

## ORIGINAL ARTICLE

# Effects of Self-Management Education on Self-Efficacy and Quality of Life in Patients with Ulcerative Colitis: A Randomized Controlled Clinical Trial

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## ABSTRACT

**Background:** Self-management (SM) as a dynamic process enables Ulcerative colitis (UC) patients to live with this chronic illness. The present study aimed to investigate the effect of SM education on self-efficacy (SE) and quality of life (QoL) in patients with UC.

**Methods:** This randomized controlled clinical trial study was conducted on 64 patients with UC from December 2016 to February 2017 at Motahari clinic, Shiraz. Patients were randomly divided into two groups of intervention and control. The education program included six 90-minute sessions in 3 weeks and one month telephone follow-up. Before, immediately and one month after the intervention, the participants filled out the Strategies Used by People to Promote Health (SUPPH) for SE, and the Inflammatory Bowel Disease Questionnaire-9 (IBDQ-9) for QoL. Then, data were entered into SPSS 18.0 and analyzed using independent samples t-test, Chi-square, repeated measures ANOVA and Pearson's correlation coefficient.

**Results:** A significant increase was observed in terms of the overall mean score for SE and its dimensions in the intervention group ( $P < 0.001$ ). These scores were significantly higher than those of the control group ( $P < 0.001$ ), except for positive attitude ( $P = 0.15$ ). The scores for overall QoL and its dimensions significantly increased in the intervention group immediately and one month after the intervention ( $P < 0.001$ ), and the difference between the two groups was significant ( $P < 0.001$ ). There was a significant positive correlation between SE and QoL ( $r = 0.32$ ,  $P = 0.01$ ).

**Conclusion:** SM improved the SE and QoL in patients with UC. SM education is recommended in nursing care of patients with UC.

**Trial Registration Number:** IRCT2016092429823N1

**KEYWORDS:** Quality of life, Self-efficacy, Self-management, Ulcerative colitis

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## INTRODUCTION

Inflammatory bowel disease (IBD) is a chronic inflammatory disease of the gastrointestinal tract, including ulcerative colitis (UC) and Crohn's disease.<sup>1,2</sup> UC is an idiopathic, chronic inflammatory disorder of the colonic mucosa. Its main symptoms include diarrhea, rectal bleeding and abdominal pain. Systemic features like fever, fatigue and weight loss are common if all or most of the colon is involved. Most commonly, UC follows a chronic intermittent course with periods of remission interspersed with relapse lasting for weeks or months. Patients with UC have reported to experience exacerbation of symptoms prior to remission.<sup>3</sup> Although the exact cause of UC has not been identified, it can be said that a combination of genetic, immunological and environmental factors are at play.<sup>4</sup> The prevalence and incidence of IBD has increased worldwide.<sup>5</sup>

In a study conducted in Iran, the annual incidence of UC was reported 3.11 per 100,000 people. This study also showed an annual prevalence of 40.67 per 100,000 people with the mean age of 32.8 years for individuals with UC.<sup>6</sup> Even though IBD has low death rate, it still causes serious pain and disability, especially in young adults.<sup>7</sup> People with UC suffer a distinct loss of Quality of life (QoL), which is usually due to unpredictable recurrence periods and frequent fluctuations in the severity of physical symptoms.<sup>8</sup> Moreover, patients with UC have a significantly lower health-related QoL than the general population.<sup>9</sup>

Some studies have shown that Self management (SM) education can increase the QoL by improving health and the outcomes in patients with IBD.<sup>10, 11</sup> SM encourages the patients to actively participate in their self-care process and become more responsible in managing the symptoms and complications; this would help the individuals to maintain their independence to a degree and improve their functionality.<sup>12</sup> Since education is the key element in inspiring the patient to participate and earn his/her trust, it would

be more effective if it is combined with SM skills. Thus, it as an important duty to develop such a program to help the patients reach their maximum capability and Self-efficacy (SE).<sup>13</sup>

