inner dialogue. The session covers cognitive distortions (mind reading, predicting, catastrophizing, personalization, and should thinking) and teaches techniques like defining terms, analyzing pros and cons, and evaluating evidence. Homework: Participants practice using the evidence for and against technique to address distressing thoughts about their

illness and apply problem-solving skills throughout the week.

Session 4: Understanding and Coping with Stress

Participants learn about stress definitions (by Selye and Lazarus & Folkman), stressors, stress responses, types of stress, and the relationship between stress and IBS. Techniques for stress relief, such as tension-free relaxation and symptom-control relaxation, and short-breath meditation are taught. Homework: Daily practice of tension-free relaxation, symptom-control relaxation, and breathing meditation.

Session 5: Managing Anger and Improving Interpersonal Relationships

This session covers the emotion of anger and ways to control it, including how anger operates in the body, stages of anger, main triggers (interpersonal issues, cognitive factors, health status, stress), and anger management techniques (exercise, counting, self-talk). It also teaches conflict resolution skills to improve interpersonal relationships. Homework: Use conflict resolution techniques to solve a problem and practice anger management techniques.

Session 6: Quality of Life in IBS Patients

The focus is on the concept of quality of life and its components, perceived social support, and social support networks. Participants discuss the relationship between mindfulness and quality of life and practice body scan meditation. Homework: Enhance relationships with spouses, family members, and friends in person or by phone, and practice body scan meditation throughout the week.

Session 7: Worry about Pain, Distress Tolerance, and Depression

Participants explore concerns related to IBS symptoms (pain worry), low distress tolerance, and depression related to IBS and serotonin. Techniques for seated meditation with awareness of breath and body and mental imagery are introduced. The session discusses the link between IBS and depression, serotonin's role in gastrointestinal function, and cognitive techniques for reducing depression. Homework: Engage in joyful activities weekly, suitable to individual capabilities, and practice seated meditation to reduce worry.

Session 8: Session Summary and Conclusion

The final session summarizes all sessions, emphasizing emotional acceptance and self-care. Participants are

encouraged to take control of their lives and to continue using the learned techniques for maintaining mental health and reducing worry. A post-test is conducted. Homework: Apply learned techniques in daily life.

2.4. Data Analysis

After eight intervention sessions, the research data were analyzed using repeated measures ANOVA and SPSS software, with a significance level of 0.05.

3. Findings and Results

The mean age of participants in the experimental group was 29.50 years with a standard deviation of 7.78 years, while in the control group, the mean age was 32.36 years with a standard deviation of 6.02 years. An independent t-

test showed no significant difference between the two groups regarding age. In the experimental group, there were 9 women and 5 men, and in the control group, there were 7 men and 7 women. Pearson's chi-square test indicated no significant difference between the two groups concerning gender. In the experimental group, 6 participants were single, 7 were married, and 1 was divorced. In the control group, 6 participants were single, 6 were married, and 2 were divorced. Fisher's exact test showed no significant difference between the two groups regarding marital status. In the experimental group, 1 participant had a high school diploma, 8 had bachelor's degrees, and 5 had master's degrees. In the control group, 2 participants had high school diplomas, 8 had bachelor's degrees, and 4 had master's degrees. Fisher's exact test indicated no significant difference between the two groups regarding education level.

Table 1

Mean (Standard Deviation) of Quality of Life and Worry in Three Phases: Pre-test, Post-test, and Follow-up

