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Original Article

Impact of Enhanced Dietary Education Program on Gastrointestinal Symptoms in Patients With Functional Gastrointestinal Disorders: A Multicenter Prospective Pilot Study

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Background/Aims
The association between diet and triggering the symptoms of functional gastrointestinal disorders (FGIDs) has been well recognized. This study aims to evaluate the impact of enhanced dietary education (EDE) on gastrointestinal symptoms in patients with FGIDs.

Methods
This was a multicenter, prospective pilot study. Subjects diagnosed with FGIDs were allocated to either 'EDE' group or 'standard dietary education (SDE)' group. Simplified EDE program developed by the Korean Society of Neurogastroenterology and Motility was used for the dietary guidance. Routine prescription of medications was allowed and the symptoms were compared between 'EDE' and 'SDE' group after 4 weeks. Subjects with SDE group also received EDE after 4 weeks and the pre-post change of symptoms was assessed in each group. The degree of gastrointestinal symptoms was evaluated using the Korean version of validated questionnaires. The 36-item Short Form survey was used for the measurement of health-related quality of life.

Results
In total, 91 subjects (65 in 'EDE'/26 in 'SDE' group) were included (27 were lost to follow-up). There was no significant difference in the symptom scores or health-related life quality scores between 'EDE' and 'SDE' group at 4 weeks. Pre-post change in these scores was not significant without education. However, pre-post decrease in symptom scores and increase of health-related life quality scores were significant after EDE in subjects with gastroesophageal reflux disease and functional constipation.

Conclusion
Although, EDE has the potential to help improving the symptoms in patients with FGIDs, further research is needed to prove the usefulness of this program.
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Key Words
Constipation; Diet; Dyspepsia; Gastroesophageal reflux; Irritable bowel syndrom

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Introduction

Functional gastrointestinal disorders (FGIDs) are prevalent in the general population and characterized by the presence of recurrent symptoms disturbing daily life activities.[1] Multiple pathophysiological factors including genetic predisposition, abnormal intestinal motility, altered visceral sensation, inflammation, immune dysfunction, gut microbiome or psychosocial factors affects the gut-brain interaction via the central nervous system and enteric nervous system processing and these are associated with the development of FGIDs.[2-4]

Food also directly or indirectly affects the motility, sensory function, inflammation or microbiome of the gastrointestinal tract, which leads to symptom onset or exacerbation of FGIDs.[5] Certain food or dietary habits are known to develop or aggravate symptoms, and dietary control is known to improve symptoms and the quality of life in a specific condition.[6-9] While the effectiveness of low fermentable oligo-, di-, mono-saccharides, and polyols diets in irritable bowel syndrome (IBS) patients is well established,[10-12] the lack of convincing data elsewhere and the lack of attention from physicians has meant that treatments based on dietary modification have played a supporting role and have been limited in their clinical application.[5]

The ideal dietary counseling should be provided with sufficient time by a multidisciplinary team of nutritionists and physicians, although the efficacy is not thoroughly validated in patients with FGIDs. However, the role of the dietary counseling in treating patients with FGIDs is still important due to the phenomenon of excessive distribution of folk remedies or dietary supplements, which are not scientifically proven and might be even harmful to health. Moreover, patients with FGIDs commonly report food related gastrointestinal symptoms and demand a physicians' feedback on their dietary habits.[13]

The Korean Society of Neurogastroenterology and Motility (KSNM) developed enhanced dietary education (EDE) manuals for patients with major FGIDs (gastroesophageal reflux disease [GERD], functional dyspepsia [FD], IBS, and functional constipation [FC]) through a systematic review in 2017.[14-21] These were produced in a leaflet form with illustrations and tables and are written in Korean for short time dietary education and guidance during outpatients care. However, the efficacy, applicability, or the satisfaction of EDE program using these manuals in patients with FGIDs has not been evaluated.

The aim of this study is to evaluate the clinical impact of short time EDE program on gastrointestinal symptoms in patients with FGIDs.

Materials and Methods

Design of the Study

This was an open-label, multicenter, prospective (non-randomized) pilot study in subjects with FGIDs. Patients diagnosed with FGIDs including GERD, FD, IBS, or FC based on Rome IV criteria were allocated to either 'EDE' group (enhanced education-first group) or 'standard dietary education (SDE)' group (enhanced education-later group). Routine prescription of medications, such as proton pump inhibitors, prokinetics, anti-spasmodics, cathartics, or anti-diarrheal agents was allowed. The gastrointestinal symptoms of FGIDs were compared between 'EDE' group and 'SDE' group through the validated gastrointestinal symptom questionnaires after 4 weeks. Subjects with 'SDE' group also received EDE after 4 weeks and the pre-post change in symptoms was assessed in each group. The detailed flow of this study is illustrated in Figure 1.

Study Participants

Participants were recruited from 10 University Hospitals (Chung-Ang University hospital, Chungnam National University hospital, Dankook University hospital, Gangneung Asan Hospital, Hallym University Chuncheon Sacred Heart hospital, Hallym University Kangdong Sacred Heart hospital, Hanyang University Guri hospital, Keimyung University Dongsan Medical Center, Kyung Hee University Hospital, Pusan National University hospital, Inje University Ilsan Paik Hospital) from May 2018 to June 2019 in Korea.

