



The Efficacy of Persian Medicine Based Life Style Modification on Functional Bloating: A Randomized Controlled Clinical Trial

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Abstract

Functional bloating is one of the gastrointestinal diseases that impacts the quality of life and social activities of the patients. The present study aimed to evaluate the effectiveness of lifestyle modification based on Persian Medicine (PM) on functional bloating improvement. Fifty patients with functional bloating and ROME III confirmation criteria were enrolled in the study groups of control and intervention. The intervention group received lifestyle modification education based on PM perspectives, and the control group did not receive any training. The score of implementing PM recommendations by patients was evaluated by the questionnaire of “compliance with the PM principles effective on functional bloating” once every two weeks during the two months of the study. The severity of clinical Complications Associated with Functional Bloating (CAFB) was also evaluated before and after the study by visual analog scale. Primary and secondary outcomes were analyzed by t-test and ANCOVA in SPSS version 19. The qualitative data analysis was performed via Chi-square and Mann-Whitney tests. The severity of clinical CAFB was significantly higher in women at baseline compare to men ($P = 0.027$). Lifestyle modification of patients led to a gradual increase in compliance with the PM principles. By the end of the study, the mean score of compliance with the PM principles in the intervention group was significantly higher compared to the pre-intervention score ($P < 0.0001$) and also compared to the control group ($P < 0.0001$). Besides, the educational intervention resulted in a significant decrease (51.8%) in the mean severity of all clinical CAFB in the intervention group compare to baseline ($P < 0.0001$) and also between the control group and the intervention group ($P < 0.0001$). Therefore, Lifestyle modification based on PM probably can be effective in improving the clinical complications of functional bloating.

Keywords: Lifestyle; Persian medicine; Functional bloating; Randomized controlled trial

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Introduction

Bloating or feeling increased pressure inside the abdomen is one of the most common and annoying gastrointestinal tract symptoms [1,2]. The Prevalence of gastric bloating in gastrointestinal disorders such as functional dyspepsia and irritable bowel syndrome is high [3,4]. Unfortunately, bloating among people without any underlying disease is also high, with 15 to 30% of the general population in the U.S. [5] and 15 to 23% in Asia [3]. Since there is no pathologic or radiologic cause of bloating in people without underlying disease, it is called functional bloating. Functional flatulence is the clinical outcome of the interplay of psychosocial factors (stress, individual psychological well-being, degree of social and family support and adaptation), altered gastrointestinal physiology (gastrointestinal motility and irritability, altered gastrointestinal inflammation, and bacterial flora), genetics, and environment [6]. Functional bloating greatly affects patients' quality of life and poses significant problems in their ability to work and participate in social activities [1]. Persian medicine (PM) encompasses all the knowledge and methods used in Iran (Persia) in the field of health and medical care from ancient times (about 5000 B.C). PM relies more on practical experience and observations passed down from generation to generation [7]. The approach of PM in the prevention and treatment of diseases is holistic and includes all contributing factors in lifestyle and health [8-10]. From the perspective of PM, gastrointestinal bloating could be caused by two general factors: the type of food consumed and the ability of the

gastrointestinal tract to digest food. Therefore, lifestyle and sticking to the principles of eating, drinking, sexual activity, and proper mental health will significantly impact the clinical status of patients with functional bloating [6].

So far, no studies have examined the holistic approach concerning the efficacy of lifestyle-related factors in bloating. The present study aimed to evaluate the efficacy of PM-based lifestyle modification in the treatment of functional bloating.

Methods

The present study is a randomized controlled clinical trial and based on a pretest-posttest design. The study was approved by the Ethics Committee of Baqiyatallah University of Medical Sciences and National Clinical Trial Registration Center, respectively, with I.R.BMSU. REC.1395.329 and IRCT20180623040211N1. Patients with functional bloating referred to the PM health center of Fasa University of Medical Sciences in the spring and summer of 2018 were enrolled in the study. A qualified internal medicine specialist, referred eligible individuals sequentially. And they were participated in the study after taking informed consent.

