

Original Research Article

Effects of Dietary Guidance without Dietary Fiber Supplements on the Symptoms, Quality of Life, and Dietary Intake in Patients with Fecal Incontinence

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Abstract

Objectives: Dietary fiber (DF) supplements improve fecal incontinence (FI). Here, we investigated the effects of dietary guidance without DF supplements in patients with FI.

Methods: This was an interventional study on the nutritional guidance alone by a dietitian where outcomes were compared before and one month after the guidance. In this study, participants attended a one 20-min dietary guidance session and received individual guidance on dietary management according to the 2017 Japanese FI guidelines, between January 2016 and March 2019. The main assessment items used were as follows: (i) the Fecal Incontinence Severity Index (FISI) to assess symptoms, (ii) the Fecal Incontinence Quality of Life Scale (FIQL) to assess the quality of life, and (iii) the dietary intake per day.

Results: Out of 61 patients who participated in this study, 50 (82%) completed the entire study and 29 (48%) continued a self-controlled diet therapy without drug treatment. Of the 50 patients, the FISI and FIQL scores were significantly improved after the guidance (FISI: 19 before vs. 10.5 after, P < 0.001; FIQL: 2.9 before vs. 3.2 after, P < 0.001). There was no statistically significant difference in the overall DF intake before and after the dietary guidance. However, foods containing DF changed significantly after the guidance. The intake of rice was significantly increased, whilst that of fruits, dairy products, and confectioneries was significantly reduced after the guidance.

Conclusions: Individual dietary guidance without DF supplements was effective. These results suggested that increasing rice consumption and restricting some foods had positive effects on improving FI.

Keywords

fecal incontinence, diet therapy, dietary fiber, starch

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Introduction

Diet therapy is one of the primary conservative treatments in patients with fecal incontinence (FI). According to the 2017 Japanese FI guidelines, the recommended diet therapies are as follows: (i) increasing dietary fiber (DF) intake and (ii) restricting meals that may induce soft or liquid stools[1].

Corresponding author: Kaoru Nakano, nakano.kaoru@kameda.jp Received: January 28, 2020, Accepted: May 20, 2020 Copyright © 2020 The Japan Society of Coloproctology Bliss et al. reported that patients with FI experienced a reduction in FI frequency after psyllium supplementation[2]. Additionally, they reported that pectin supplementation had the highest percentage of loose, unformed, or liquid stools among DF supplements of psyllium, gum arabic, and pectin[3]. Pectin is a DF that is abundant in fruits. Our previous study showed that, although the DF intake in patients with FI was approximately the same as the national mean, their DF intake was derived more from wheat products, fruits, and confectioneries and less from rice[4].

Ingesting caffeine, alcohol, fructose, lactose, and greasy or spicy foods may induce soft or liquid stools[5-9]. Patients with diarrhea-predominant irritable bowel syndrome (IBS-D) experienced stool form improvement and stool frequency reduction following a diet low in fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FOD-MAP) such as fructose, sucrose, and lactose[10]. FODMAPs are short-chain carbohydrates that are difficult to absorb[10]. Another study showed that patients with IBS-D experienced a significant reduction in the urgency of defecation following a low-fat dietary (consuming 42 g of fats per day) intervention[11]. Although the presence of excessive bile acids in the colon can lead to the urgency of defecation and FI, a lower-fat diet reduced bile acid production and release[11].

However, evidence regarding the effects of dietary guidance without DF supplements for patients with FI is insufficient. Hence, this study aimed to investigate the effects of diet therapy without DF supplements in patients with FI.

Methods

Study design

This study was an interventional study on the dietary guidance without DF supplements by a dietitian for patients with FI. The FI symptoms, daily stool form, quality of life, and dietary intake were compared before and one month after the dietary guidance session. Patients with FI did not receive other advice or treatments during this study. Patients with the following characteristics were excluded in the study: (i) aged less than 20 years, (ii) who did not provide informed consent for inclusion in the study, (iii) who were ineligible to be included in the study per doctor's assessment, and (iv) who were not able to understand the study. This study was approved by the Ethical Committee of Kameda Medical Center (Approved number: 15-089).