According to Bandura's theory, SE refers to a person's ability to perform self-care behaviors. Furthermore, this theory introduces SE as an important prerequisite for successful SM and behavior modification. SE leads to better SM, increases life expectancy, and modifies health behaviors. Improved SE is associated with management of signs, treatment, physical outcomes and psychosocial influences in chronic patients. Overall, SE is an important concept in managing chronic diseases.<sup>14, 15</sup>

Numerous studies have confirmed the usefulness and efficiency of SM training programs in chronic diseases,<sup>10, 16, 17</sup> especially in patients with chronic metabolic disease<sup>18</sup> and cirrhotic patients.<sup>14</sup> Other studies have shown that SM training programs can increase the QoL in patients with chronic illnesses.<sup>10, 19</sup> For example, a higher family-oriented SM scores were significantly associated with improved QoL in individuals with type 2 diabetes.<sup>20, 21</sup> Another study showed that SE and depression were the predictors of the health related QoL in outpatients with congestive heart failure.<sup>22</sup> Despite the mentioned studies, little is known about SE in UC patients and the relationship between SE and QOL. In addition, the chronic nature of UC, possible hospitalization, frequent visits to the physician, the complications of medication or surgery, and sometimes obscure information and misunderstanding of the disease seriously impairs the QoL of these patients.<sup>23</sup> Hence, we aimed to investigate the effect of SM education on the SE and QoL in patients with UC, hoping to take an important step toward better QoL for these patients and lay the foundation for further research in this field.

## MATERIALS AND METHODS

In this single-blind randomized controlled clinical trial, 84 UC patients who had referred

to gastrointestinal clinic of Motahari Clinic, Shiraz, Iran, which is the main referral center for gastrointestinal diseases in southern Iran, were recruited. Data were collected from December 2016 to February 2017. Patients who met the inclusion criteria were selected through convenient sampling. They were acquainted with the objectives of the study and signed a written informed consent. Then, they were divided into two groups of 42 by block randomization. To perform the division, (conventionally) the intervention group and control group were named A and B. Then, 84 numbers of the random numbers table were selected by computer; if the first number was between 0 to 4 it was identified as A (intervention group), and first numbers from 5 to 9 were identified as B (control group). Eventually, the status of 1 to 84 was identified for each group. The intervention group received SM training, while the control group received the routine care and management. Inclusion criteria were confirmed UC diagnosis by a specialist according to colonoscopy and pathology reports, age over 18 and under 65, understanding Persian language, possibility to communicate via telephone, willing to participate, lack of other chronic diseases, being a resident of Shiraz or being capable of attending the sessions, and lack of confirmed mental disease according to patients and their families. The exclusion criteria included the presence of acute illnesses, absence from more than two training sessions, and lack of willingness to continue cooperation during the course of research. Sample size was determined as 64 (32 individuals per group), based on data from a study conducted in Los Angeles in 2012 by Labus et al.,<sup>24</sup> considering a type I error of 0.05 and a power of 0.9 using the following formula in the Power SCC software:

$$n = \frac{\left( z_{1-\frac{\alpha}{2}} + z_{1-\beta} \right)^2 \sigma^2}{d^2}$$

$$d = \mu_1 - \mu_2 = 12.6 - 10.1 = 2.5$$

$$\sigma^2 = (s_1^2 + s_2^2) = (3.7^2 + 4.2^2) = 31.33$$

$$\text{Power} = 1 - \beta = 0.9(90\%)$$

$$\alpha = 0.05 \quad \beta = 0.1$$

The sample size was then raised to 84 individuals (42 per group) in order to compensate for exclusions or any other possible reasons. Overall, 95 patients met the inclusion criteria, but 5 of them were excluded because they did not reside in Shiraz, and 6 were unwilling to participate. Therefore, this study was initially run with 84 participants who met the inclusion criteria. Nevertheless, 20 patients (10 in each group) were later excluded due to various reasons, such as lack of willingness to continue cooperation, disease recurrence, migration and absence for more than two training sessions. Eventually, a total of 64 individuals (32 per group) participated in our study. CONSORT diagram shows the study participants (Figure 1).