Sample size

The sample size was determined by statistical software G power 3.3, and based on a previous study with the alpha error of 0.05, beta error equals 0.2, and effect size of 0.2 [11]. The sample size was calculated as 18 individuals in each group (total 36 patients). About the probability of some subjects leaving the study or being

excluded, fifty patients with functional bloating was included in the study. Participants were divided into intervention (30 patients) or control

groups (20 patients) using simple random sampling and lottery (Figure 1).

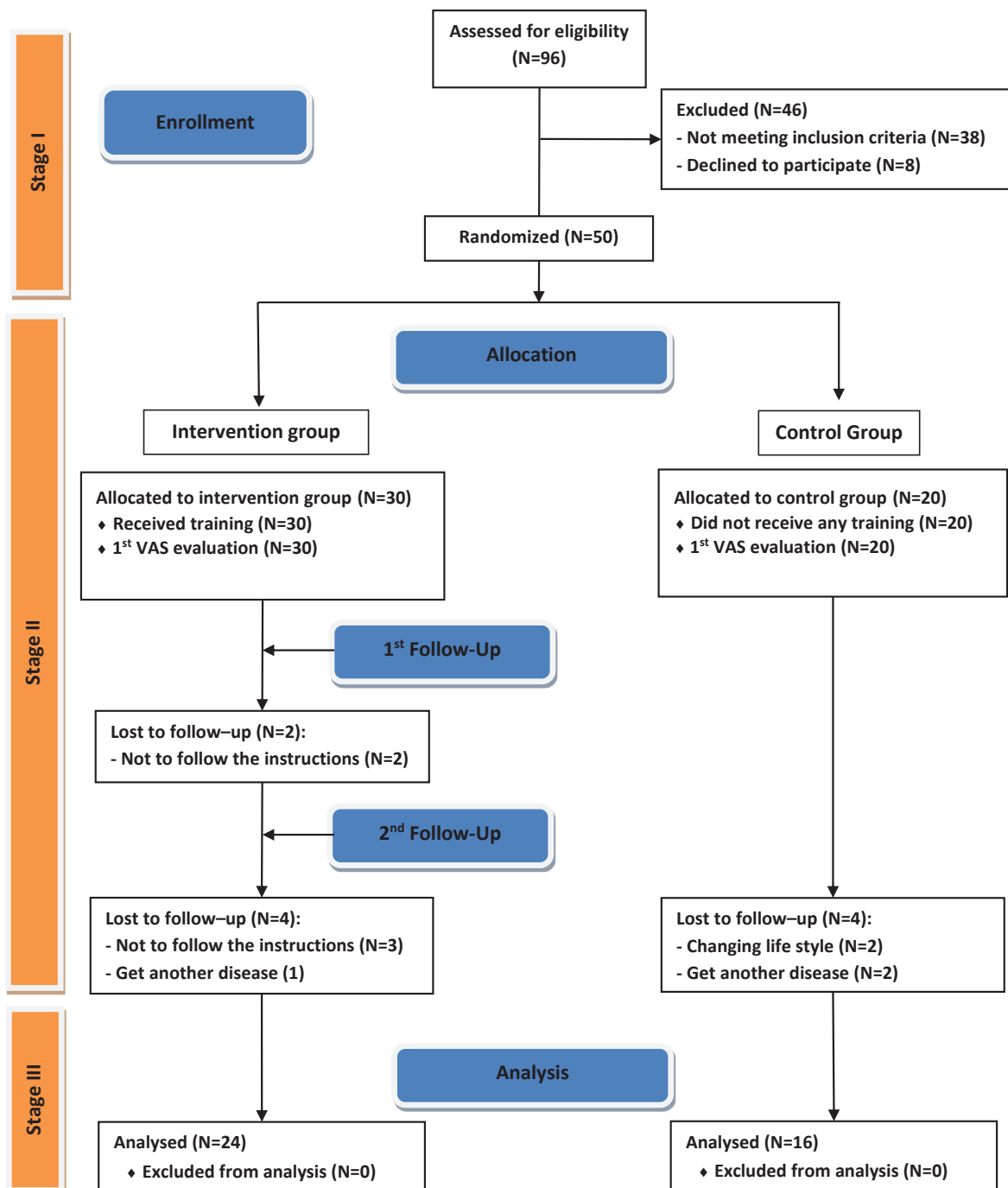


Figure 1. The CONSORT flow chart of the study

Inclusion and exclusion criteria

The ROME III index was used as the primary inclusion criterion, which was administered by an internal specialist to patients aged 18 to 60 who had functional bloating.

ROME III Index for Patients with functional bloating includes the following criteria:

1. Recurrent bloating at least for three days/month during the past three months.
2. Not to have other gastrointestinal disorders such as functional dyspepsia, irritable bowel syndrome, etc.
3. The onset of symptoms should be at least six months before the first two criteria are fully present, and also, the last two criteria should have been fully presented within the last three months [6].

The study's exclusion criteria were gastrointestinal diseases such as active peptic ulcers or acute abdominal pain, inflammatory bowel disease, functional constipation, acute or severe psychological disorders, uncontrolled systemic diseases like heart, liver, kidney or lung failures, pregnancy or lactation, severe weight loss, and melena. Also, consumption of Aspirin or non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, antibiotics, proton-pump inhibitors, and other drugs such as ranitidine, cimetidine, famotidine, and domperidone and any medicinal plant affecting bloating was the other exclusion criteria

Data gathering tools

The data collection tool consisted of three questionnaires that were completed by interviewing the participants. The first questionnaire in-

cludes demographic characteristics such as age, height, weight, BMI, gender, education, marital status, and Occupation. This questionnaire was completed before the study. The second was the questionnaire of "compliance with the PM principles effective on functional bloating." The questionnaire contains fifteen items and assesses different aspects of lifestyle affecting functional bloating. These lifestyle aspects include eating pattern, drinking