Patients

In the study, participants were recruited from patients complaining of FI between January 2016 and March 2019. All recruited patients provided oral and written informed consent for inclusion in the study. The sample size was determined using power calculation. According to a previous study, 50 patients with FI underwent treatment with psyllium 3.25 g daily and a DF-rich diet, and this completely resolved the complaints of soiling in 12 patients (24%)[12]. Here, we expected a 3-g per day increase in the DF intake after the dietary guidance session. Accordingly, the sample size was determined to be 50 based on an 80% power and 5% significance level.

Individual guidance on diet management

Each patient with FI attended a one 20-min dietary guidance session conducted by a dietitian. The objectives of the dietary guidance session were as follows:

- 1. To increase 3-g DF intake per day derived from side dish.
- 2. To ingest a higher amount of rice as a staple food than bread or noodles.
- To restrict the consumption of fruits, confectioneries, milk, yogurt, greasy or spicy foods, caffeinated beverages, and alcoholic drinks.

Information regarding the dietary guidance was provided orally using charts and illustrative drawings, and written information was also provided.

FI symptoms and daily stool form assessment

The Fecal Incontinence Severity Index (FISI) was used to assess the severity of FI[13]. It is developed to assess the symptoms of patients with FI and consists of questions based on the frequency of gas, mucus, liquid stool, and solid stool incontinence, with lower scores indicating fewer FI symptoms.

Defecation frequency per day and passive and urgent FI frequency per month were reported verbally. Additionally, the patients rated their daily fecal shape using the validated Bristol stool form scale[14], with a higher score indicating looser stools.

Assessment of quality of life

The quality of life in patients with FI was assessed using the Fecal Incontinence Quality of Life Scale (FIQL)[15] and the 12-Item Short-Form Health Survey acute Japanese version 2.0 (SF-12v2) questionnaires[16,17].

The FIQL questionnaire is a FI-specific quality of life measure to assess physical and psychosocial function as a result of FI. The questionnaire consists of a total of 29 items and comprises the following four domains: lifestyle, coping/ behavior, depression/self-perception, and embarrassment[15].

The SF-12v2 questionnaire is a reliable and relevant health-related quality of life scale that is already widely used in clinical practice. It has been constructed based on a universal concept of health, not limited to certain diseases. Therefore, it is used in patients with various diseases and in healthy individuals. The acute version of the SF-12v2 questionnaire with a retroactive period of one week was used in this study. This questionnaire consists of a total of 12 items and comprises the following eight domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health[16,17].

Dietary assessment

Dietary intake of patients with FI was recorded based on



Figure 1. Participants' flowchart. FI: fecal incontinence

the quantity of all foods and beverages consumed in one week. The one-week dietary records were kept just before and one month after the dietary guidance. For each patient, the mean intake per day was calculated from a one-week dietary record. The survey of main nutrients was limited to proteins, fats, carbohydrates, caffeine, and alcohol. Additionally, proteins, fats, and carbohydrates were calculated as the percentage per energy. Carbohydrates included starch, fructose, sucrose, lactose, and DF. DF included water-soluble and water-insoluble DF. Survey foods were limited to 16 groups such as rice, vegetable, and fruit groups. Rice group referred to something cooked and not only polished rice but also unpolished rice, half-polished rice, rice cakes, and rice vermicelli. Moreover, we determined the food group sources

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of the consumed DF. We used the analysis software Eiyo-Pro version 3.01 and the 2015 Standard Tables of Food Composition in Japan for nutrition calculations.

Statistical analysis

Results are presented as median and range. Regarding comparison before and one month after the guidance, the Wilcoxon signed-rank test was used for statistical analysis, and a P-value <0.05 was considered significant. Besides, we used the Fisher's exact test to compare the proportions of categorical variables (such as sex) and the Wilcoxon rank-sum test to compare the median of continuous variables (such as age) between completion and dropout groups. Easy R version 1.40 was used for all calculations[18].

Results

Patients

Participants' flowchart is presented in Figure 1. The doctor assessed the 230 patients as being ineligible to the study and excluded. The doctor judged that the individual dietary guidance for the 230 patients excluded may take more than 20 min or several times, because they did not show much interest in self-management of the diet therapy. Of the 61 patients with FI who received dietary guidance, 50 (82%) completed the entire study and 29 (48%) continued a self-controlled diet therapy without using the medicine. In other words, of the 50 patients who completed the entire study, 58% (29/50) of the patients continued a self-controlled diet therapy without using the medicine of the study.