After obtaining approval from the local ethics committee (IR.SUMS.REC.1395.8), the researcher visited the gastrointestinal center at Motahari Clinic. After obtaining permission from the authorities, 84 patients were selected through convenient sampling. The patients were assured of the confidentiality of their information and were given the right to withdraw from the study at any time during the course of research. Numerical codes and general data were used to maintain anonymity; the data were entered into SPSS version 18 and analyzed by one who was blind to the groups. Next, the participants filled out the demographic information, SE and Qol questionnaires. Demographics information included age, gender, marital status, education, occupation, housing conditions (rent/own), history of addiction, and duration of the disease. SM was considered as an independent variable in this study and dependent variables were SE and Qol. SE was evaluated using Strategies Used by People to Promote Health (SUPPH). This questionnaire was first created in 1996 by Lev et al.<sup>25</sup>

Lev et al. stated that the items of SUPPH were empirically generated, validated by an expert panel, and tested (N=275) for psychometric properties, factor composition, and convergent and discriminant evidence with the existing scales. The SUPPH was

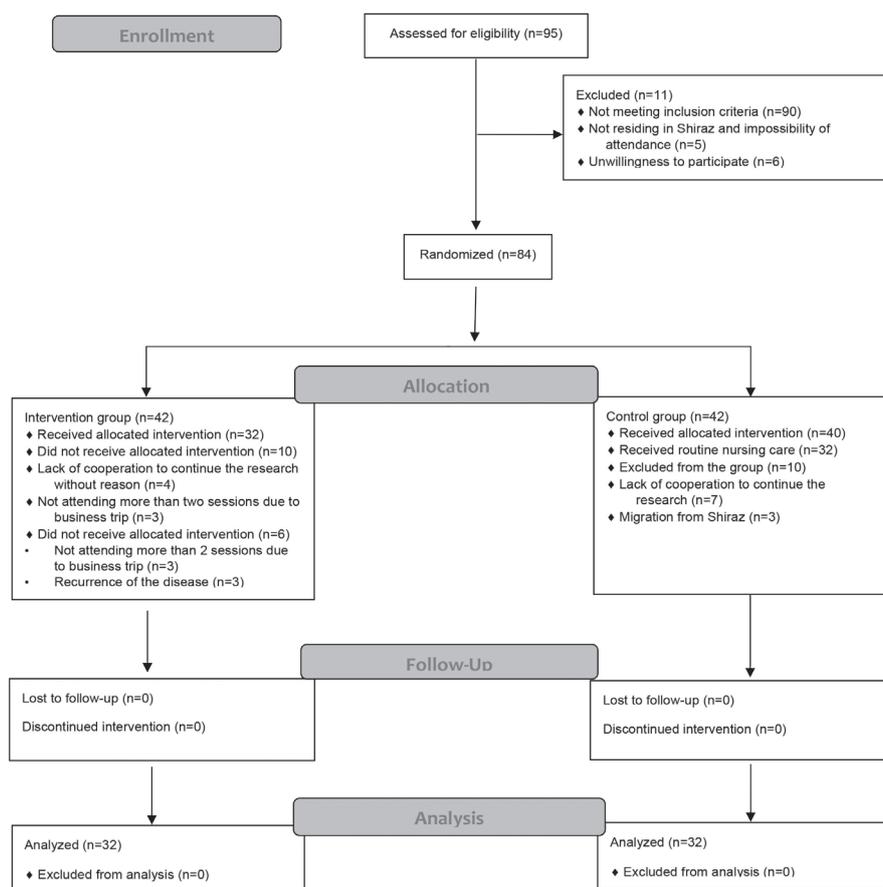


Figure 1: CONSORT flow diagram of the participants

correlated with HBS (Health Behavior Scale) at 0.61 ( $P<0.001$ ), and with the RGEI (Revised Grief Experience Inventory) at 0.38 ( $P<0.01$ ). Thus as hypothesized, the higher one's self-care, self-efficacy, the more positive were his/her health beliefs and the less grief was experienced.<sup>25, 26</sup> Good initial psychometric properties were found for the SUPPH, and four factors emerged: coping, stress reduction, making decision and enjoying life with exploratory factor analysis. Four factors explained 81% of the item covariation. These factors are consistent with the underlying SE theory, upon which the scale is based. Correlations among the factors ranged from 0.27 (between Enjoying Life and Making Decisions) to 0.56 (between Stress Reduction and Coping). Factor internal consistency estimates were high, ranging from 0.76 to 0.92. The reliability of stress relief, decision making and positive attitude dimensions in the original form was approved by Cronbach's alpha coefficients