pattern, sleeping pattern, and sexual activity. The questionnaire indicates the score of implementation of PM recommendations by patients. It was completed by interviewing patients once every two weeks during the two months of the study (before the study, 2th, 4th, 6th, and 8th weeks). The total score of the questionnaire was between 0-4. The reliability and validity of the questionnaire have been evaluated and validated in the previous study [12]. The third was the Visual Analogue Scale (VAS) questionnaire of the clinical Complications Associated with Functional Bloating (CAFB). It evaluates the severity of functional bloating in patients by VAS scale. VAS scale indicates the severity of the clinical CAFB as a percentage ranging from very low (equal to 0 %) to very high (equal to 100 %). The questionnaire was completed before and after the study by interviewing patients.

The clinical CAFB assessed fourteen complications as follows: 1. the amount of epigastric distension after a usual meal; 2. the amount of distension and bulging in the lower abdomen; 3. the intensity of bloating (flatulence); 4. The amount of burping (eructation); 5. The intensity of abdominal rumbling; 6. The intensity of early

satiety in eating (The inability to finish the usual meal); 7. The severity of postprandial fullness after a typical meal; 8. The intensity of bloating after eating foods can cause bloating; 9. The intensity of bloating in hunger and fasting; 10. The intensity of bloating during menstruation period; 11. The intensity of nausea after eating; 12. The intensity of nausea in hunger and fasting; 13. The intensity of retching and 14. The intensity of epigastric pain.

Educational intervention of patients

The intervention group was trained on the PM principles effectively in bloating. Participants of the control group did not receive any training and were asked not to implement any change in

their lifestyle in the two-month interval of the clinical trial. At the end of the study, the severity of 14 clinical CAFB and the implementation of PM recommendations were assessed by the related questionnaire. Patients in the intervention group were strongly requested to adhere to these principles during the two months of the research project. Moreover, every two weeks were contacted to monitor their compliance with the PM recommendations by completing the related questionnaire. The PM principles in functional bloating were trained by an expert in PM expert that included training in eating, drinking, sleeping habits, and sexual activity, as shown in Table 1.