Table 1 shows the characteristics of patients who received dietary guidance. Regarding the 50 patients who completed the entire study, 92% (46/50) were women. The median age was 67 (range, 35-79) years, with 33 (66%) patients aged greater than 65 years. Of the 46 women, 39 (85%) had a birth history. Seven patients had a history of surgery in the rectum or anus. Of the 49 patients who underwent anal ultrasonography, 36 (73%) had no internal and external anal sphincter injury. Thirty-one (62%) patients were diagnosed with idiopathic incontinence.

Of the 50 patients who completed the entire study, anorectal manometry was performed in 49, where the maximum resting pressure was median 49.0 (range, 14.8-125.7) cmH₂O and the maximum squeeze pressure was median 155.0 (range, 49.0-534.8) cmH₂O.

FI symptoms and daily stool form

The total FISI scores decreased significantly from 19 to 10.5 after the dietary guidance session (P<0.001). This improvement was statistically significant in gas, liquid stool, and solid stool incontinence, with the exception of mucus

Table 1. Characteristics of Patients Who Received Dietary G	uidance (1	n = 61	1)
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	Patients who received dietary guidance (n = 61)	Patients who completed the entire study (n = 50)	Patients who dropped out of the study (n = 11)	P-value
Male/female	5/56	4/46	1/10	1
Median age (range) (years)	67 (31-79)	67 (35-79)	66 (31-79)	0.21
Patients with a birth history	48	39	9	1
History of surgery				
Hemorrhoid	6	5	1	1
Anal fistula	1	0	1	0.18
Rectal cancer	1	1	0	1
Mucosal prolapse	1	1	0	1
Anal ultrasonography observations				
No internal and external anal sphincter injury	44	36	8	1
Internal anal sphincter injury	4	2	2	0.13
External anal sphincter injury	7	7	0	0.59
Internal and exterior anal sphincter injury	4	4	0	1
Diagnosis				
Idiopathic incontinence	39	31	8	0.73
Incontinence after surgery	3	2	1	0.46
Obstetric anal sphincter injuries	7	6	1	1
Irritable bowel syndrome	1	1	0	1
Rectal prolapse	2	2	0	1
Rectal intussusception	1	1	0	1
Diarrhea by laxative overdose	4	3	1	0.56
Functional diarrhea	4	4	0	1

Table 2. The FISI Components and Total Scores of Patientswith FI before and after the Dietary Guidance Session.

	Before the dietary guidance session	After the dietary guidance session	P-value
Gas	4 (0-12)	0 (0-12)	0.005
Mucus	0 (0-10)	0 (0-12)	0.76
Liquid stool	13 (0-19)	8 (0-19)	< 0.001
Solid stool	0 (0-18)	0 (0-18)	0.034
Total scores	19 (6-42)	10.5 (0-49)	< 0.001

Values are presented as median (range).

FISI: fecal incontinence severity index

FI: fecal incontinence

incontinence (Table 2).

The defecation frequency per day significantly decreased after the dietary guidance session. Passive and urgent FI frequency per month was significantly reduced after the dietary guidance session. The Bristol stool form scale was significantly smaller after the dietary guidance session than before the dietary guidance session (Table 3).

Quality of life

For FIQL, patients' generic scores were significantly

higher after the dietary guidance session than before the dietary guidance session. This improvement was statistically significant in all four domains (Table 4).

Table 5 shows the SF-12v2 scores before and after the dietary guidance session. The mental health scores improved significantly after the dietary guidance session, although there were no statistically significant changes in the other seven domains.

Dietary intake

Table 6 shows the patients' daily intake of macronutrients, caffeine, and alcohol before and after the dietary guidance session. There were no statistically significant changes in the intake of energy, proteins, carbohydrates, total DF, water-soluble and water-insoluble DF, caffeine, and alcohol after the dietary guidance session. Total fats intake and fats/energy ratio decreased significantly after the dietary guidance session. Although there was no statistically significant difference in the intake of total carbohydrates, the intake of starch constituting carbohydrates significantly increased and that of fructose, sucrose, and lactose constituting carbohydrates significantly decreased after the dietary guidance session.

Daily intake of each of the food groups in patients with FI before and after the dietary guidance session is shown in Table 7. After the dietary guidance session, rice consump-

Table 3. Daily Defecation Frequency, Passive and Urgent FI Frequency per Month, and Bristol Stool Form Scale of Patients with FI before and after the Dietary Guidance Session.