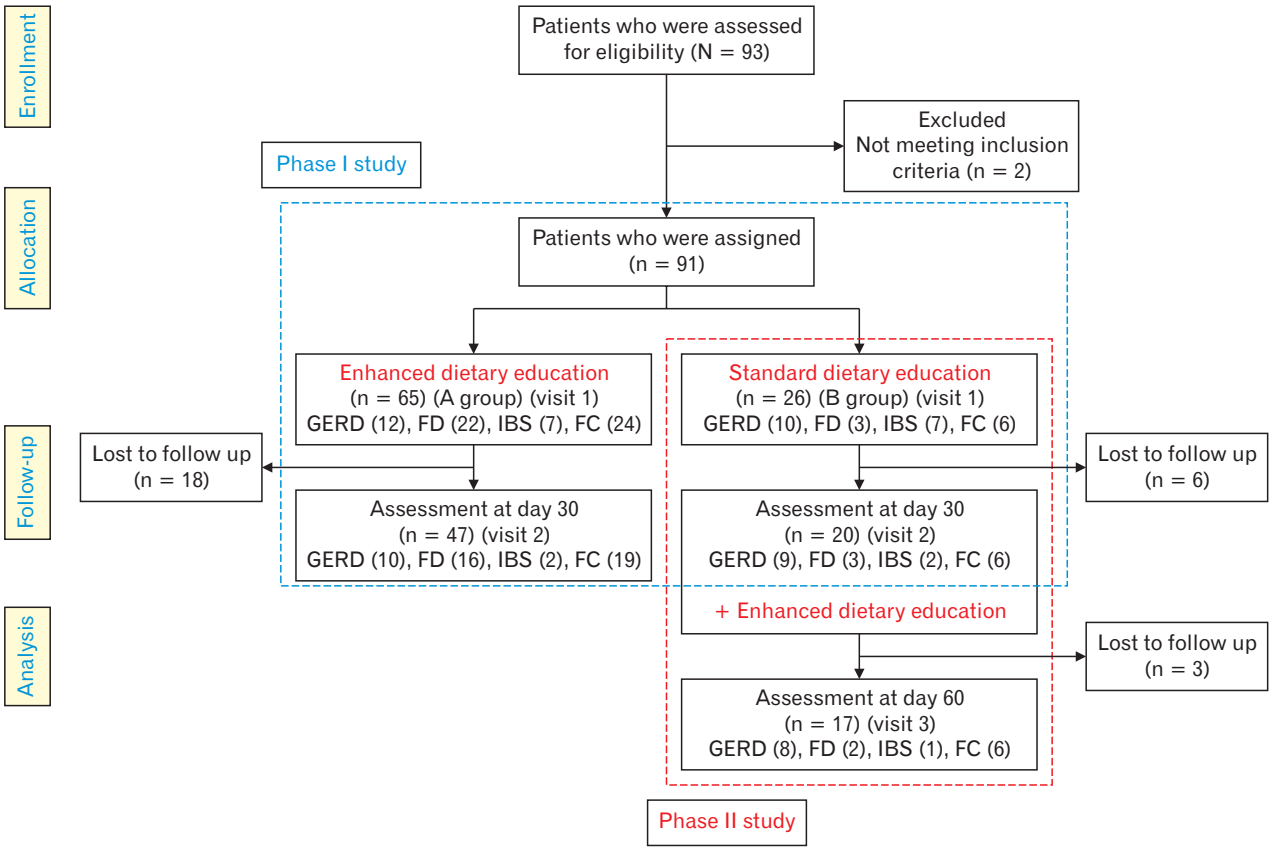

Figure 1. Patient enrolment flow chart. Phase I study is a comparison of gastrointestinal symptoms and quality of life between 'enhanced dietary education group' and 'standard education group.' Phase II study is a pre-post change of gastrointestinal symptoms and quality of life of dietary education in each group. GERD, gastroesophageal reflux disease; FD, functional dyspepsia; IBS, irritable bowel syndrome; FC, functional constipation.

Eligible patients with FGIDs were recruited voluntarily. The exclusion criteria were as follows: (1) underwent surgery of gastrointestinal tract; (2) history of gastrointestinal cancers or neoplasms; (3) primary or secondary esophageal motility disorders (achalasia, scleroderma, autonomic neuropathy, peripheral neuropathy, or myopathy, etc); (4) Barrett's esophagus; (5) eosinophilic esophagitis; (6) peptic ulcer; (7) organic bowel diseases (ulcerative colitis, Crohn's disease, intestinal stenosis, ischemic colitis, intestinal diverticulitis, intestinal tuberculosis, volvulus, or hernia, etc); (8) who need continuous administration of the following medications; aspirin, non-steroidal anti-inflammatory drugs, clopidogrel, anticoagulants (warfarin, dabigatran, rivaroxaban, or apixaban, etc), or steroid psychiatric illness; (9) pregnant or breast-feeding participants; (10) age < 18 years; and (11) who refuse to participate in this study. All enrolled patients had symptoms for at least 6 months, and no patients were enrolled who were taking medications that would affect the course of treatment other than individualized disease-modifying agents. Endoscopy was performed prior to enrolment in the study and individuals who met the above inclusion and exclusion criteria were enrolled.

Enhanced Dietary Guidance

Basic knowledge of the impact of foods on patients' symptoms is important. We examined education level and previous dietary education experience for the baseline information for the enrolled patients.

Each enrolled patient was counseled and educated by doctors during outpatient care using simplified education leaflet. The general dietary information was provided orally with illustrations and tables on the leaflet. Individualized advice was also provided based on the information of the leaflet and the patient was encouraged to keep the dietary guidance for 1 month. The leaflet was provided to prevent the patients from forgetting the contents. The contents and the duration of education was standardized by researchers before

initiation of this study. The contents of EDE were decided to follow the flow of the leaflet and the duration of education was decided to reach 10 minutes.

The representative enhanced guidance is described in the Supplementary Material.[14-21]

Outcome Assessment

The primary outcome of this study was the changes of gastrointestinal symptoms and quality of life between 'EDE' group and 'SDE' groups. The secondary outcome was the changes of gastrointestinal symptoms and quality of life before and after EDE. Additionally, we evaluated the perceived understanding level of patients and overall satisfaction degree of patients for the EDE program.

The degree of gastrointestinal symptoms was assessed using the Korean version of validated questionnaires and the 36-item Short Form (SF-36) health survey questionnaire was also used for the assessment of health-related life quality.

All enrolled patients were asked to complete the 3 questionnaires at first visit (baseline before enhanced education) and second visit (4 weeks after EDE in 'enhanced education-first' group/with SDE in 'enhanced education-later' group). Patients in the 'enhanced education-later' group were also asked to complete the questionnaires at third visit (4 weeks after EDE in 'enhanced education-later' group).

Three questionnaires include the Korean version of Gastrointestinal Symptom Rating Scale (KGSRS) for the global assessment of gastrointestinal symptoms, the Korean version of symptom severity scale questionnaires for each disease-specific assessment of gastrointestinal symptoms (gastroesophageal reflux disease questionnaire [GerdQ] for GERD, Nepean dyspepsia index-Korean version [NDI-K] for FD, IBS-severity scoring system [IBS-SSS] for IBS, and patientassessment of constipation symptoms [PAC-SYM] questionnaire for FC), and SF-36 questionnaire for the assessment of health-related quality of life.

KGSRS has 15 items and encompasses general gastrointestinal symptom assessment. The reliability and validity of the KGSRS are well described.[22,23] The SF-36 questionnaire contains 36 items, which can be calculated into 8 subscores.[24] Two summary scores of physical component summary (PCS) and mental component summary (MCS) can be calculated based on 8 sub-scores via orthogonal-factor analytic model and the advantages of using these summary scores rather than the 8 subscale scores include smaller confidence intervals and smaller floor and ceiling effects.[25] PCS and MCS were used for the assessment of quality of life in this study and higher score indicates better health status. Korean version of GerdQ has 6 items and has been found to be useful for the diagnosis and management of GERD.[26] NDI-K symptom checklist contains 15 items and is a reliable and valid disease-specific index for measuring symptoms of dyspepsia.[27,28] The Korean version of IBS-SSS has 7 items. Among them, 5 items are used for the calculation of symptom severity and are known to be appropriate for the characterization of the severity of IBS.[29,30] PAC-SYM contains 12 items of symptom subscales and provides a responsive change of symptom status of constipation.[31] Higher score of KGSRS or disease-specific symptoms severity scales (GerdQ, NDI-K, IBS-SSS, and PAC-SYM) indicates worse symptoms.

We evaluated the perceived understanding level, applicability, and overall satisfaction degree of patients for the EDE program. This was assessed through the 6-point Likert scale questionnaire with higher score means better understanding, applicability, and higher level of satisfaction.

All subjects were asked to complete a self-reported questionnaire at each outpatient department visit. Physicians were also asked about estimated degree of recovery in gastrointestinal symptoms of patients after EDE program.

