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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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,1 and in the United Kingdom, 10–12% of the population are diagnosed with IBS.2 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 difficult to treat because the symptoms are often related to patient eating conditions, activities, and psychology.3 In Vietnam, according to a study by Vo Thi Thuy Kieu4 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.5–9 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. 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. 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. 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 do 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, 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:

\[ n = \frac{2C}{ES^2} = \frac{2C}{(\mu_1 - \mu_2)^2} \]

\[ C = 7.85 \quad (\alpha = 0.05, \text{ reliability } 95\%, \beta = 0.2, \text{ and power } = 0.8). \]

\( \sigma \) 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, 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 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 and research by McKenzie. 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 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 ± 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,
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          | Group                  |          |          |      |      |      |
|--------------------------|------------------------|----------|----------|------|------|------|
|                          | IG (n = 132)           | NIG (n = 141) | P value |
| Gender                   |                        |          |          |      |      |      |
| Male                     | 44 (56)                | 56 (64)  | 42.4 (44.5) | 0.622 |
| Female                   | 56 (76)                | 76 (77)  | 57.6 (54.6) |
| Mean age                 |                        |          |          |      |      |      |
| ≤20                      | 2.2 (2)                | 2 (4)    | 1.5 (2.8)  | 0.367 |
| 21–30                    | 16.8 (24)              | 18.2 (22)| 22 (15.6) |
| 31–40                    | 28.2 (41)              | 31.1 (36)| 25.5 (26.5)|
| 41–50                    | 24.2 (35)              | 26.5 (31)| 22.0 (20.0) |
| 51–60                    | 19.0 (19)              | 14.4 (33)| 23.4 (23.4) |
| >60                      | 9.5 (11)               | 8.3 (15)| 10.6 (10.6) |
| Job                      |                        |          |          |      |      |      |
| Farmer                   | 14.3 (21)              | 15.9 (18)| 12.8 (12.8) | 0.027 |
| Worker                   | 11.0 (19)              | 14.4 (11)| 7.8 (7.8)  |
| Officer                  | 2.6 (3)                | 27.3 (34)| 24.1 (24.1) |
| Business                 | 16.8 (24)              | 18.2 (22)| 15.6 (15.6) |
| Student                  | 4.8 (8)                | 6.1 (5)  | 3.5 (3.5)  |
| Other                    | 27.5 (24)              | 18.2 (51)| 36.2 (36.2) |
| Type IBS                 |                        |          |          |      |      |      |
| IBS-D                    | 67 (92)                | 69.7 (91)| 64.5 (64.5) | 0.310 |
| IBS-C                    | 11.4 (11)              | 8.3 (20)| 14.2 (14.2) |
| IBS-M                    | 21.6 (29)              | 22.0 (30)| 21.3 (21.3) |
| Education level          |                        |          |          |      |      |      |
| Not graduated common     | 59.7 (82)              | 62.1 (81)| 57.4 (57.4) | 0.728 |
| High school graduation   | 9.9 (12)               | 9.1 (15)| 10.6 (10.6) |
| On high school common    | 30.4 (38)              | 28.8 (45)| 31.9 (31.9) |
| Marital status           |                        |          |          |      |      |      |
| Single                   | 16.8 (23)              | 17.4 (23)| 16.3 (16.3) | 0.806 |
| Married                  | 83.2 (109)             | 82.6 (118)| 83.7 (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; IG-D, irritable bowel syndrome with diarrhea; IG-C, irritable bowel syndrome, and IG-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 ΔQoL that increased by 5.9 units (P = 0.001), Δ health worry score that increased by 16.4 units (P < 0.001), and a Δ 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          | Group                  |          |          |      |      |      |
|--------------------------|------------------------|----------|----------|------|------|------|
|                          | IG (n = 132)           | NIG (n = 141) | P value |
| Stress                   |                        |          |          |      |      |      |
| Yes                      | 61.2 (85)              | 64.4 (82)| 58.2 (58.2) | 0.291 |
| No                       | 38.8 (47)              | 35.6 (59)| 41.8 (41.8) |
| Smoking status           |                        |          |          |      |      |      |
| Yes                      | 9.9 (10)               | 7.6 (15)| 10.6 (10.6) | 0.381 |
| No                       | 90.8 (122)             | 92.4 (126)| 89.4 (89.4) |
| Drinking alcohol         |                        |          |          |      |      |      |
| Yes                      | 71.4 (95)              | 72.3 (100)| 70.9 (70.9) | 0.799 |
| No                       | 28.6 (35)              | 27.7 (30)| 29.1 (29.1) |
| Regularly (everyday)     |                        |          |          |      |      |      |
| Sometimes                | 23.1 (31)              | 23.5 (32)| 22.7 (22.7) |
| Regularly (everyday)     | 5.5 (6)                | 4.5 (9)| 6.4 (6.4)  |
| Coffee                   |                        |          |          |      |      |      |
| No                       | 63.4 (76)              | 57.6 (97)| 68.8 (68.8) | 0.136 |
| Sometimes                | 20.5 (26)              | 22.7 (26)| 18.4 (18.4) |
| Regularly (everyday)     | 16.1 (21)              | 19.7 (18)| 12.8 (12.8) |
| Carbonated soft drinks   |                        |          |          |      |      |      |
| No                       | 76.6 (110)             | 83.3 (99)| 70.2 (70.2) | 0.011 |
| Physical activity        |                        |          |          |      |      |      |
| No                       | 23.4 (22)              | 16.7 (42)| 29.8 (29.8) |
| Sometimes                | 40.7 (55)              | 41.7 (56)| 39.7 (39.7) | 0.898 |
| Regularly (at least 30 min a day, 3 days a week) | 22.3 (30) | 22.7 (31) | 22.0 (22.0) |
| Regularly (at least 30 min a day, 3 days a week) | 37.0 (47) | 35.6 (54) | 38.3 (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.
In the NIG. The results of research by Jarrett showed a significant increase in QoL in the IG was higher than that with the respective scores before intervention. The study also observed that IBS Symptom Severity Score (IBS-SSS) was significantly lower after intervention compared with before intervention. Harvie (2017) found that the QoL in the IG improved significantly compared to that in the NIG. Kang (2011), Jarrett (2009), Ghayyasvandian (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 Mono- saccharides 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 Ghayyasvandian (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 the QoL of patients with IBS. In reality, clinical pharmacist practices in Vietnam still remain limited. However, a new intervention 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 to other studies that have explored nonpharmacological interventions in IBS subjects, including Kang (2011), Jarrett (2009), Schneider (2017), Ghayyasvandian (2016), Kamat (2019), and Harvie (2017). Research by Kang et al. 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 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 revealed that QoL improvements in 3 months were statistically significant. Randomized controlled clinical trials by Ghayyasvandian et al. 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. found that the QoL in the IG improved significantly compared to that in the NIG. Harvie et al. 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 the research design, our research is similar to that of Kang (2011), Jarrett (2009), Ghayyasvandian (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 Ghayyasvandian (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.