	Before the dietary guidance session	After the dietary guidance session	P-value
Defecation times per day	2 (0.3-7)	1 (0.3-4)	< 0.001
Passive FI times per month	10 (0-30)	2 (0-30)	< 0.001
Urgent FI times per month	0 (0-30)	0 (0-12)	< 0.001
Bristol stool form scale	4.5 (1-7)	4 (2.5-6)	0.004

Values are presented as median (range).

FI: fecal incontinence

	Before the dietary guidance session	After the dietary guidance session	P-value
Lifestyle (10)	3.2 (1.5-4.0)	3.4 (1.4-4.0)	0.004
Coping/behavior (9)	2.75 (1.6-3.8)	3.0 (1.4-4.0)	< 0.001
Depression/self-perception (7)	3.0 (1.4-4.3)	3.4 (1.3-4.3)	0.003
Embarrassment (3)	2.3 (1.0-4.0)	2.7 (1.3-4.0)	< 0.001
Generic scores (29)	2.9 (1.6-3.8)	3.2 (1.4-4.0)	< 0.001

Table 4.Scores on the Four Domains and Generic Scores of the FIQL Questionnaire in Patients with FI before and after the Dietary Guidance Session.

Values are presented as median (range).

FIQL: fecal incontinence quality of life scale

FI: fecal incontinence

Parentheses: number of items

Table 5. Scores on the Eight Domains of the SF-12v2 Question-naire in Patients with FI before and after the Dietary Guidance Session.

	Before the dietary guidance session	After the dietary guidance session	P-value
Physical functioning	100 (25-100)	100 (25-100)	0.14
Role physical	87.5 (25-100)	87.5 (25-100)	0.45
Bodily pain	100 (0-100)	100 (25-100)	0.31
General health	60 (0-100)	60 (0-85)	1
Vitality	50 (0-100)	62.5 (0-100)	0.79
Social functioning	87.5 (25-100)	100 (0-100)	0.27
Role emotional	87.5 (25-100)	87.5 (25-100)	0.73
Mental health	62.5 (25-100)	75 (37.5-100)	0.033

Values are presented as median (range).

SF-12v2: 12-Item Short-Form Health Survey acute Japanese version 2.0

FI: fecal incontinence

tion increased significantly, and the intake of fruits, dairy products, and confectioneries decreased significantly. There were no statistically significant changes in the consumption of other food groups after the dietary guidance session.

Table 8 shows the daily DF intake derived from each of

the food groups against the total DF intake in patients with FI before and after the dietary guidance session. After the dietary guidance session, the DF intake derived from rice increased significantly, and the DF intake derived from fruits and confectioneries decreased significantly. There were no

	Before the dietary guidance session	After the dietary guidance session	P-value
Energy (kcal)	1902 (1070-2593)	1781 (1029-2549)	0.066
Proteins (g)	74.5 (36.8-108.2)	75.7 (42.0-100.4)	0.60
P % En (%)	16 (11-21)	16 (12-24)	0.33
Fats (g)	62.6 (39.4-113.2)	57.7 (27.5-96.7)	0.005
F % En (%)	32 (21-42)	30 (22-39)	0.016
Carbohydrates (g)	245.1 (133.8-364.7)	232.6 (125.3-375.6)	0.56
C % En (%)	51 (41-65)	53 (43-62)	0.069
Starch (g)	133.7 (64.4-189.3)	143.9 (75.6-230.7)	< 0.001
Fructose (g)	11.1 (2.8-33.6)	7.6 (2.1-16.7)	< 0.001
Sucrose (g)	23.7 (5.0-59.2)	17.4 (5.1-39.4)	< 0.001
Lactose (g)	7.3 (0.2-16.9)	3.8 (0.0-14.3)	< 0.001
DF (g)	16.6 (6.9-27.4)	16.8 (7.6-29.2)	0.87
Water-soluble DF (g)	3.9 (1.8-6.9)	3.8 (2.1-8.5)	0.62
Water-insoluble DF (g)	12.2 (4.9-20.4)	11.9 (5.2-20.2)	0.94
Caffeine (mg)	50 (0-60)	0 (0-60)	1
Alcohol (g)	1.5 (0.2-21.0)	1.0 (0.1-21.7)	0.30

Table 6. Daily Intake of Macronutrients, Caffeine, and Alcohol in Patients with FI be-fore and after the Dietary Guidance Session.