of 0.89, 0.83, and 0.92.<sup>26</sup> The new version of the questionnaire consisted of 29 questions and three domains of positive attitude (16 questions), stress reduction (10 questions), and decision making (3 questions) using Likert scale (5 options) from very low to very high for scoring. The maximum score is 145 and minimum is 29; higher scores indicate higher SE.<sup>26</sup> In a previous study by Moatari et al. in Shiraz, the validity of the questionnaire was approved as the questionnaire was translated into Persian and back-translated into English to ensure its validity, which was further confirmed by a panel of experts. Then, its reliability was confirmed by Cronbach's alpha (0.91): for stress reduction 0.79, the decision 0.80, and the positive attitude 0.87.<sup>27</sup>

In this study, QoL was assessed using the short form of the Inflammatory Bowel Disease Questionnaire (IBDQ-9). The questionnaire was developed by casellas et al., from the original version (34 questions). Its short version is similar to the original questionnaire and

evaluates four dimensions of gastrointestinal disorders, systemic, emotional, and social symptoms through 9 items. Each score is answered with a rating scale from 1 to 7 (worst to best condition) scores ranging from 1 to 63, with higher scores indicating better QoL.<sup>28</sup> Gholamrezaei et al. conducted a study entitled “linguistic validation of the (IBDQ) – Short Form (IBDQ-9) in an Iranian population”. Reliability was confirmed and Chronbach’s alpha was obtained as 0.75 for all patients, and 0.77 and 0.76 for patients with UC and Crohn’s disease, respectively. As to the construct and discriminant validities, the IBDQ-9 and its subscales were correlated to SF-36 total and subscale scores and disease activity indices and HADS (Hospital Anxiety and Depression Scale) score, respectively. The Cronbachs’ alpha coefficient of the IBDQ-9 was 0.76. There was a significant correlation between the IBDQ-9 score and SF-36 total ( $r=0.524$ ,  $P<0.001$ ) and subscale scores ( $r=0.476$  to  $0.541$ ,  $P<0.001$ ). Also, there was a significant correlation between the IBDQ-9 score and CDAI (crohn’s disease activity index) ( $r=-0.424$ ,  $P=0.025$ ), UCAI (Ulcerative colitis activity index) ( $r=-0.530$ ,  $P<0.001$ ), depression ( $r=-0.417$ ,  $P<0.001$ ) and anxiety ( $r=-0.362$ ,  $P<0.001$ ) scores.<sup>29</sup> In an investigation that compared the effect of the clinical and endoscopic activity of IBDQ-9, the authors used two questionnaires: the IBDQ-36 and its shortened version IBDQ-9; they found that IBDQ-9 had a good correlation with disease activity evaluated with clinical indexes. The correlation was better for UC than for CD (Crohns Disease). They concluded that HRQOL (Health Related Quality Of Life) might be equally appropriately assessed with the shortened questionnaire as with the conventional IBDQ-36. According to the present study, IBDQ was the most often used tool for assessing QoL in patients with IBD.<sup>30</sup>