| Group | IG (n = 132) | NIG (n = 141) | P value |
|-------|--------------|--------------|---------|
| 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).

| Quality of life score after 2 months of follow-up | Group | IG (n = 117) | NIG (n = 121) | P value |
|-------------------------------------------------|-------|--------------|--------------|---------|
| Total score | 85.4 ± 8.8 | 82.7 ± 8.3 | 0.004 |
| 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 | <0.001 |
| Food avoidance score | 63.5 ± 23.1 | 63.9 ± 19.4 | 0.988 |
| Social reaction score | 91.9 ± 13.2 | 83.7 ± 13.7 | <0.001 |
| Sexual score | 87.1 ± 20.2 | 88.6 ± 16.0 | 0.669 |
| Relationship score | 94.7 ± 10.6 | 84.9 ± 13.2 | <0.001 |
| Δ Total score | 20.1 ± 12.1 | 13.2 ± 13.4 | <0.001 |
| Δ Dysphoria score | 29.4 ± 17.4 | 24.9 ± 14.4 | 0.007 |
| Δ Interference with activity score | 21.8 ± 18.3 | 15.9 ± 18.6 | 0.027 |
| Δ Body image score | 12.9 ± 14.2 | 7.5 ± 15.2 | 0.032 |
| Δ Health worry score | 32.1 ± 23.2 | 14.6 ± 19.5 | <0.001 |
| 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 | 0.002 |
| Δ Sexual score | 7.9 ± 16.5 | 2.3 ± 25.1 | 0.092 |
| Δ Relationship score | 15.2 ± 17.9 | 2.0 ± 21.5 | <0.001 |

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

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.