Values are presented as median (range).

FI: fecal incontinence

P % En: proteins/energy ratio

F % En: fats/energy ratio

C % En: carbohydrates/energy ratio

DF: dietary fiber

Table 7.	Daily Intake of Each	of the Food	Groups in	Patients	with	FI b	e -
fore and af	ter the Dietary Guida	nce Session.					

Food groups	Before the dietary guidance session	After the dietary guidance session	P-value
Rice	173.2 (52.9-387.1)	229.0 (56.0-407.1)	< 0.001
Wheat products	106.5 (7.1-232.1)	85.5 (2.9-192.0)	0.12
Potatoes	46.5 (0.0-133.0)	48.5 (0.0-160.0)	0.55
Pulses	64.5 (0.0-333.0)	65.0 (0.0-304.0)	0.14
Seeds	2.0 (0.0-25.0)	1.0 (0.0-19.0)	0.39
Vegetables	308.0 (118.0-662.0)	329.0 (114.0-565.0)	0.56
Fruits	149.0 (0.0-479.0)	75.0 (1.0-251.0)	< 0.001
Mushrooms	7.0 (0.0-36.0)	9.0 (0.0-71.0)	0.62
Seaweeds	6.5 (0.0-24.0)	7.0 (0.0-44.0)	0.94
Fish and shellfish	69.5 (8.0-194.0)	68.0 (3.0-200.0)	0.29
Meat	77.5 (4.0-127.0)	74.0 (7.0-182.0)	0.95
Eggs	35.0 (0.0-82.0)	34.0 (17.0-73.0)	0.61
Dairy products	172.0 (2.0-418.0)	100.0 (0.0-388.0)	< 0.001
Fats and oils	15.0 (4.0-40.0)	15.5 (2.0-35.0)	0.99
Confectioneries	34.0 (0.0-138.0)	19.5 (0.0-95.0)	< 0.001
Spices	0.2 (0.0-1.2)	0.3 (0.0-3.8)	0.14

Values are presented as median (range) (g).

FI: fecal incontinence

statistically significant changes in DF intake derived from other food groups after the dietary guidance session.

Discussion

This study demonstrated that the symptoms of FI im-

Food groups	Before the dietary guidance session	After the dietary guidance session	P-value
Rice	0.7 (0.2-1.6)	0.9 (0.4-1.9)	< 0.001
Wheat products	2.1 (0.5-8.0)	1.9 (0.0-8.9)	0.27
Other grains	0.0 (0.0-1.4)	0.0 (0.0-2.3)	0.92
Potatoes	0.7 (0.0-2.2)	0.7 (0.0-2.3)	0.31
Pulses	1.4 (0.0-6.8)	1.5 (0.0-6.5)	0.37
Seeds	0.2 (0.0-1.8)	0.1 (0.0-2.0)	0.28
Vegetables	6.1 (2.3-14.5)	7.3 (2.0-12.8)	0.063
Fruits	1.8 (0.0-5.9)	0.9 (0.0-6.7)	< 0.001
Mushrooms	0.4 (0.0-1.6)	0.4 (0.0-2.4)	0.53
Seaweeds	0.6 (0.0-2.8)	0.6 (0.0-4.5)	0.61
Confectioneries	0.6 (0.0-1.7)	0.0 (0.0-2.0)	0.001
Seasoning	0.4 (0.0-1.3)	0.5 (0.0-1.6)	0.37
Total DF	16.6 (6.9-27.4)	16.8 (7.6-29.2)	0.87

Table 8. Daily DF Intake Derived from Each of the Food Groups againstthe Total DF Intake in Patients with FI before and after the Dietary Guidance Session.

Values are presented as median (range) (g).

DF: dietary fiber

FI: fecal incontinence

proved after the dietary guidance session. Regarding the quality of life, a previous study reported that FIQL significantly improved in two domains (lifestyle and coping/behavior) when using methylcellulose[9]. However, our study demonstrated that all four domains (lifestyle, coping/behavior, depression/self-perception, and embarrassment) of the FIQL and the mental health of the SF-12v2 improved without DF supplements after the dietary guidance session. Our results suggested that the improved quality of life led to the continuation of a self-controlled diet therapy without using the medicine in 29 patients after the completion of the study (Figure 1).