Table 1. The PM principles in functional were bloating in the field of lifestyle modification. The recommendations were trained to the intervention group of the study by an expert in PM.

Rows	Recommendations	Field
1	Do not eat until you have an appetite and feel hungry.	Eating pattern
2	Avoid eating before complete satiation. Don't overeat food or drink (to the degree that you feel full and heavy, and digestion becomes difficult).	Eating pattern Drinking pattern
3	Avoid eating very hot, steaming foods or freezing foods and drinks containing ice and excessive consumption of ice cream.	Eating pattern Drinking pattern
4	Eat different foods in different meals. Moreover, avoid eating several foods and raw and cooked edible things together.	Eating pattern
5	Side dishes are forbidden! Avoid eating side dish with your main course. For example, eating desserts and jellies or caramel, salads, vegetables, yogurt, fruits, and sweets with leading food should be avoided. Such things should be consumed at least one hour before or after meals.	Eating pattern
6	Do not consume water or drinks (soda, yogurt, Delster, or cold milk) with food. Do not drink from a half-hour before until one hour after meals. According to the doctor's diagnosis, people with hot temperament are allowed to drink small sips of water or drink if they are thirsty and needy.	Eating pattern Drinking pattern
7	Avoid over-consumption of sour foods such as sour grape juice, vinegar, and sour fruits.	Eating pattern
8	Use yogurt and dairy as a separate meal or snack with righter ingredients (Mos-lehat), for example, cheese with walnuts or yogurt with mint, cinnamon, thyme, or ginger.	Eating pattern
9	When eating, take a small bite and try to chew it thoroughly (do not eat fast), as long as it leaks into the mouth.	Eating pattern
10	Avoid talking while eating. Moreover, pay attention to what you eat.	Eating pattern

11	Try to eat meals at regular intervals. For example, eat breakfast between 6 and 8 am lunch between 12 and 2 pm, and dinner between 7 and 9 pm.	Eating pattern
12	Avoid sleeping until 2 hours after eating, so eating late at night is a mistake.	Sleeping pattern Eating pattern
13	Do not engage in moderate or vigorous physical activity right after eating (until your stomach feels light).	Eating pattern
14	In the autumn and winter, sleeping should be before 23:00 (and even sooner), and in the spring and summer, it should be before 24:00 (before midnight).	Sleeping pattern
15	Avoid eating at least one hour before and after sexual activity (intercourse).	Sexual activity Eating pattern
16	Avoid drinking cold water for half an hour before and after intercourse.	Sexual activity Drinking pattern

Statistical analysis of data

Results analysis was performed using SPSS version 19. Moreover, analysis was accomplished by calculating mean and standard deviation for descriptive data, using paired t-test in pre and post comparisons, independent t-test for comparison between control and intervention groups, and ANCOVA to eliminate the effect of the pre-intervention score for quantitative tests. Also, confounding effects were eliminated using regression, and qualitative data analysis was performed via Chi-square and Mann-Whitney tests [13]. The significance level was considered as < 0.05 .

Results

Demographic data

During the study period, ten patients were excluded from the study for various reasons such as lifestyle changes, no response to phone monitoring calls, get additional disease and proton-pump inhibitor drug use. The remaining 40 subjects (24 in intervention and 16 in the control group) were assigned to the final analysis. According to Table 2, intervention and control groups were homogeneous in terms of gender, marital status, education level, employment, and BMI, and there was no statistically significant difference between the two groups.