Statistical Methods

The sample size was not calculated because this study was conducted as a pilot format. Continuous variables were expressed as the median with interquartile range because they were not normally distributed. Categorical variables were expressed as number and percentage. First, we compared the baseline characteristics of the enrolled subjects between 'EDE' group and 'SDE' group at first visit using the Mann-Whitney test and Fisher's exact test for continuous and categorical variables, respectively. We then performed comparison analysis of KGSRS, SF-36, and each disease-specific symptom severity scale at second visit through the Mann-Whitney test between 'EDE' group and 'SDE' group. Pre-post change of KGSRS, SF-36, and each disease-specific symptom severity scale (between those at first and second visit in 'EDE' group and between those at second and third visit in 'SDE' group) was evaluated by Wilcoxon signed rank test. In this study, a two-tailed P-value of < 0.05 was used as the threshold for statistical significance for all tests. All analyses were performed using SPSS version 24.0. (IBM Corp., Armonk, NY, USA).

Ethics

This study was conducted according to the principles expressed in the Declaration of Helsinki. Voluntary participation was requested, and written informed consent was obtained from each

participant. We received approval from the Institutional Review Board of each hospital before the study was initiated (Approval No: Chuncheon Sacred Heart hospital [2018-21], Yonsei University [3-2018-0097], Hanyang University [GURI 2018-05-007], Keimyung University [2018-02-036], Daegu Catholic University [CR-18-024], Dankook University [2018-05-015], Catholic University [XC18QCDI0016], Gangneung Asan hospital [GNAH 2018-03-011-005], Kangdong sacred heart hospital [2018-05-002]).

All authors had access to the study data, reviewed and approved the final manuscript.

Results

Baseline Characteristics of the Enrolled Population

A total of 91 subjects (22 subjects with GERD, 25 with FD, 14 with IBS, and 30 with FC) were allocated to either 'EDE'

Table 1. Clinical Characteristics of Enrolled Population in Patients With Functional Gastrointestinal Disorders

Variable in patients with GERD	Enhanced education group (n = 12)	Standard education group (n = 10)	*P*-value	Variable in patients with FD	Enhanced education group (n = 22)	Standard education group (n = 3)	*P*-value
Age (yr)	56 (43.3-61.3)	52.5 (35.5-66.3)	0.974		66 (54.5-70.8)	58 (47-66)	0.276
Sex, male/female	7/5	5/5	> 0.999		6/16	0/3	0.554
Urban vs Rural residence	9/3	9/1	0.594		21/1	3/0	> 0.999
Level of education			0.215				0.818
Middle school	2	0			10	2	
High school	2	5			7	1	
University or college	7	5			4	5	
Graduate school	1	0			1	0	
Dietary education experience	0	0	> 0.999		2	1	0.330
Initial KGSRS score	13 (8-13.8)	8 (5.8-11.3)	0.025		6.5 (3.8-10.3)	5 (1-15)	0.900
Initial PCS score	64.4 (58.2-74.4)	66.1 (51.3-74.4)	0.821		59.1 (43.6-65.9)	60 (48.1-62.5)	0.933
Initial MCS score	62.8 (48.8-67.7)	65.2 (55.2-69.4)	0.313		46.6 (40.4-61.8)	59.9 (45.6-69.4)	0.358
Initial GerdQ score	9.5 (8-12)	9 (8-12)	0.628	Initial NDI-K score	53 (33.5-77.3)	47 (33-86)	0.967

Variable in patients with IBS	Enhanced education group (n = 7)	Standard education group (n = 7)	*P*-value	Variable in patients with FC	Enhanced education group (n = 24)	Standard education group (n = 6)	*P*-value
Age (yr)	42 (32-56)	45 (36-49)	0.847		60.5 (44.3-73.8)	56 (34.5-75.5)	0.667
Sex, male/female	4/3	3/4	> 0.999		14/10	3/3	> 0.999
Urban vs Rural residence	4/3	6/1	0.559		19/5	4/2	0.602
Level of education			> 0.999				0.343
Middle school	1	1			8	0	
High school	2	2			6	3	
University or college	4	4			8	2	
Graduate school	0	0			2	1	
Dietary education experience	0	0	> 0.999		4	1	> 0.999
Initial KGSRS score	6 (4-15)	11 (7-18)	0.275		9.5 (7-11.8)	8 (5.8-13.5)	0.743
Initial PCS score	66.9 (50.6-70.6)	53.8 (44.4-75)	0.655		62.5 (41.9-73.6)	51.9 (38.6-79.7)	0.781
Initial MCS score	55.2 (26.6-66.9)	54.4 (35-66.6)	0.949		60.5 (46.6-69.8)	62.3 (39.3-72.3)	> 0.999
Initial IBS-SSS score	283 (216-366)	257 (216-366)	0.898	Initial PAC-SYM score	18 (12.3-22.5)	12 (6.5-26.8)	0.462

GERD, gastroesophageal reflux disease questionnaire; FD, functional dyspepsia; KSGRS, Korean version of gastrointestinal symptom rating scale; PCS, physical component summary; MCS, mental component summary; GerdQ, gastroesophageal reflux disease questionnaire; NDI-K, Nepean dyspepsia index-Korean version; IBS, irritable bowel syndrome; FC, functional constipation; IBS-SSS, irritable bowel syndrome severity scoring system; PAC-SYM, patient assessment of constipation symptoms questionnaire.

group (n = 65) or 'SDE' group (n = 26). The characteristics of the enrolled population are summarized in Table 1. Among the enrolled population, 27 subjects were lost to follow-up (4 subjects with GERD, 7 with FD, 11 with IBS, and 5 with FC). The baseline characteristics were not significantly different between the 2 groups, except for baseline KGSRS in patients with GERD (13.0 [8.0-13.8] in 'EDE' group vs 8.0 [5.8-11.3] in 'SDE' group, $P = 0.025$) (Table 1). The detailed flow diagram of this study is demonstrated in Figure 1.

Gastrointestinal Symptoms and Quality of Life Between 'Enhanced Dietary Education' Group and 'Standard Dietary Education' Group

There was no significant difference in the global gastrointestinal symptom scores (KGSRS), health-related life quality scores (PCS and MCS), and disease-specific symptom severity scores (GerdQ, NDI-K, IBS-SSS, and PAC-SYM) between 'EDE' group and 'SDE' group at 4 weeks (second visit, *P*-values > 0.05). The detailed scores of questionnaires categorized by the specific conditions are described in Table 2.

Pre-post Change of Gastrointestinal Symptoms and Quality of Life of Enhanced Dietary Education

Pre-post change in gastrointestinal symptom scores and the quality of life scores is illustrated in Figures 2-5 and Tables 3 and 4.

Pre-post change in gastrointestinal symptom scores and the quality of life scores was significant in patients with GERD (initial [visit 1] vs after EDE [visit 2] = 13.0 [10.0-14.3] vs 3.5 [1.0-14.5], $P < 0.001$ in KGSRS, 64.4 [59.0-71.9] vs 77 [64.4-88.4], $P = 0.006$ in PCS, 9.0 [8.0-12.0] vs 7.0 [5.0-8.8], $P < 0.001$ in GerdQ) (Fig. 2A, 2B, and 3A), FD (initial [visit 1] vs after EDE [visit 2] = 53.0 [33.5-77.3] vs 33.5 [17.0-60.8], $P = 0.011$ in NDI-K) (Fig. 3B), and FC (initial [visit 1] vs after EDE [visit 2] = 9.0 [7.0-11.0] vs 7.0 [5.0-10.0], $P = 0.022$ in KGSRS, 18.0 [12.0-21.0] vs 10.0 [7.0-17.0], $P < 0.001$ in PAC-SYM) (Fig. 2A and 3D) of 'education-first' group (Table 3).

