

ORIGINAL ARTICLE

# Effectiveness of educational intervention carried out by clinical pharmacists for the quality of life of patients with irritable bowel syndrome: A randomized controlled trial

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## Key words

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## Introduction

Irritable bowel syndrome (IBS) is a pathology with gastrointestinal symptoms, such as abdominal pain, bloating, and flatulence. Although IBS is quite common, its diagnosis and treatment are relatively difficult. Although IBS does not lead to death, it affects the daily life, labor, study, and quality of life of patients. In an epidemiological study conducted in the United Kingdom, about 11% of the global population is affected by IBS,<sup>1</sup> and in the United Kingdom, 10–12% of the population are diagnosed with IBS.<sup>2</sup> The disease revolves around common symptoms related to the gastrointestinal tract, such as diarrhea, constipation, and bloating. IBS is associated with repetitive gastrointestinal symptoms that greatly reduce the patient's quality of life (QoL). Although IBS has a diagnostic standard of ROME III, it is still difficult to distinguish from other gastrointestinal diseases and is

## Abstract

**Background and Aim:** Irritable bowel syndrome (IBS) is associated with repetitive gastrointestinal symptoms that greatly reduce the patient's quality of life (QoL). Training regarding IBS-related knowledge, medication adherence, lifestyle, and diet adjustments has been demonstrated to strengthen patient QoL. The aim of this study was to evaluate the effectiveness of an educational intervention carried out by clinical pharmacists to improve the QoL of patients with IBS.

**Methods:** Our research included data collected at the University Medical Center, Ho Chi Minh City, from April 2018 to December 2018, and was designed as a randomized controlled clinical trial. Patients with IBS were randomized into an intervention group (IG) and nonintervention group (NIG). The intervention program included training about IBS-related knowledge, the importance of medication adherence, symptom recognition, lifestyle, and diet adjustments. Participants were followed up by monthly telephone calls. The outcome was the change in patient QoL scores (IBS-QoL) 8 weeks after they took part in the research.

**Results:** Of 273 patients in the trial, there were 132 patients in the IG cohort and 141 in the NIG cohort. At 8 weeks, IG QoL score changes were statistically higher than those of NIG:  $20.1 \pm 12.1$  (IG) *versus*  $13.2 \pm 13.4$  (NIG). Furthermore, pharmacist intervention played an important role in increasing QoL after 8 weeks, as confirmed by multivariate regression analysis ( $B = 5.9$ ; 95% confidence interval 2.4–9.4,  $P = 0.001$ ).

**Conclusions:** Patient education, lifestyle, and dietary intervention, administered by clinical pharmacists, improves IBS-QoL compared to standard medical therapy over 8 weeks.

difficult to treat because the symptoms are often related to patient eating conditions, activities, and psychology.<sup>3</sup> In Vietnam, according to a study by Vo Thi Thuy Kieu<sup>4</sup> on the dietary risk factors of patients with IBS in the Vietnamese student community, the incidence of IBS is approximately 10.3%, of which females account for 10.6% and males for 9.9%.

Research on IBS is fairly common throughout the world, and investigators pay much attention to the factors that affect IBS, such as patient anxiety, depression, and QoL, as well as measures that help patients improve IBS symptoms.<sup>5–9</sup> However, there is a lack of clinical and patient information on IBS in Vietnam. The impact of IBS on the daily life of patients is huge, and therefore, more research is needed for this syndrome. On the other hand, when socioeconomic life is growing, as it is currently, QoL will become an increasing concern because of its

close relationship with the health status of each individual. Some studies have shown that IBS reduces QoL.<sup>9,10</sup> In addition to drug therapy, the nonpharmacological treatment of IBS patients also needs to be investigated. Diet and exercise (running, cycling, yoga) have been shown to reduce IBS symptoms.<sup>3,8</sup> In Vietnamese laws on pharmacy, clinical pharmacists' activities included providing counseling on the use of drugs and drug information and use instructions for medicine practitioners, drugs users, and the community to ensure reasonable, safe, and effective use of drugs. Clinical pharmacists' counseling services have recently been applied in several hospitals in Vietnam.<sup>11</sup> This study was conducted with the aim of surveying patient characteristics and evaluating the effectiveness of an educational intervention carried out by clinical pharmacists to improve the QoL of patients with IBS.