SM training was carried out in Motahari clinic’s conference hall, in six 90-minute sessions held twice a week. During the first three sessions, the patients received the necessary information about their

disease (symptoms, diagnosis, treatment, complications, diet and medication) from the researcher. During the second and third sessions, they received education and practice of problem-solving; decision-making techniques; cognitive therapy techniques; and topics related reinforcement of positive abilities by the co-researcher. In the course of these sessions, cognitive errors were discussed and examples provided. Then based on bandura theory, the patients were encouraged to express their emotions and experiences in regard to the disease, during which their cognitive errors were identified and discussed. It is worth mentioning that 15 minutes of each session was allocated to education and practice of muscle relaxation exercises. Educational materials were collected from textbooks, designed according to the patients’ culture, beliefs and knowledge levels, and presented in simple and understandable words. The educational intervention was performed through lecture, group discussion and question and answer. Furthermore, the learning process was facilitated by the use of Power Points, slides and educational pamphlets. During the study, the control group received the routine training; however, educational pamphlets were distributed among the control group at the end of the study. All patients filled out the QoL and SE questionnaires immediately and one month after the intervention under the researcher’s supervision in the conference hall of Motahari clinic. Data analysis was done using SPSS version 18.0. The kolmogorov smirnov test showed normal distribution of the data. Independent t-test and the Chi-square test were used to evaluate the inter-group differences concerning demographic characteristics. Moreover, the two groups were also compared using the repeated measures ANOVA. Pearson’s correlation coefficient was used to assess the relationship between the variables of QoL and SE.  $P<0.05$  was considered statistically significant. It should be noted that data analysis was performed by one individual with no prior knowledge of the two groups’ backgrounds.

## RESULTS

The results of the Chi-square test did not reveal any statistically significant differences between the groups as to the qualitative demographic variables at baseline ( $P>0.05$ ) (Table 1). The mean score of age was  $43.83\pm 8.63$  in the intervention group and  $43.19\pm 12.51$  in the control, with no statistically significant difference by the independent samples t-test ( $P>0.05$ ). Before the study, the difference between the mean overall SE scores of the intervention and control groups was not statistically significant ( $P=0.15$ ). Results of the ANOVA related to the overall SE score and dimensions of stress relief and decision-making revealed a statistically significant difference between the two groups both immediately and one month after the intervention ( $P<0.001$ ); however, this difference was not statically significant for the dimension of positive attitude either immediately or one month following the intervention ( $P=0.15$ ) (Table 2).

Furthermore, no significant differences were observed between the groups as to the score for Qol before the intervention ( $P=0.38$ ). The repeated measures ANOVA indicated statistically significant differences between the groups regarding the scores of the Qol and its four dimensions immediately and one month after the intervention ( $P<0.001$ ) (Table 3). Results of the Pearson's correlation coefficient showed a significant positive correlation between SE and Qol in patients with UC ( $r=0.32$ ;  $P=0.01$ ).

## DISCUSSION

The results of the present study showed that SM education could have positive effects on the scores for SE and all its dimensions in patients with UC. Our findings were consistent with the results of a study on cirrhotic patients, which reported significant increases in the overall and dimension-based scores for SE in the experimental group immediately and one