These changes were not significant between initial values (first visit) and values with SDE (second visit) in patients with 'educa-

Table 2. Gastrointestinal Symptoms and Quality of Life Between 'Enhanced Dietary Education' and 'Standard Education' Group at Second Visit

Variables in patients with GERD	Enhanced education group (n = 10)	Standard education group (n = 9)	*P*-value
KGSRS	3.5 (1.0-14.5)	4.5 (1.75-8.0)	0.869
PCS	77.0 (64.4-88.4)	76.3 (69.2-79.2)	0.595
MCS	65.0 (45.9-77.6)	76.3 (69.2-79.2)	0.414
GerdQ	7.0 (5.0-8.8)	6.0 (6.0-9.0)	0.934
Variables in patients with FD	Enhanced education group (n = 16)	Standard education group (n = 3)	
KGSRS	5.5 (2.3-6.8)	2.0 (0.0-10.0)	0.652
PCS	54.7 (45.8-63.9)	65.0 (43.1-73.1)	0.502
MCS	54.6 (42.2-64.3)	73.1 (54.6-79.1)	0.083
NDI-K	33.5 (17.0-60.8)	20.0 (3.0-116.0)	0.737
Variables in patients with IBS	Enhanced education group (n = 2)	Standard education group (n = 2)	
KGSRS	6.5 (4.5-69.5)	8.5 (2.3-66.8)	> 0.999
PCS	68.75 (50.6-116.8)	76.9 (52.5-119.1)	0.221
MCS	49.1 (35.8-102.1)	70.6 (48.8-113.4)	0.121
IBS-SSS	232.0 (155.3-257.0)	266.0 (105.8-349.5)	> 0.999
Variable in patients with FC	Enhanced education group (n = 19)	Standard education group (n = 6)	
KGSRS	7.0 (5.0-10.0)	6.5 (3.8-14.0)	0.975
PCS	60.0 (55.0-73.8)	57.2 (43.9-84.7)	0.975
MCS	61.9 (53.4-71.3)	70.5 (57.6-79.7)	0.176
PAC-SYM	10.0 (7.0-17.0)	13.5 (7.5-20.0)	0.555

GERD, gastroesophageal reflux disease; FD, functional dyspepsia; KSGRS, Korean version of gastrointestinal symptom rating scale; PCS, physical component summary; MCS, mental component summary; GerdQ, gastroesophageal reflux disease questionnaire; NDI-K, Nepean dyspepsia index-Korean version; IBS, irritable bowel syndrome; IBS-SSS, irritable bowel syndrome severity scoring system; FC, functional constipation; PAC-SYM, patient assessment of constipation symptoms questionnaire.

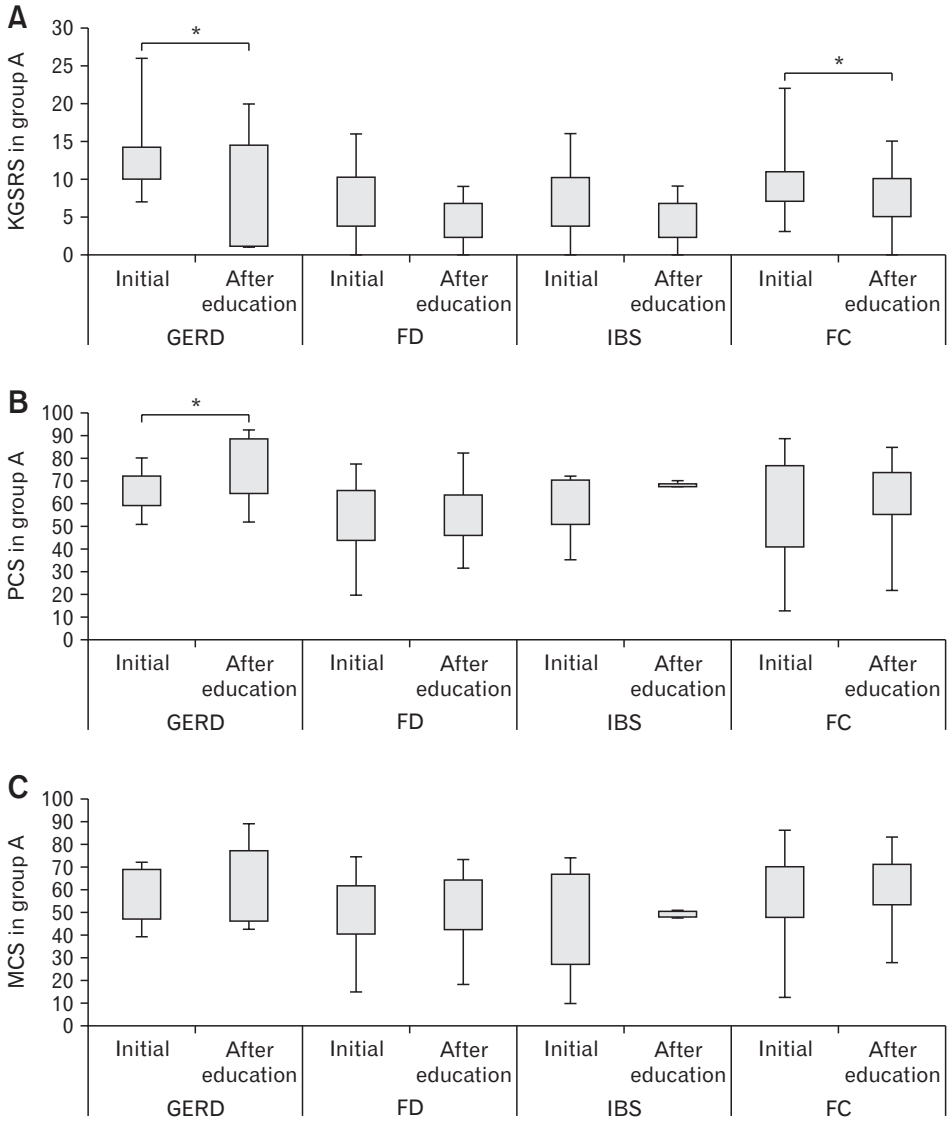

Figure 2. Box plots for pre-post change of gastrointestinal symptoms and quality of life of in 'education-first' group. (A) Korean version of gastrointestinal symptom rating scale (KGSRS), (B) physical component summary (PCS), (C) mental component summary (MCS). The bottom and top edges of the box indicate the interquartile ranges. The lines in the boxes represent the median values. The lines protruding from the box indicate the range of total values. *$P < 0.05$. GERD, gastroesophageal reflux disease; FD, functional dyspepsia; IBS, irritable bowel syndrome; FC, functional constipation.