## Methods

**Study settings.** This was a parallel-group, randomized controlled trial with an 8-week follow-up. The protocol was approved by the institutional review board of the University of Medicine and Pharmacy at Ho Chi Minh City, Vietnam (Project Number: 605/DHYD-HD—29/12/2017).

**Participants.** Outpatients are diagnosed with IBS, examined, and treated at the gastroenterology clinic at the University of Medicine and Pharmacy Hospital in Ho Chi Minh City. Patients were selected for this study according to the following inclusion criteria: patients diagnosed with IBS according to the ROME III criteria who are 18 years of age or older and visited the gastroenterology clinic at the University of Medicine and Pharmacy at Ho Chi Minh City from 1 April 2018 to 31 December 2018, and agreed to participate in the study. The exclusion criteria included patients who did not have enough personal information, patients in whom IBS was not classified, patients who were not alert or were impaired or incapacitated, patients with Mini-Mental State Examination (MMSE) <17,<sup>12</sup> patients who were illiterate or lacked communication equipment, and patients who could not use a phone.

**Sample size.** The required sample size for each group was calculated using the following formula:

$$n = \frac{2C}{ES^2} = \frac{2C}{\left(\frac{\mu_1 - \mu_2}{\sigma_1}\right)^2}$$

$C = 7.85$  ( $\alpha = 0.05$ , reliability 95%,  $\beta = 0.2$ , and power = 0.8).  $\sigma$  is the standard deviation of the mean QoL score using the IBS-QoL questionnaire.  $\Delta$  is the difference in QoL score between the IG and the NIG. According to a study by Patrick DL,<sup>13</sup> which reported the mean QoL score of patients with IBS as  $\mu_1 = 63.2$ ,  $\sigma_1 = 18.5$ , we expected a higher QoL score of 70 after intervention. Therefore, the minimum sample size for each group was 117. In this study, we selected 141 patients in the IG and 132 patients in the NIG.

**Study process.** Sampling took place at the Gastroenterology Clinic, University Medical Center, while follow-ups were

conducted via phone calls every 2 weeks. Selected patients were randomized into two groups, IG and NIG, using a list composed by the [www.random.org](http://www.random.org) website. The patients of the NIG only received usual hospital outpatient care by doctors and nurses. In addition to usual care, the IG patients were educated by a clinical pharmacist regarding IBS knowledge, lifestyle changes, diet, and medication adherence (see Appendix S1). Patient counseling materials were developed by the research team based on the lifestyle changes guide for IBS patients of the Australian Association of Gastroenterology<sup>14,15</sup> and research by McKenzie.<sup>16</sup> The counseling sessions were carried out in IG patients at the hospital and lasted about 15–20 min. Patient education materials about IBS information, lifestyle changes, diet, and medication adherence were prepared and distributed to patients to reinforce the content delivered through counseling. Patients were allowed to take a copy home. The IG patients received phone calls from a clinical pharmacist at 2, 4, 6, and 8 weeks after the first meeting at the clinic. During each telephone consultation, the pharmacist asked the patient about his or her current condition, medication, and lifestyle; reinforces information; and advises the patient on lifestyle changes and medication adherence.

Data on baseline characteristics, lifestyle, and living habits of patients were collected by pharmacists at the beginning of the study. QoL scores based on the validated Vietnamese version of the IBS-QoL questionnaire<sup>17</sup> were also calculated for all patients, at the beginning of the study at the hospital and after 2 months of follow-up, by telephone. Higher IBS-QoL score denotes a higher QoL.