Variable	Component	Group	Pre-test	Post-test	Follow-up
Quality of Life	Physical Health	Experimental	17.86 ± 3.68	24.00 ± 4.42	23.36 ± 3.52
		Control	17.29 ± 3.32	18.14 ± 4.02	17.64 ± 3.20
	Psychological Health	Experimental	17.64 ± 4.20	22.57 ± 2.65	21.93 ± 2.20
		Control	16.93 ± 3.77	16.21 ± 3.56	16.64 ± 3.25
	Social Relationships	Experimental	7.00 ± 2.15	10.29 ± 2.56	10.57 ± 2.38
		Control	7.71 ± 2.40	7.50 ± 2.10	7.64 ± 1.99
Environmental Health	Experimental	26.57 ± 6.25	29.43 ± 4.47	28.36 ± 4.05	
	Control	25.64 ± 6.43	26.00 ± 3.33	25.21 ± 3.60	
Total Score	Experimental	69.07 ± 12.14	86.29 ± 7.01	84.21 ± 5.79	
	Control	67.57 ± 7.29	67.86 ± 6.51	67.14 ± 7.46	
Worry	Experimental	46.29 ± 10.11	35.00 ± 5.48	36.21 ± 5.49	
	Control	45.21 ± 11.00	46.00 ± 6.85	46.50 ± 7.72	

Table 2 shows that the group × time interaction effect was significant for the components of physical health ($\eta^2 = .157$, $p = .017$, $F = 4.85$), psychological health ($\eta^2 = .302$, $p = .001$, $F = 11.27$), social relationships ($\eta^2 = .234$, $p = .001$, $F = 7.96$), and total quality of life score ($\eta^2 = .362$, $p = .001$, $F =$

14.72). The effect of the independent variable on worry was also significant ($\eta^2 = .352$, $p = .001$, $F = 14.15$). It should be noted that the group × time interaction effect was not significant for the environmental health component.

Table 2

Results of Mixed ANOVA in Explaining the Effect of the Independent Variable on Quality of Life and Worry Factors

Dependent Variable	Effects	Sum of Squares	Error Sum of Squares	F	p	η^2
Physical Health	Group Effect	344.05	396.43	22.57	.001	.465
	Time Effect	120.07	333.36	9.37	.005	.265
	Group × Time Interaction	126.95	680.29	4.85	.017	.157
Psychological Health	Group Effect	356.30	580.02	15.97	.001	.381
	Time Effect	56.00	181.86	8.01	.009	.235
	Group × Time Interaction	125.74	290.05	11.27	.001	.302

Social Relationships	Group Effect	58.33	207.14	7.32	.012	.220
	Time Effect	42.88	100.18	11.13	.003	.300
	Group × Time Interaction	59.60	194.71	7.96	.001	.234
Environmental Health	Group Effect	131.25	1116.31	3.06	.092	.105
	Time Effect	6.45	479.89	0.35	.560	.013
	Group × Time Interaction	26.21	713.33	0.96	.352	.035
Total Score	Group Effect	3194.33	2771.62	29.97	.001	.535
	Time Effect	757.79	1387.57	14.20	.001	.353
	Group × Time Interaction	1238.74	2187.38	14.72	.001	.362
Worry	Group Effect	953.44	3792.79	6.54	.017	.201
	Time Effect	270.16	847.89	8.28	.008	.242
	Group × Time Interaction	642.17	1180.29	14.15	.001	.352

The results in Table 2 show significant correlations between attachment styles, loneliness, cognitive emotion regulation, and social anxiety. Specifically, there is a significant negative correlation between secure attachment style and social anxiety among the subjects. Positive significant correlations were found between avoidant and anxious-ambivalent attachment styles, loneliness, and social anxiety (including fear of negative evaluation, social avoidance and new distress, social avoidance and general distress) among the subjects.

4. Discussion and Conclusion

The present study aimed to evaluate the effectiveness of an intervention protocol based on grounded theory on depression, worry, and stress in patients with irritable bowel syndrome (IBS). The results showed that the intervention protocol designed based on grounded theory was effective in improving the quality of life and reducing worry in patients with IBS.

In explaining the effectiveness of the intervention protocol on the quality of life of patients, it can be stated that the protocol considered the control and management of emotions, both physical and mental aspects, allowing the individual to become fully aware of their thoughts and feelings (10, 17). The first explanation is based on the premise that improving and managing stress reduces IBS symptoms, leading to simultaneous improvement in quality of life and general health. Another hypothesis is that reducing stress and mental turmoil increases general health, which, in turn, improves the quality of life for IBS patients. Thus, a reciprocal relationship between quality of life and general health can be considered (13, 16).