In this study, patients were provided with dietary guidance with the following objectives: (i) to increase 3-g DF intake per day derived from side dish; (ii) to ingest a higher amount of rice as a staple food than bread or noodles; and (iii) to restrict the consumption of fruits, confectioneries, milk, yogurt, greasy or spicy foods, caffeinated beverages, and alcoholic drinks.

According to the 2015 Japanese dietary reference intake guidelines, the recommended DF intake is more than 18 g per day for women and more than 20 g per day for men[19]. In this study, the DF intake in patients with FI was less than 18 g per day after the dietary guidance session, but overall DF intake was approximately the same as the median intake of the Japanese individuals[20]. Although this result did not demonstrate increasing 3-g DF intake per day derived from side dish, after the dietary guidance session, their DF intake was derived less from fruits and confectioneries and more from rice (Table 8). Therefore, the components of DF after the dietary guidance session should be different from those before the dietary guidance session. When providing dietary guidance, it may be necessary to consider not only the total amount but also the contents of DF. Our results suggested that the components of DF had significant effects on stool form and frequency.

Regarding staple food, increased rice consumption led to an increased intake of starch in this study. According to a previous study, resistant starch is similar to DF and increases fecal mass and moisture[21]. Resistant starch is a starch that is abundant in rice. Our results suggested that increased starch consumption derived from rice improved the symptoms of FI.

With reference to restricted fruits, confectioneries, milk, and yogurt, a previous study showed that dietary manipulation with a low FODMAP diet was a beneficial tool to treat patients with FI due to soft stool[22]. Fruits, confectioneries, milk, and yogurt contain FODMAP, such as fructose, sucrose, and lactose. The mechanisms of action of FODMAP on the large intestine comprise rapid fermentation, osmotic effect, luminal distension, and laxative effect[10]. Therefore, our results suggested that restricting the consumption of fructose, sucrose, and lactose improved liquid stool incontinence, defecation frequency, and stool form.

Regarding the restricted greasy foods, the total fat intake and fats/energy ratio decreased significantly (Table 6) because the intake of dairy products and confectioneries decreased after the dietary guidance session (Table 7). According to the 2015 Japanese dietary reference intake guidelines, the ratio of nutrients per energy is recommended that proteins, fats, and carbohydrates are 13%-20%, 20%-30%, and 50%-65%, respectively[19]. In our study, although the fats/ energy ratio exceeded the upper limit of the goal value before the dietary guidance session, it decreased within the normal range after the dietary guidance session (Table 6).

Regarding spicy foods, caffeinated beverages, and alcoholic drinks, a small intake of those was observed before the dietary guidance session, and the intake did not significantly decrease after the dietary guidance session (Table 6, 7).

This study has several limitations. First, although we calculated the dietary intake per day in patients with FI using a one-week dietary record, meal recording might have been a burden on the patients. In the future, we would like to consider the use of a self-administered diet history questionnaire (DHQ) or brief-type DHQ instead of a dietary record to reduce the burden on the patients and facilitate their participation in the study [23,24]. Second, although this study recommended rice as a staple food, in some areas, it could be difficult to consider rice as a staple food due to some different food cultures depending on the areas. Third, in this study, the dietary guidance session was given only once, and the follow-up period was only one month. It is unclear if the short-term improvement in the study could last for a long time. Fourth, in this study, patients who did not show much interest in self-management of the diet therapy were excluded. When providing dietary guidance session for patients who are indifferent or skeptical about the diet therapy, motivational interviewing may take more than 20 min or several times.

In conclusion, this study demonstrated that the symptoms of FI and the quality of life improved without DF supplements after a one 20-min dietary guidance session conducted by a dietitian. Further studies are required to confirm the results.

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Conflicts of Interest There are no conflicts of interest.

Author Contributions

All authors contributed to the conception and design of the study. Kaoru Nakano and Tomoko Takahashi prepared the materials and collected and analyzed the data. Kaoru Nakano wrote the first draft of the manuscript, and all authors commented on the previous versions of the manuscript and read and approved the final manuscript.

Approval by Institutional Review Board (IRB)

This study was conducted in accordance with the Declaration of Helsinki and approved by the Ethical Committee of Kameda Medical Center (Approved number: 15-089).

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