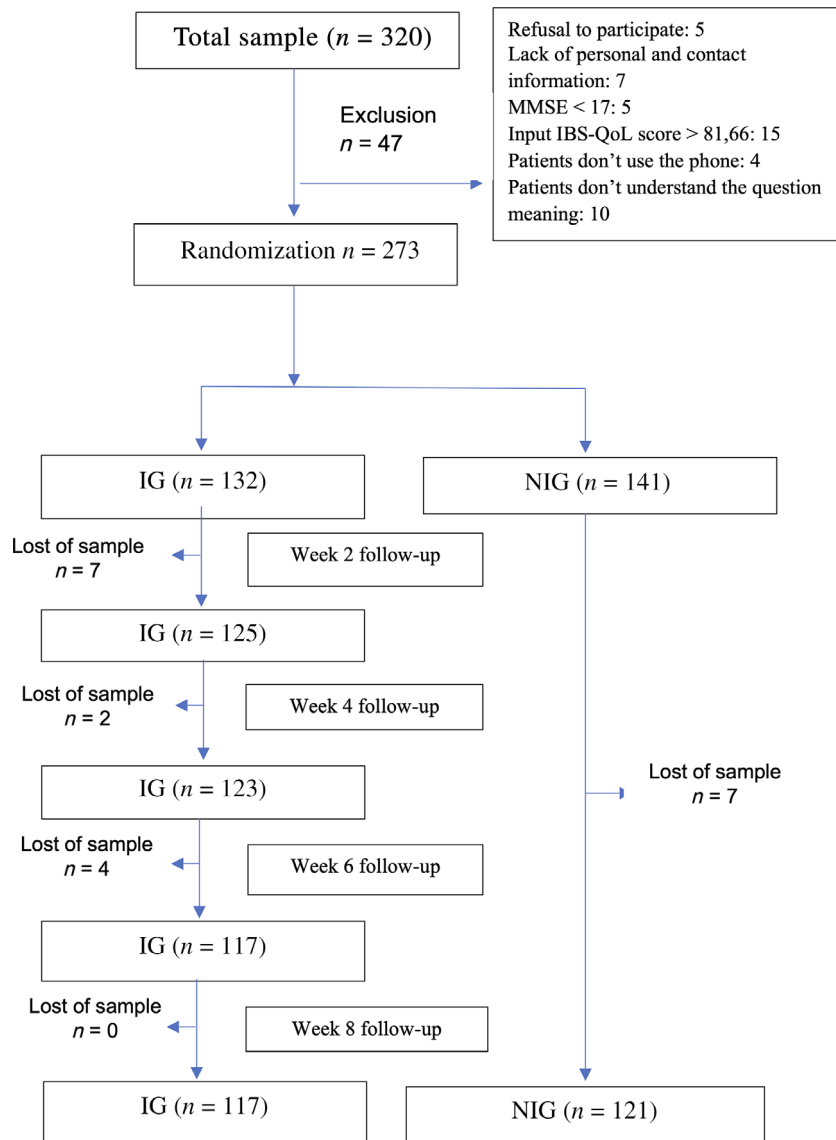
**Statistical analysis.** The data were analyzed using the Statistical Package for Social Sciences (SPSS) program, version 20.0. Data are presented as mean  $\pm$  SD, median (interquartile range 25–75%), or percentage. The comparison of percentages between the IG and the NIG was assessed using the Chi-square test. The t-test or Mann–Whitney test was used to test for significant differences in QoL scores and the mean change ( $\Delta$ ) in QoL score 2 months after the intervention. The possible factors associated with changes in QoL scores were evaluated by multivariate linear regression analysis. A  $P$ -value of <0.05 was considered statistically significant.

## Results

Overall, 320 patients were initially identified in our study, and the process and patients are summarized in Figure 1. Based on the exclusion criteria, a total of 273 patients were enrolled in our study, including 132 patients in the IG and 141 patients in the NIG. After 2 months of follow-up, 238 patients completed the study (117 patients in the IG and 121 in the NIG).

### Baseline characteristics of the two study groups.

Of the 273 patients with IBS who were diagnosed according to Rome III criteria, the percentage of female patients (56.0%) was greater than male patients (44.0%). Patients aged 31–50 years have a higher incidence of IBS than other patients. The majority of patients in the study were office workers (25.6%), and IBS-D dominated the remaining classification. Patients with IBS-D accounted for more than two-thirds of all patients and often had symptoms of loose stools, frequent bowel movements, bloating,



**Figure 1** Flow diagram of the study. IG, intervention group; NIG, nonintervention group.

and farting. The incidence of IBS is the highest among those who had not graduated from high school, followed by patients with upper high school education. The proportion of surveyed married people was quite high (83.2%) compared to single individuals, 16.8%. There was no statistically significant difference between the IG and NIG in terms of gender, age, IBS type, education level, and marital status. However, occupational factors showed statistical differences between the IG and NIG. This is considered a confounding factor and was adjusted by the regression model during the analysis (Table 1).