**Table 1:** Socio-demographic characteristics of participants in the intervention (n=32) and control groups (n=32)

Socio-demographic characteristics		Intervention N (%)	Control N (%)	Intervention N/A <sup>a</sup>	Control N/A <sup>a</sup>	P value
Gender	Female	16 (50)	15 (46.9)			0.8*
	Male	16 (50)	17 (53.1)			
Marital status	Single	4 (12.5)	9 (28.1)			0.13*
	Married	28 (87.5)	22 (68.8)			
	Widowed	0 (0)	1 (3.1)			
Education level	Primary school	12 (37.5)	11 (34.4)			0.33*
	Middle school	8 (25)	4 (12.5)			
	High school and above	12 (37.5)	17 (53.1)			
Employment status	Governmental	8 (25)	10 (32.3)	0	1	0.79*
	Non governmental	12 (37.5)	8 (25.8)			
	Unemployed	1 (3.1)	1 (3.2)			
	Housewife	11 (34.4)	12 (38.7)			
Housing situation (rent/own)	Personal	17 (54.8)	22 (68.8)	1	0	0.26*
	Leasing	14 (45.2)	10 (31.1)			
Addiction history	Cigarette	1 (3.2)	3 (9.4)	1	0	0.85*
	Other cases	2 (6.5)	2 (6.2)			
	No addiction	28 (90.3)	27 (84.4)			
Duration of illness	1-10 years	14 (45.2)	18 (56.3)	1	0	0.25*
	11-20 years	13 (42)	14 (43.7)			
	21-30 years	2 (6.4)	0 (0)			
	More than 30 years	2 (6.4)	0 (0)			

<sup>a</sup>None answered; \*Chi-square test

**Table 2:** Comparison of the mean changes in Self-Efficacy at baseline, immediately after and one month after the intervention between the intervention and control groups.

Variables	Time Group	Baseline (mean±SD)	Immediately after the intervention (mean±SD)	One month after the intervention (mean±SD)	P value	
					Within group*	Between group*
Total SE <sup>a</sup>	Intervention	101.22±21.1	109.47±17.98	119.31±14.68	0.001	<0.001
	Control	94.25±17.79	95.81±9.79	94.22±15.42	0.64	
Stress reduction	Intervention	31.44±9.36	35.3±7.01	39.56±7.25	<0.001	<0.001
	Control	28.34±7.6	28.88±7.12	27.84±7.17	0.62	
Decision making	Intervention	9.63±3.17	10.75±2.67	12.38±1.82	<0.001	<0.001
	Control	8.69±3.20	8.72±3.15	7.94±2.24	0.08	
Positive attitude	Intervention	60.16±11.49	63.34±10.87	67.38±9.23	0.009	0.15
	Control	57.22±9.42	58.22±10.32	58.44±8.59	0.68	

<sup>a</sup>Self-efficacy; \*Repeated measurement ANOVA

**Table 3:** Comparison of the mean changes in the QoL at baseline, immediately after and one month after the intervention between the intervention and control groups

Variables	Time Group	Baseline (mean±SD)	Immediately after the intervention (mean±SD)	One month after the intervention (mean±SD)	P value	
					Within group*	between group*
Total QoL	Intervention	37.53±7.61	44.69±5.04	55.19±5.92	<0.001	<0.001
	Control	39.03±5.97	38.56±6.27	38.22±6.02	0.76	
Bowel symptoms	Intervention	17.69±4.70	20.03±3.86	23.44±4.03	<0.001	<0.001
	Control	18.25±4.29	18.13±4.33	18.03±4.20	0.88	
Systemic symptoms	Intervention	12.25±3.25	14.78±2.94	18.34±3.10	<0.001	<0.001
	Control	12.69±3.16	12.53±3.16	12.41±3.08	0.92	
Emotional function	Intervention	3.69±1.25	4.81±1.28	5.56±0.8	<0.001	<0.001
	Control	3.97±0.89	3.87±0.87	3.81±0.89	0.58	
Social functional	Intervention	3.91±1.27	5.06±1.13	6.84±0.36	<0.001	<0.001
	Control	4.13±1.23	4.03±1.20	3.97±1.15	0.84	