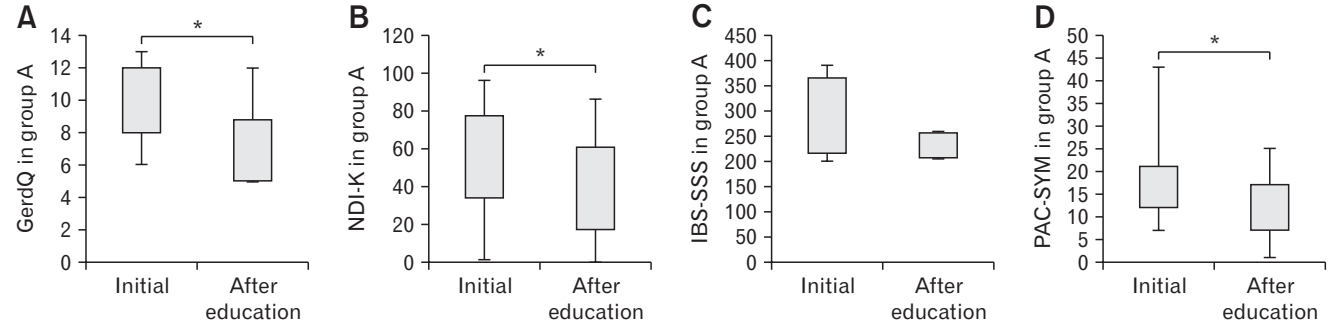

Figure 3. Box plots for pre-post change of symptom severity scale for each disease-specific assessment of gastrointestinal symptoms in 'education-first' group. (A) Gastroesophageal reflux disease questionnaire (GerdQ) in GERD, (B) Nepean dyspepsia index-Korean version (NDI-K) in functional dyspepsia (FD), (C) irritable bowel syndrome severity scoring system (IBS-SSS) in IBS, (D) patient assessment of constipation symptoms questionnaire (PAC-SYM) in functional constipation (FC). The bottom and top edges of the box indicate the interquartile ranges. The lines in the boxes represent the median values. The lines protruding from the box indicate the range of total values. *$P < 0.05$.

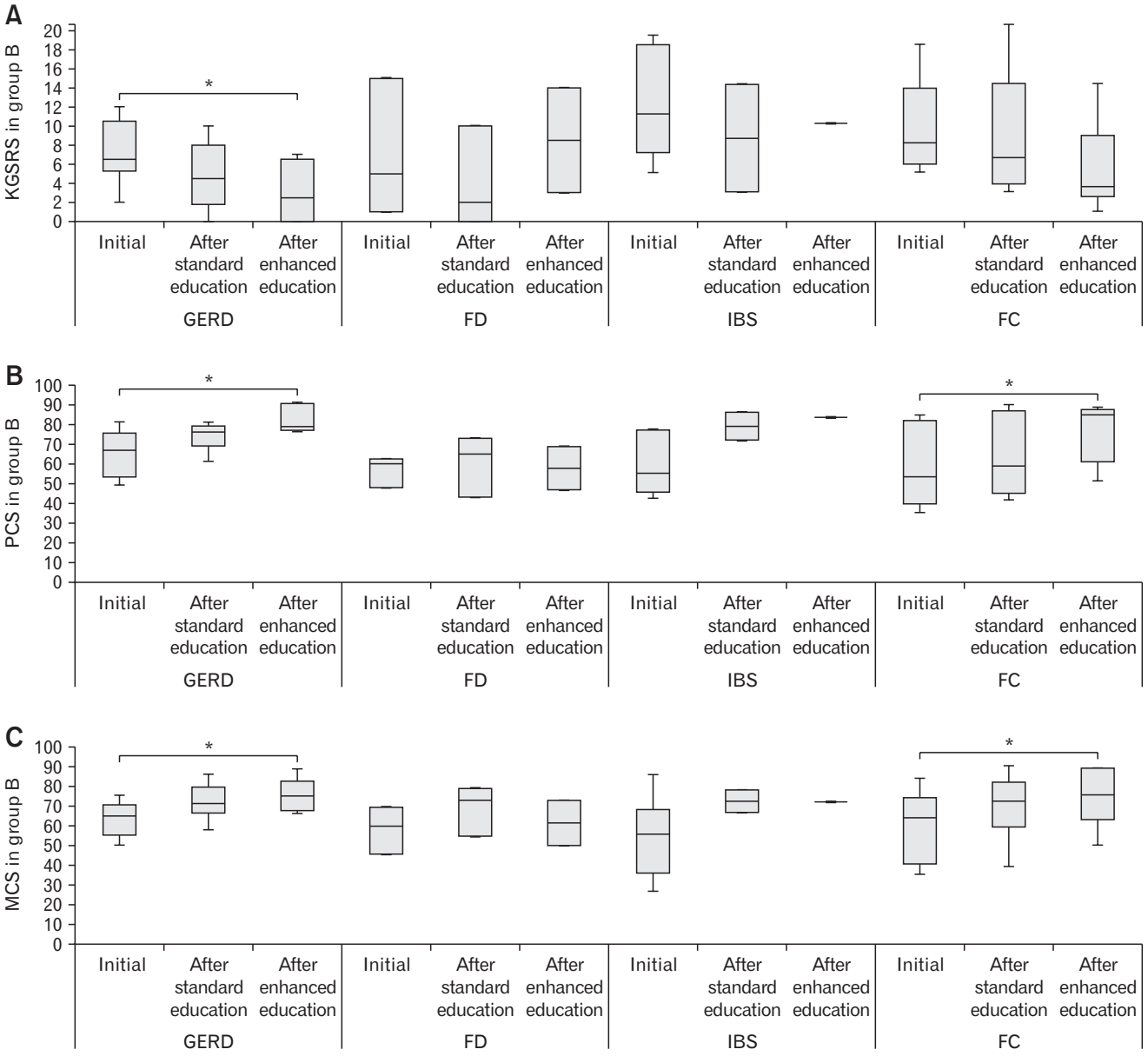

Figure 4. Box plots for pre-post change of gastrointestinal symptoms and quality of life of in 'education-later' group. (A) Korean version of gastrointestinal symptom rating scale (KGSRS), (B) physical component summary (PCS), (C) mental component summary (MCS). The bottom and top edges of the box indicate the interquartile ranges. The lines in the boxes represent the median values. The lines protruding from the box indicate the range of total values. *$P < 0.05$. GERD, gastroesophageal reflux disease; FD, functional dyspepsia; IBS, irritable bowel syndrome; FC, functional constipation.

tion-later' group (Table 4). However, pre-post decrease in symptom scores and increase of health-related life quality scores were also significant after EDE in patients with 'education-later' group, consistently with GERD (initial [visit 1] vs after education [visit 3] = 6.5 [5.25-10.5] vs 2.5 [0.0-6.5], $P = 0.031$ in KGSRS, 67.0 [53.4-75.6] vs 78.9 [77.0-90.6], $P = 0.016$ in PCS, 65.2 [55.3-70.6] vs 75.3 [67.7-82.7], $P = 0.023$ in MCS, 9.0 [8.0-9.0] vs 0.0 [0.0-1.0], $P = 0.031$ in GerdQ) (Fig. 4 and 5A) and FC (initial [visit 1] vs after EDE [visit 3] = 51.9 [38.6-79.7] vs 82.5 [59.4-85.3], $P = 0.031$ in PCS, 62.3 [39.3-72.3] vs 73.4 [61.2-86.9], $P = 0.031$ in MCS) (Fig. 4B and 4C) (Table 4).