**Patient lifestyle and living habits.** The analysis showed that the percentage of patients with IBS with anxiety and stress was 61.2%, accounting for more than half of the total number of survey samples. This shows that anxiety and stress are common in patients with IBS. The percentage of patients who smoked

was not high, only 9.2%, and all smokers were men. There was no statistically significant difference between the IG and NIG in terms of stress, smoking, drinking, coffee, and physical activity. There was a statistically significant difference in the proportion of carbonated drinks between the IG and NIG. This is considered a confounding factor and was adjusted by the regression model during the analysis (Table 2).

**QoL characteristics.** From the QoL survey scores of the two groups (IG and NIG), there was no statistically significant difference between the two groups at baseline ( $P > 0.05$ ) (Table 3).

**Evaluating the effectiveness of education intervention carried out by clinical pharmacists to improve IBS patient QoL.** After 2 months of intervention,

**Table 1** Baseline patient characteristics

Characteristics	(n = 273) (%)	Group				P value
		IG (n = 132)		NIG (n = 141)		
		n	%	n	%	
Gender						
Male	44	56	42.4	64	45.4	0.622
Female	56	76	57.6	77	54.6	
Mean age						
≤20	2.2	2	1.5	4	2.8	0.367
21–30	16.8	24	18.2	22	15.6	
31–40	28.2	41	31.1	36	25.5	
41–50	24.2	35	26.5	31	22.0	
51–60	19.0	19	14.4	33	23.4	
>60	9.5	11	8.3	15	10.6	
Job						
Farmer	14.3	21	15.9	18	12.8	<b>0.027</b>
Worker	11.0	19	14.4	11	7.8	
Officer	2.6	36	27.3	34	24.1	
Business	16.8	24	18.2	22	15.6	
Student	4.8	8	6.1	5	3.5	
Other	27.5	24	18.2	51	36.2	
Type IBS						
IBS-D	67	92	69.7	91	64.5	0.310
IBS-C	11.4	11	8.3	20	14.2	
IBS-M	21.6	29	22.0	30	21.3	
Education level						
Not graduated common	59.7	82	62.1	81	57.4	0.728
High school graduation	9.9	12	9.1	15	10.6	
On high school common	30.4	38	28.8	45	31.9	
Marital status						
Single	16.8	23	17.4	23	16.3	0.806
Married	83.2	109	82.6	118	83.7	

\* Chi-square test

There was no statistically significant difference between Intervention and Non-Intervention groups on gender, age, IBS type, education level, marital status. Occupational factors had statistical differences between the IG and NIG IBS, irritable bowel syndrome; IBS-D, irritable bowel syndrome with diarrhea; IBS-C, irritable bowel syndrome with constipation; IBS-M, irritable bowel syndrome with alternating constipation and diarrhea.

the study found that the overall QoL score and its health anxiety aspects, social response, and relationship were significantly higher in the IG than the NIG ( $P < 0.001$ ). At the same time, the change in overall QoL and unpleasant aspects, obstructing activities, body shape, health anxiety, social reactions, and relationships in the IG were also significantly higher than those in the NIG. Statistical significance was set at  $P < 0.05$  (Table 4).

**The influence of other factors on quality assurance.** The results showed that there was a correlation between the change in each score and IG baseline factors. From the results recorded after 2 months, pharmacist intervention helped improve the QoL of patients with IBS. Specifically, the IG had a

total  $\Delta$ QoL that increased by 5.9 units ( $P = 0.001$ ),  $\Delta$  health worry score that increased by 16.4 units ( $P < 0.001$ ), and a  $\Delta$  relationship that increased by 13.3 ( $P < 0.001$ ), all of which were higher than those of the NIG (Table 5).

## Discussion

There were differences in occupational factors and soft drink consumption, with statistical significance, between the IG and NIG. The patient baseline characteristics and other life habits did not significantly differ between the two groups.