\*Repeated measurement ANOVA

month after the intervention.<sup>14</sup> The results were also in the same line with those of the studies that had emphasized the role of education in increasing SE in chronic diseases,<sup>16, 31, 32</sup> and effectiveness of a family-oriented SM program in improving SE,<sup>20</sup> which was consistent with our findings. Also, it was reported that diabetes self-management was positively associated with diabetes self-efficacy.<sup>21</sup>

On the contrary, a study showed that SM education was not able to improve SE in patients having undergone heart surgery, which seems to be due to the limited data on the patient's history. If they had taken a more objective approach with longer follow-up periods, they might have reached different results.<sup>33</sup> Our study showed the SM training

caused a statistically significant increase in overall and dimension-based scores for SE in the intervention group; no statistically significant differences were observed between the groups in the dimension of positive attitude. An explanation in this regard could be that the control group had received information related to positive attitude from other sources, which resulted in their high scores for this dimension. In line with this finding, a study reported significant differences between groups in terms of the mean score for overall SE and the dimension of decision-making; however, this difference was not significant in the dimensions of stress relief and positive attitude, which were both attributed to the small sample size.<sup>27</sup> In the mentioned research,

the sample size was estimated 64 individuals to avoid such issues. Furthermore, the patients performed Jacobson's progressive muscle relaxation technique, which could have been influential in reducing the patients' stress levels. In our study, we also used relaxation technique at the beginning of each session. Relaxation techniques can generally increase SE and reduce the psychosocial burden in the case of chronic diseases.<sup>14</sup> The other study reported that in patients with implantable cardioversion defibrillator self-care improved through self relaxation.<sup>34</sup>

Furthermore, according to our results, SM education had positive effects on the scores for overall QoL and its four dimensions both immediately and one month after the intervention, which is consistent with the results of the studies emphasizing the role of psycho-educational intervention more specifically SM education in increasing QoL in chronic diseases.<sup>10, 16, 17, 35, 36</sup> In line with our study, another study showed the effect of SM in improving the QoL of diabetic patients.<sup>20</sup> In contrast to the results obtained by this study, as well as the aforementioned studies, a research on the effectiveness of a SM exercise intervention in patients with venous leg ulcers showed that the intervention could not improve the patients' physical functionality and QoL. The researcher attributed these results to the intervention period that wasn't long enough to significantly affect the health related quality of life; also, the questionnaire for measurement of quality of life needs to be disease-specific.<sup>32</sup> In our study, we used IBD questionnaire that may explain this difference. In the present study, although correlation between QoL and SE was not highly positive, it was significant. In this regard, there are many studies that were consistent with our findings.<sup>37, 38</sup> Another study stated that men with prostate cancer who had the lowest SE had lower mean health related QoL scores.<sup>39</sup> Therefore, to improve the QoL, we can plan toward increasing their SE. It is believed that the shared experience amongst patients is the most important factor of SM, while considering poor communication with

healthcare providers and lack of knowledge as barriers to a SM program.<sup>40</sup> Moreover, it was stated that by reinforcing positive abilities in patients, the healthcare providers can play an important role in the SM capability of patients with IBD.<sup>11</sup> As an educational intervention, effective SM would only be possible when the patient-nurse relationship is continuous; therefore, the present study aimed to increase the patients' knowledge and support for effective communication with the nursing staff by engaging them in group discussions and reinforcing their positive abilities. Overall, our study in line with the mentioned studies showed the effect of SM education on SE and QoL. In addition we considered psychological aspects and some cognitive therapies in our patients. Therefore, we can design and implement SM training programs as part of our treatment strategy for UC.

A limitation of this study was the short follow up after the intervention, specially for changing the QoL. Thus, we recommend that future studies consider this factor and plan for longer periods of follow-up.

## CONCLUSION

The results of the current study indicate the positive impact of SM education program on SE in patients with UC. Furthermore, SM training was effective in reducing physical, psychological and social problems, and consequently increasing the QoL among patients. Nevertheless, there is still need for further research on this subject with longer follow-up periods.

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**Conflict of Interest:** None declared.

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