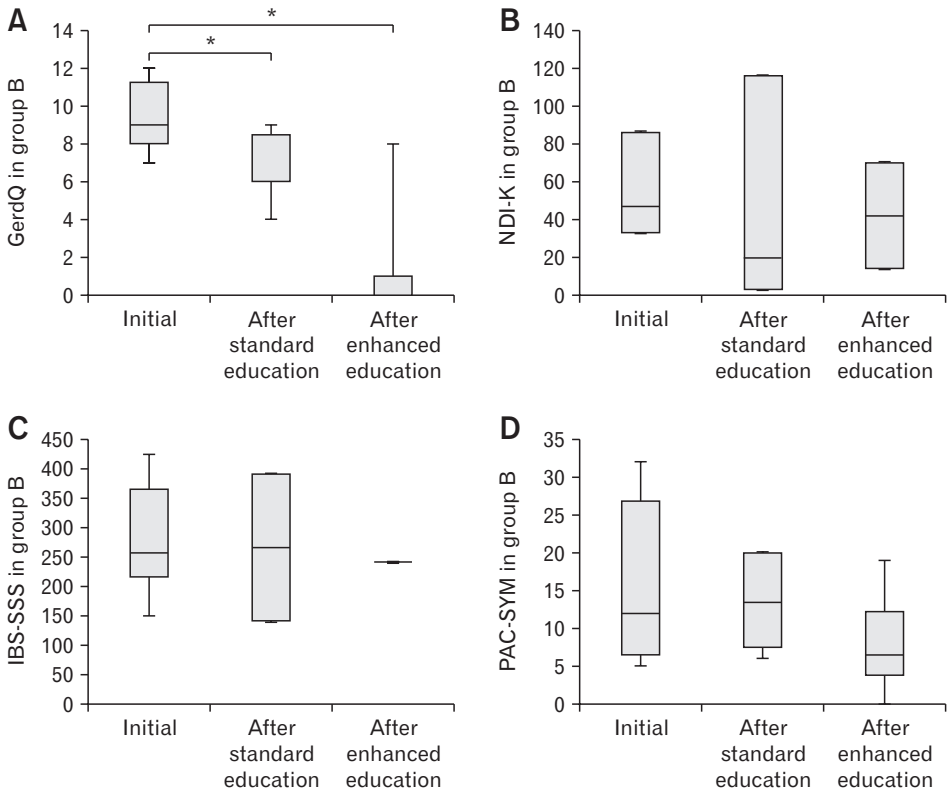

Figure 5. Box plots for pre-post change of symptom severity scale for each disease-specific assessment of gastrointestinal symptoms in 'education-later' group. (A) Gastroesophageal reflux disease questionnaire (GerdQ) in GERD, (B) Nepean dyspepsia index-Korean versio (NDI-K) in functional dyspepsia, (C) irritable bowel syndrome severity scoring system (IBS-SSS) in IBS, (D) patient assessment of constipation symptoms questionnaire (PAC-SYM) in functional constipation. The bottom and top edges of the box indicate the interquartile ranges. The lines in the boxes represent the median values. The lines protruding from the box indicate the range of total values. *$P < 0.05$.

Perceived Understanding Level of Participants and Overall Satisfaction Degree of Participants for the Enhanced Dietary Education Program

These were assessed with 6-point Likert scale questionnaire with higher score means better understanding, applicability, satisfaction, and recovery from symptoms. There was no significant difference in the level of perceived understanding, applicability, overall satisfaction, recovery in gastrointestinal symptoms (both of participants' and physicians' view) between 'education-first' group and 'education-later' group after EDE (these were assessed at second visit in patients with 'education-first' group and at third visit in patients with 'education-later' group, *P*-values > 0.05). The overall perceived understanding level of EDE was 4 (4-5) and the degree of applicability of EDE program was 4 (3-4). The overall degree of satisfaction of EDE program in participants was 4 (3-5). The overall subjective degree of recovery in gastrointestinal symptoms in participants and physicians was similar as 4 (3-4). Sixty out of 64 participants (93.8%) showed willingness to reuse of EDE leaflet.

The detailed scores of questionnaires categorized by the specific conditions are described in Table 5.

Discussion

There was no significant difference in the gastrointestinal symptom scores or health-related life quality scores between 'EDE' group and 'SDE' group at 4 weeks in the present study. Pre-post change in these scores was not significant with SDE, whereas, pre-post decrease in symptom scores and increase of health-related life quality scores were significant after EDE in subjects with GERD and FD.

Although this study did not show evidence to support the following, the presumed reason for the no difference of symptom scores between 'EDE' group and 'SDE' group at 4 weeks might be due to food sensitivity rather than diet modification. A previous population-based case-control study conducted in US revealed that there was no difference in the consumption of frequently suspected 'culprit' foods between subjects with and without FGID symptoms.[32] Food sensitivity rather than food components was presumed as the reason of no difference in the dietary composition between 2 groups, although this study did not explore the mechanism of symptom development in FGIDs.[32]

However, the current study revealed the efficacy of SDE on

Table 3. Pre-post Change of Gastrointestinal Symptoms and Quality of Life in Patients With 'Enhanced Education-first' Group

Variables in patients with GERD	Score	*P*-value of difference	Variables in patients with FD	Score	*P*-value of difference
KGSRS					
Initial (Visit 1)	13.0 (10.0-14.3)	Null		6.5 (3.8-10.3)	Null
After enhanced education (Visit 2)	3.5 (1.0-14.5)	< 0.001		5.5 (2.3-6.8)	0.075
PCS					
Initial (Visit 1)	64.4 (59.0-71.9)	Null		59.1 (43.6-65.9)	Null
After enhanced education (Visit 2)	77.0 (64.4-88.4)	0.006		54.7 (45.8-63.9)	0.708
MCS					
Initial (Visit 1)	62.8 (46.9-69.2)	Null		46.6 (40.4-61.8)	Null
After enhanced education (Visit 2)	65.0 (45.9-77.6)	0.116		54.6 (42.2-64.3)	0.280
GerdQ			NDI-K		
Initial (Visit 1)	9.0 (8.0-12.0)	Null		53.0 (33.5-77.3)	Null
After enhanced education (Visit 2)	7.0 (5.0-8.8)	0.001		33.5 (17.0-60.8)	0.011
Variables in patients with IBS	Score	*P*-value of difference	Variables in patients with FC	Score	*P*-value of difference
KGSRS					
Initial (Visit 1)	6.0 (4.0-1.05)	Null		9.0 (7.0-11.0)	Null
After enhanced education (Visit 2)	6.5 (4.5-69.5)	0.500		7.0 (5.0-10.0)	0.022
PCS					
Initial (Visit 1)	66.9 (50.6-70.6)	Null		63.8 (40.6-76.9)	Null
After enhanced education (Visit 2)	68.75 (50.6-116.8)	0.500		60.0 (55.0-73.8)	0.961
MCS					
Initial (Visit 1)	55.2 (26.6-66.9)	Null		61.9 (47.5-70.3)	Null
After enhanced education (Visit 2)	49.1 (35.8-102.1)	0.500		61.9 (53.4-71.3)	0.686
IBS-SSS			PAC-SYM		
Initial (Visit 1)	283.0 (216.0-366.0)	Null		18.0 (12.0-21.0)	Null
After enhanced education (Visit 2)	232.0 (155.3-257.0)	0.500		10.0 (7.0-17.0)	< 0.001