After 2 months of intervention, there was a significant improvement in QoL in the IG compared to the NIG. Specifically, QoL improved with respect to specific aspects: discomfort, hindering activities, physical shape, health anxiety, social reactions, and relationships. The multivariate linear regression analysis results confirmed the positive relationship between the pharmacist counseling program and QoL improvements in patients with IBS. Therefore, this study is the first in Vietnam to prove the intervention effectiveness of pharmacists in improving

**Table 2** Patient lifestyle characteristics and living habits

Characteristics	(n = 273) (%)	Group				P value
		IG (n = 132)		NIG (n = 141)		
		n	%	n	%	
Stress						
Yes	61.2	85	64.4	82	58.2	0.291
No	38.8	47	35.6	59	41.8	
Smoking status						
Yes	9.9	10	7.6	15	10.6	0.381
No	90.8	122	92.4	126	89.4	
Drinking alcohol						
No	71.4	95	72.3	100	70.9	0.799
Sometimes	23.1	31	23.5	32	22.7	
Regularly (everyday)	5.5	6	4.5	9	6.4	
Coffee						
No	63.4	76	57.6	97	68.8	0.136
Sometimes	20.5	30	22.7	26	18.4	
Regularly (everyday)	16.1	26	19.7	18	12.8	
Carbonated soft drinks						
No	76.6	110	83.3	99	70.2	<b>0.011</b>
Yes	23.4	22	16.7	42	29.8	
Physical activity						
No	40.7	55	41.7	56	39.7	0.898
Sometimes	22.3	30	22.7	31	22.0	
Regularly (at least 30 min a day, 3 days a week)	37.0	47	35.6	54	38.3	

\* Chi-square test

There was no statistically significant difference between the IG and NIG on stress, smoking, drinking, coffee, physical activity. There was a statistically significant difference in the proportion of carbonated drinks between the IG and NIG.

**Table 3** Comparison of initial quality of life characteristics between intervention group (IG) and nonintervention group (NIG) cohorts

Characteristics	Group		P value
	IG (n = 132)	NIG (n = 141)	
Original quality-of-life score			
Total score	66.8 ± 15.4	70.0 ± 11.7	0.100
Dysphoria score	59.9 ± 17.0	62.5 ± 12.3	0.237
Interference with activity score	59.4 ± 23.0	63.9 ± 16.3	0.116
Body image score	80.3 ± 18.8	84.4 ± 12.4	0.228
Health worry score	58.5 ± 22.1	62.4 ± 15.9	0.108
Food avoidance score	54.6 ± 27.4	55.3 ± 24.7	0.477
Social reaction score	78.0 ± 22.4	78.6 ± 18.9	0.596
Sexual score	80.6 ± 26.1	87.7 ± 18.9	0.387
Relationship score	80.5 ± 21.5	83.9 ± 17.2	0.501

\* Mann-Whitney test

Δ score = score after 2 months – baseline score.

There has not statistically significant difference for the two groups on aspects of both groups at the baseline ( $P > 0.05$ ).

the QoL of patients with IBS. In reality, clinical pharmacist practices in Vietnam still remain limited. However, a new government policy has been developed to encourage clinical pharmacist practices to facilitate intervention in patients with IBS. The intervention will bring advantages to IBS treatment and pharmacotherapy. The intervention was performed by phone, so our evaluation was limited.

The results of this research are similar other studies that have explored nonpharmacological interventions in IBS subjects, including Kang (2011), Jarrett (2009), Schneider (2017), Ghiyasvandian (2016), Kamat (2019), and Harvie (2017). Research by Kang *et al.*<sup>10</sup> showed that the QoL score significantly increased after intervention compared with before intervention, with statistical significance. In addition, the QoL scores after intervention increased significantly in each group compared with the respective scores before intervention. The study also showed that the increase in QoL in the IG was higher than that in the NIG. The results of research by Jarrett<sup>19</sup> showed a significant improvement in IBS symptoms and the QoL score of advanced treatment groups 1 and 2 compared to group 3, which received only regular treatment. Groups 1 and 2 had the same level of improvement, with no significant difference. Schneider's research<sup>20</sup> revealed that QoL improvements in 3 months were statistically significant. Randomized controlled clinical trials by Ghiyasvandian *et al.*<sup>21</sup> showed that self-care programs can improve QoL and reduce the severity of IG symptoms after follow-up, and no statistically significant differences in symptom severity and QoL in the NIG were observed after 2 months of follow-up. Kamat *et al.*<sup>22</sup> found that the QoL in the IG improved significantly compared to that in the NIG. Harvie *et al.*<sup>23</sup> also observed that IBS Symptom Severity Score (IBS-SSS) was significantly lower after intervention than before, and statistically significant QoL improvements were observed in group I compared to group II.