The second explanation for the effectiveness of the protocol on stress in IBS patients is that stress caused by IBS

can lead to irrational thoughts and beliefs about health (e.g., thoughts of having cancer and catastrophizing symptoms). This mental state, where the individual loses awareness of their thoughts, behaviors, emotions, and feelings, and lacks presence in the moment, losing what is termed mindfulness, can be detrimental (10). Mindfulness, as employed in the present protocol, allows individuals to detach from all internal and external shortcomings, view themselves and their surroundings more broadly, and approach life's challenges with a sense of liberation and compassion (16, 17). Mindfulness enables patients to focus consciously on the present moment and accept unpleasant events and negative emotions as integral parts of life, finding the best ways to deal with adverse events (18).

In explaining the effectiveness of the intervention protocol on depression and worry in IBS patients, it appears that these issues stem from irrational thinking, incorrect inferences, abnormal thoughts, and inadequate learning (1). Inability to control and direct attention and avoidance of worry-provoking stimuli are prominent symptoms of worry (10, 14). A significant symptom of depression is feeling overwhelmed and ruminating on problems. The designed intervention protocol helps depressed patients look back and see what has influenced their depression (e.g., cognitive distortions) and how they can change these using cognitive restructuring methods. Since unpleasant events are not the sole cause of negative emotional responses, but rather how individuals think and mentally organize these upsetting events, this approach targets dysfunctional thoughts and beliefs and maladaptive cognitive processes and themes, using learned, explicit, and goal-directed techniques to treat depression (1, 13).

Overall, training in the techniques of the designed intervention protocol based on grounded theory encourages

individuals to practice focused attention on neutral stimuli and intentional awareness of body and mind, freeing them from preoccupation with threatening thoughts and worries about their performance in life. Thus, patients who received the designed intervention protocol based on grounded theory learned to be less affected by their negative thoughts and emotions. By accepting the pain and suffering caused by the disease instead of ruminating or avoiding it, they were able to confront their illness and evaluate disease-related events more positively, improving their quality of life. Behavioral stress management strategies such as relaxation and calming helped reduce tension and worry in IBS patients, improving their quality of life. Finally, patients who received the intervention protocol based on grounded theory demonstrated more problem-solving skills in the face of stress and pressures, and unique adaptability to overcome risks. Additionally, coping and problem-solving skills training enabled patients to respond adaptively, increasing their abilities and reducing the demands of stressful situations (problem-focused strategy).

Authors' Contributions

Y.G.A. conceptualized the study, designed the research methodology, and supervised the overall project implementation. M.S. conducted the qualitative analysis based on the grounded theory method, facilitated data collection from books, articles, and patient interviews, and contributed to the development of the intervention protocol. K.A.A. coordinated the quantitative study, managed the random assignment of participants to control and experimental groups, and oversaw the implementation of the intervention sessions. M.A. assisted with data analysis using repeated measures ANOVA, interpreted the statistical results, and contributed to drafting and revising the manuscript. All authors participated in discussing the findings, critically reviewed the manuscript for important intellectual content, and approved the final version for publication.

Declaration

In order to correct and improve the academic writing of our paper, we have used the language model ChatGPT.

Transparency Statement

Data are available for research purposes upon reasonable request to the corresponding author.

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Declaration of Interest

The authors report no conflict of interest.

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Ethics Considerations

This study is part of Yasamin Ghorbani Ashin's doctoral dissertation in Health Psychology, supervised by Dr. Mohammad Reza Sayarfi at the Islamic Azad University, UAE Branch. It is registered with the National Ethics Committee in Biomedical Research under code IR.IAU.AHVAVZ.REC.1400.163 and funded by personal resources. The study placed a high emphasis on ethical considerations. Informed consent obtained from all participants, ensuring they are fully aware of the nature of the study and their role in it. Confidentiality strictly maintained, with data anonymized to protect individual privacy. The study adhered to the ethical guidelines for research with human subjects as outlined in the Declaration of Helsinki.

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