GERD, gastroesophageal reflux disease; FD, functional dyspepsia; KSGRS, Korean version of gastrointestinal symptom rating scale; PCS, physical component summary; MCS, mental component summary; GerdQ, gastroesophageal reflux disease questionnaire; NDI-K, Nepean dyspepsia index-Korean version; IBS, irritable bowel syndrome; FC, functional constipation; IBS-SSS, irritable bowel syndrome severity scoring system; PAC-SYM, patient assessment of constipation symptoms questionnaire.

the pre-post change of gastrointestinal symptoms and health-related life quality, although those were limited in subjects with GERD and FC. The reason why the discrepancy exists between independent group analysis (non-significant results in comparison between those of 'EDE' group vs 'SDE' group) and paired-group analysis (significant results in comparison between those of pre-education vs post-education) might be explained via several hypotheses. First, patients with FGIDs have various dietary habits and individualized dietary guidance could be more effective than generalized guidance. Patients were provided both of general- and individualized dietary guidance based on the content of education leaflet. Dietary guidance might not be sufficient to show the statistical significance between 'EDE' group and 'SDE' group, irrespective of the characteristics of the EDE (whether it is focussed on the generalized guidance or

Table 4. Pre-post Change of Gastrointestinal Symptoms and Quality of Life in Patients With 'Enhanced Education-later' Group

Variables in patients with GERD	Score	*P*-value of difference	Variables in patients with FD	Score	*P*-value of difference
KGSRS					
Initial (Visit 1)	6.5 (5.3-10.5)	Null		5.0 (1.0-15.0)	Null
With standard education (Visit 2)	4.5 (1.8-8.0)	0.125		2.0 (0.0-10.0)	0.750
After enhanced education (Visit 3)	2.5 (0.0-6.5)	0.031		8.5 (2.3-32.0)	0.500
PCS					
Initial (Visit 1)	67.0 (53.4-75.6)	Null		60.0 (48.1-62.5)	Null
With standard education (Visit 2)	76.3 (69.2-79.2)	0.078		65.0 (43.1-73.1)	> 0.999
After enhanced education (Visit 3)	78.9 (77.0-90.6)	0.016		57.8 (35.2-73.1)	> 0.999
MCS					
Initial (Visit 1)	65.2 (55.3-70.6)	Null		59.9 (45.6-69.4)	Null
With standard education (Visit 2)	71.3 (66.4-79.8)	0.148		73.1 (54.6-79.1)	0.500
After enhanced education (Visit 3)	75.3 (67.7-82.7)	0.023		61.5 (37.4-76.3)	> 0.999
GerdQ			NDI-K		
Initial (Visit 1)	9.0 (8.0-9.0)	Null		47.0 (33.0-86.0)	Null
With standard education (Visit 2)	6.0 (6.0-9.0)	0.016		20.0 (3.0-116.0)	> 0.999
After enhanced education (Visit 3)	0.0 (0.0-1.0)	0.031		42.0 (10.5-74.0)	0.500
Variables in patients with IBS	Score	*P*-value of difference	Variables in patients with FC	Score	*P*-value of difference
KGSRS					
Initial (Visit 1)	11.0 (7.0-18.0)	Null		8 (5.8-13.5)	Null
With standard education (Visit 2)	8.5 (2.3-66.8)	0.500		6.5 (3.8-14)	0.813
After enhanced education (Visit 3)	10.0			3.5 (2.5-8.8)	0.063
PCS					
Initial (Visit 1)	53.8 (44.4-75.0)	Null		51.9 (38.6-79.7)	Null
With standard education (Visit 2)	76.9 (52.5-119.1)	> 0.999		57.2 (43.9-84.7)	0.563
After enhanced education (Visit 3)	81.3			82.5 (59.4-85.3)	0.031
MCS					
Initial (Visit 1)	54.4 (35.0-66.6)	Null		62.3 (39.3-72.3)	Null
With standard education (Visit 2)	70.6 (48.8-113.4)	0.500		70.5 (57.6-79.7)	0.156
After enhanced education (Visit 3)	70.3			73.4 (61.2-86.9)	0.031
IBS-SSS			PAC-SYM		
Initial (Visit 1)	257.0 (216.0-366.0)	Null		12.0 (6.5-26.8)	Null
With standard education (Visit 2)	266.0 (105.8-349.5)	0.500		13.5 (7.5-20.0)	0.719
After enhanced education (Visit 3)	241.0			6.5 (0.8-12.3)	0.125

GERD, gastroesophageal reflux disease; FD, functional dyspepsia; KSGRS, Korean version of gastrointestinal dymptom tating dcale; PCS, physical component summary; MCS, mental component summary; GerdQ, gastroesophageal reflux disease questionnaire; NDI-K, Nepean dyspepsia index-Korean version; IBS, irritable bowel syndrome; FC, functional constipation; IBS-SSS, irritable bowel syndrome severity scoring system; PAC-SYM, patient assessment of constipation symptoms questionnaire.

Table 5. Perceived Understanding Level of Participants and Overall Satisfaction Degree of Participants for the Enhanced Dietary Education Program

Variable in patients with GERD	'Enhanced education-first' group (n = 10)	'Enhanced education later' group (n = 8)	*P*-value	Variable in patients with FD	'Enhanced education-first' group (n = 16)	'Enhanced education later' group (n = 2)	*P*-value
Perceived understanding level	4.0 (3.0-6.0)	4.0 (4.0-6.0)	0.887		4.5 (3.0-5.0)	5.5 (range: 5.0-6.0)	0.209
Degree of applicability	3.5 (3.0-5.3)	4.0 (3.0-5.0)	0.813		4.0 (3.0-4.0)	4.0 (range: 2.0-6.0)	> 0.99
Overall degree of satisfaction (participants' view)	4.0 (3.0-5.3)	4.0 (4.0-5.0)	0.813		4.0 (3.0-5.0)	3.5 (range: 3.0-4.0)	0.392
Degree of recovery in gastrointestinal symptoms (participants' view)	4.0 (2.8-5.0)	4.0 (3.0-5.0)	0.740		4.0 (3.0-4.0)	3.5 (range: 3.0-4.0)	0.732
Degree of recovery in gastrointestinal symptoms (physicians' view)	4.0 (3.0-5.0)	4.0 (3.0-4.8)	0.829		3.0 (3.0-5.0)	4.0 (range: 4.0-4.0)	0.721
Variable in patients with IBS	'Enhanced education later' group (n = 2)	'Enhanced education later' group (n = 1)	*P*-value	Variable in patients with FC	'Enhanced education later' group (n = 19)	'Enhanced education later' group (n = 6)	*P*-value
Perceived understanding level	3.5 (range: 3.0-4.0)	5	0.667		5.0 (4.0-5.0)	4.0 (4.0-5.0)	0.274
Degree of applicability	1.5 (range 0.0-3.0)	3	0.667		3.0 (3.0-4.0)	4.0 (3.0-4.0)	0.400
Overall degree of satisfaction (participants' view)	4.0 (range: 3.0-5.0)	4	> 0.999		4.0 (3.0-5.0)	3.5 (3.0-4.3)	0.687
Degree of recovery in gastrointestinal symptoms (participants' view)	2.0 (range: 1.0-3.0)	4	0.667		3.0 (3.0-4.0)	3.0 (3.0-4.0)	0.975
Degree of recovery in gastrointestinal symptoms (physicians' view)	2.0 (range: 1.0-3.0)	4	0.667		4.0 (3.0-4.0)	3.5 (3.0-4.0)	> 0.999