The above studies demonstrate that educating patients with IBS helps improve the QoL related to health and helps patients

better manage IBS-related symptoms by increasing knowledge related to IBS and the time spent with patients by medical staff.

This observation can be explained as follows. Regarding research design, our research is similar to that of Kang (2011), Jarrett (2009), Ghiyasvandian (2016), Kamat (2019), and Harvie (2017) with respect to their use of randomized controlled intervention trials. Regarding the method and content intervention, our study is similar to Harvie (2017) with respect to patient dietary intervention, and our study built a diet based on the low FODMAP (Fermentable Oligosaccharides Disaccharides Monosaccharides And Polyols) diet that is exclusive for patients with IBS. Our study is similar to Kang's research (2011) with respect to lifestyle changes (smoking, drinking, diet, exercise). Regarding the context and characteristics of the research sample, our investigation is similar to the research of Ghiyasvandian (2016), which used samples collected at gastroenterology clinics in Iraq and Iran that were randomly divided into two groups, IG and NIG, and monitored for 2 months. Both groups received routine care from their doctors, and the IG groups received an IBS self-management guide.

There was also a relationship between carbonated beverages and improved QoL. Specifically, patients who drank carbonated drinks had a statistically significant change in discomfort

**Table 4** Quality of life score after 2 months of follow-up

Quality of life score after 2 months of follow-up	Group		P value
	IG (n = 117)	NIG (n = 121)	
Total score	85.4 ± 8.8	82.7 ± 8.3	<b>0.004</b>
Dysphoria score	87.8 ± 13.4	87.9 ± 6.9	0.127
Interference with activity score	79.2 ± 14.1	79.7 ± 11.8	0.982
Body image score	91.3 ± 10.4	91.0 ± 10.1	0.551
Health worry score	88.5 ± 15.4	76.6 ± 14.1	<b>&lt;0.001</b>
Food avoidance score	63.5 ± 23.1	63.9 ± 19.4	0.988
Social reaction score	91.9 ± 13.2	83.7 ± 13.7	<b>&lt;0.001</b>
Sexual score	87.1 ± 20.2	88.6 ± 16.0	0.669
Relationship score	94.7 ± 10.6	84.9 ± 13.2	<b>&lt;0.001</b>
Δ Total score	20.1 ± 12.1	13.2 ± 13.4	<b>&lt;0.001</b>
Δ Dysphoria score	29.4 ± 17.4	24.9 ± 14.4	<b>0.007</b>
Δ Interference with activity score	21.8 ± 18.3	15.9 ± 18.6	<b>0.027</b>
Δ Body image score	12.9 ± 14.2	7.5 ± 15.2	<b>0.032</b>
Δ Health worry score	32.1 ± 23.2	14.6 ± 19.5	<b>&lt;0.001</b>
Δ Food avoidance score	9.3 ± 24.5	10.2 ± 29.0	0.861
Δ Social reaction score	14.6 ± 19.1	5.8 ± 23.0	<b>0.002</b>
Δ Sexual score	7.9 ± 16.5	2.3 ± 25.1	0.092
Δ Relationship score	15.2 ± 17.9	2.0 ± 21.5	<b>&lt;0.001</b>

\* Mann-Whitney test

After 2 months of intervention, the score of quality of life and its on health anxiety aspects, social response, and relationship significantly higher than the NIG group ( $p < 0.001$ ). At the same time, the change in overall the score of quality of life and unpleasant aspects, obstructing activities, body shape, health anxiety, social reactions, relationships in the IG group is also significantly higher than that in NIG group. Statistical significance ( $P < 0.05$ )

Δ score = score after 2 months – baseline score.