GERD, gastroesophageal reflux disease; FD, functional dyspepsia; IBS, irritable bowel syndrome; FC, functional constipation.

individualized guidance). However, the impact of individualized guidance might be greater to show the statistical significance on the pre-post education changes of symptoms because this analysis was based on the same subjects (symptom change of the same subjects between that of pre-education and post-education). Previous study also showed that individualized 3 sessions of 45-minutes dietary guidance reduced the gastrointestinal symptoms and improved the life quality in patients with IBS.[33] Further studies exploring the efficacy of EDE categorized by generalized- and individualized approach could elucidate this theory more clearly. Second, the content of the education leaflet might be insufficient to change the daily habitus of subjects with FGIDs. Although, the degree of applicability and satisfaction of participants in EDE program through the self-reported questionnaire was median 4 among 6-point Likert scale, 2 physicians pointed out the lack of illustrations or content of education leaflet. The standard education time of 10 minutes could be insufficient to change the individual dietary habit for the subsequent 4 weeks, although the aim of this study was to explore the efficacy of short-time EDE for the outpatient clinic setting. Another explanation would be the lack of sufficient enrolled subjects in this study. Because this study was performed in a pilot-setting, sample size calculation was not possible and only a small number of subjects were enrolled, especially in the FD and IBS group. This is the presumed reason why the results of pre-post change of gastrointestinal symptoms and health-related life quality were valid only in subjects with GERD and FC. Box plot results of the subjects with FD and IBS also showed trend of decreasing gastrointestinal symptoms and increasing life-related quality scores after EDE, although those could not reach the statistical significance (Fig. 3 and 4).

Food serves as an important trigger for the symptom develop-

ment in patients with FGIDs who have underlying alterations in physiology, which render them hypersensitive to a variety of stimuli.[5] However, measuring specific component in food intake or dietary adjustment tailored to their symptoms are very difficult. Only 11-27% of patients could accurately identify their presumed offending food when re-challenged in a double-blind, placebo-controlled food challenge study.[13,34] Moreover, a previous study showed that intake of food items containing wheat, lactose, caffeine, fructose and alcoholic beverages are not different between patients with FGIDs and controls, although they are often claimed as causing a FGID symptom.[6,32] Recently published study in Greece showed that children with abdominal pain-related FGIDs showed excessive junk-food and reduced fish intake compared to controls.[8] This study also used a self-report, semiquantitative questionnaire to assess the dietary characteristics of enrolled population. However, the dietary parameters of interest included only dairy, meat, fish, fiber, junk food, and non-lactose-simple carbohydrates, which cannot contain or reflect real-life diet. Previous study which explored the type of diet associated with overlap of FD and GERD showed that consumption of canned food, fast food, and alcoholic beverages might be symptom provocative foods.[35] However, the study setting was cross-sectional in manner, which cannot render a causal relationship, and the measurement of specific nutrients was also impossible in this study.

Food is complex and the evidence is still limited for the application of EDE. Patients with FGIDs frequently state that they avoid certain food items. However, this does not seem to influence their intake of nutrients to any large extent, rather raises the risk of inadequate micro-nutrient intake, particularly of vitamins and minerals.[33,36] Therefore, enhanced dietary guidance should be simple, balanced, and easy to apply.[33] The strength of this study is that it provides evidence on the efficacy of simple, evidence-based, short-time enhanced dietary guidance on the gastrointestinal symptoms and quality of life in patients with GERD and FC.

Despite these strengths, this study also has several limitations. First, this was not a randomized-controled trial which could provide a robust evidence. It was conducted in a pilot-setting to enable the sample size calculation for further studies (for a future randomized study powered at 80% with $\alpha = 0.05$, we estimate needing roughly 35-40 patients per arm in the GERD subgroup, 40-50 per arm for FD, about 100 per arm for IBS, and approximately 30 per arm for FC. These projections reflect the effect sizes and variances observed in our pilot and should guide recruitment targets to ensure adequate power for between-group comparisons. In the pilot, GERD patients showed a median GerdQ improvement from 9 to 7 [$P < 0.001$] and a KGSRS reduction from 13 to 3.5 [$P < 0.001$] after EDE. FD subjects experienced a decrease in NDI-K scores from 53 to 33.5 [$P = 0.011$]. IBS cases had a non-significant IBS-SSS change from 283 to 232 [$P = 0.500$], indicating high variability. FC patients improved in PAC-SYM from 18 to 10 [$P < 0.001$], suggesting a large effect size). The study was planned as in a randomized manner and patients were allocated by randomization (block randomization by a research assistant nurse), however, the original study was stopped due to non-recruitment of some subjects and the study format was changed (institutional review board approved) for analysis of enrolled patients. Second, the self-reported questionnaire survey could not specify or quantitate the specific substances related to the symptom development and authors also could not collect the objective data on whether enrolled subjects adhered to the enhanced education guidance or changed their dietary habits in effective way. Third, among the enrolled population in this study, 29.7% (27/91) were lost to follow-up, which is substantial incompletion rate. However, previous studies with similar design also showed 30-40% of incompletion rate of study protocol and improving the adherence would be another challenge of dietary education program.[33,37] Fourth, basic knowledge of the impact of foods on patients' symptoms is important. However, this study only examined the education level and previous dietary education experience, which may not be directly related to the level of basic knowledge of the impact of foods. Future research is expected to address the above limitations (ie, randomized manner, specific substance-based self-reported questionnaire, objective data on whether enrolled subjects adhered to the enhanced education guidance or changed their dietary habits, minimizing the confounder, such as basic knowledge of the impact of foods on patients' symptoms). Fifth, it is challenging to measure how well patients actually adhered to the EDEs' content in real life, even though we administered them in this study. In the future, we will have to create measures that take this into account.

Although the limitations stated above, there is currently no definite or uniform recommendation on specific food or nutrient consumption over an extended period at a population level for the patients with FGID.[32] This evidence-based simplified dietary education program might be useful and 93.8% of enrolled subjects showed willingness to reuse of EDE leaflet in this study. Effective nutritional education techniques, in our opinion, are patient-specific, intuitive, and offer continuous acceptance and feedback, all of which will improve adherence. We think this EDE illustrates the possibility for optimal dietary education in clinical practice, even though it is not a perfect representation.

In conclusion, short-term outpatient clinic-based EDE pro-

gram has the potential to help improving the gastrointestinal symptoms in patients with FGIDs. However, further research is needed to prove the usefulness of enhanced dietary education programs.

Supplementary Material

Note: To access the supplementary material mentioned in this article, visit the online version of *Journal of Neurogastroenterology and Motility* at http://www.jnmjournal.org/, and at https://doi.org/10.5056/jnm23060.

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