**Table 5** Degree of impact caused by pharmacist intervention and interference factors on changes of quality of life (QoL) score after 2 months of follow-up

Factor (independent variables)	Changes ( $\Delta$ ) in QoL score (dependent variable)	Slope	P value	CI (95%)
IG	$\Delta$ Total score	5.9	<b>0.001</b>	2.4–9.4
	$\Delta$ Dysphoria score	2.5	0.259	(–1.8)–6.7
	$\Delta$ Interference with activity score	4.4	0.081	(–0.5)–9.4
	$\Delta$ Body image score	—	—	—
	$\Delta$ Health worry score	16.4	<b>&lt; 0.001</b>	10.7–22.1
	$\Delta$ Food avoidance score	—	—	—
	$\Delta$ Social reaction score	—	—	—
	$\Delta$ Sexual score	—	—	—
Job	$\Delta$ Relationship score	13.3	<b>&lt; 0.001</b>	7.8–18.8
	$\Delta$ Total score	0.3	0.488	(–0.6)–1.3
	$\Delta$ Dysphoria score	0.1	0.816	(–1.1)–1.4
	$\Delta$ Interference with activity score	0.2	0.781	–1.2–1.6
	$\Delta$ Body image score	—	—	—
	$\Delta$ Health worry score	–0.4	0.638	–2.0 to 1.2
	$\Delta$ Food avoidance score	—	—	—
	$\Delta$ Social reaction score	—	—	—
Carbonated soft drinks	$\Delta$ Sexual score	—	—	—
	$\Delta$ Relationship score	–0.4	0.602	(–2.0)–1.1
	$\Delta$ Total score	–4.2	0.053	(–8.5)–0.1
	$\Delta$ Dysphoria score	–8.8	<b>0.001</b>	(–14.1)–3.5
	$\Delta$ Interference with activity score	–3.8	0.221	(–10.0)–2.3
	$\Delta$ Body image score	—	—	—
	$\Delta$ Health worry score	–8.4	<b>0.019</b>	(–15.5)–(–1.4)
	$\Delta$ Food avoidance score	—	—	—
	$\Delta$ Social reaction score	—	—	—
	$\Delta$ Sexual score	—	—	—
	$\Delta$ Relationship score	2.0	0.566	(–4.8)–8.8

\* Multivariate linear regression

The IG group had  $\Delta$  a total quality of life higher than 5.9 units ( $P = 0.001$ );  $\Delta$  Health worry score is higher than 16.4 units ( $P < 0.001$ );  $\Delta$  the relationship score is 13.3 score higher ( $P < 0.001$ ) compared to the NIG group.

level that was lower than the change observed for patients who did not (8.8 units). Patients who drank carbonated beverages also had a statistically significant change in anxiety points that was less than that of patients who did not (8.4 units).

When using carbonated beverages, patients will experience typical or atypical IBS symptoms. Carbonated beverages produce gases that stimulate the intestinal receptors to increase sensitivity and permeability through the intestinal epithelial barrier and change intestinal motility. Therefore, the patient will feel pain and have bowel movements with an urgent, uncontrollable feeling. In addition, carbonated drinks contain high levels of sugar and other chemicals that worsen IBS symptoms. These symptoms occur massively and make the patients feel fatigue and discomfort and affect daily life and QoL. Therefore, global dietary recommendations for patients with IBS suggest limiting carbonated foods and drinks to improve IBS status.<sup>8,16</sup>

In conclusion, the research has proven that clinical pharmacist intervention, including IBS information counseling, lifestyle change counseling, medication adherence, and regular reminders that reinforce lifestyle changes improve the condition of patients with IBS. This research is a prerequisite for further studies related to IBS and demonstrates that counseling for patients can support QoL improvements.

However, the present study was limited in certain aspects. The clinical pharmacists provided advice on dietary intervention, but they were not trained dietitians. A low FODMAP diet has been shown to be best effective when directed by a dietitian. QoL improvement in the IG may have been simply because of regular phone calls and contact by the clinical pharmacists. As the majority of IBS patients had anxiety, just regular phone calls can provide reassurance to patients, regardless of any intervention provided. Phone calls for QoL assessment were made by assessors not blinded to the intervention provided, which may have biased the results. Patient counseling materials on lifestyle and diet were based on Australian and Western guidelines, but IBS adults in Vietnam have a different lifestyle and diet than Caucasian/Western IBS adults, and hence, this may not have been appropriate nor can it be sustained longer than 8 weeks.

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## Supporting information

Additional supporting information may be found in the online version of this article at the publisher's website:

**Appendix S1.** Instructions/counseling materials provided by the clinical pharmacists to IBS patients.