Table 2. The demographic data of intervention and control groups

Qualitative variables		Control (n=16)		Intervention (n=24)		P-value
		Count	Percent	Count	Percent	
Gender	female	7	43.8%	10	41.7%	0.896
	male	9	56.3%	14	58.3%	
Marital status	single	4	25.0%	7	29.2%	0.772
	married	12	75.0%	17	70.8%	
Level of education	diploma or less	9	56.3%	10	41.7%	0.366
	college	7	43.8%	14	58.3%	
Occupation	unemployed	6	37.5%	9	37.5%	0.999
	employed	10	62.5%	15	62.5%	
Monthly income	Very low	8	50.0%	11	45.8%	0.522
	Low	6	37.5%	6	25.0%	
	Average or higher	2	12.5%	7	29.1%	

Quantitative variables	Control (n=16)		Intervention (n=24)		P-value
	Mean	SD	Mean	SD	
Age	35.94	8.87	40.92	12.4	0.174
Height	169.81	9.12	169.42	10.03	0.9
Weight	75.06	15.13	71.87	13.81	0.495
BMI	25.93	4.33	24.94	3.52	0.432

The effect of gender on the severity of clinical CAFB

According to Table 3, the overall severity of these complications in women was significantly higher than in men ($P = 0.027$); especially Post-

meal nausea ($P = 0.024$), nausea in hunger ($P = 0.019$), Feeling heavy and whole after a regular meal ($P = 0.074$), bloating in hunger ($P = 0.075$) and epigastric distention and enlargement after a regular meal ($P = 0.077$).

Table 3. The severity of clinical CAFB in male and female participants at the beginning of the study.

Sign	Group	Mean	SD	P-value
The amount of epigastric distension after the usual meal	Female	52.35	29.902	0.077
	Male	35.65	27.770	
The amount of distension and bulging in the lower abdomen	Female	52.94	33.497	0.236
	Male	41.74	21.031	
The intensity of rectal gas (flatulence)	Female	65.59	24.359	0.570
	Male	69.57	17.183	
The amount of burping (eructation)	Female	36.76	27.211	0.624
	Male	40.87	25.030	
The intensity of abdominal rumbling	Female	38.82	31.748	0.911
	Male	37.83	24.487	
The intensity of early satiety in eating (The inability to finish the usual meal)	Female	34.71	28.965	0.453
	Male	27.83	27.954	
The severity of postprandial fullness after a typical meal	Female	62.94	22.013	0.074
	Male	47.83	28.116	
The intensity of bloating after bloatable food eating	Female	79.41	20.758	0.216
	Male	72.17	15.654	
The intensity of bloating in hunger and without food	Female	50.00	28.940	0.075
	Male	34.35	25.014	
The intensity of bloating during menstruation	Female	46.47	35.168	-
	Male	0	0	
The intensity of nausea after eating	Female	22.35	23.593	0.024*
	Male	6.96	13.630	
The intensity of nausea in hunger and without food	Female	40.59	32.107	0.019*
	Male	17.83	22.504	

The intensity of retching	Female	19.41	18.865	0.555
	Male	15.22	24.049	
The intensity of epigastric pain	Female	41.18	24.971	0.294
	Male	31.30	31.595	
Total score	Female	45.97	13.91	0.027*
	Male	36.86	11.18	

The effect of educational intervention and telephone monitoring

At the beginning of the study, the total score of the questionnaire of “compliance with the PM principles effective on functional bloating” was 1.88 ± 0.37 and 1.89 ± 0.56 in the experimental and control group, respectively ($P= 0.969$). Also, no significant difference was found between the control and intervention groups in any questionnaire domains.

At the end of the study, the total score of the questionnaire underwent a dramatic rise of

86.17% to 3.61 ± 0.27 compared to the pre-intervention ($P < 0.0001$) and control group ($P= 0.0001$). Every four domains of the questionnaire also showed a significant amplification compared to before the study and control group ($p < 0.05$). According to Figure 2, telephone monitoring and patient guidance on following the recommendations led to a boost in the questionnaire score, indicating an increase in compliance with the recommendations of PM in controlling bloating.

Table 4. Mean score of the compliance with PM Questionnaire on bloating in the study groups of control and intervention.

Field	stage	Control (n=16)			Intervention (n=24)			P-value
		Mean	SD	P-value	Mean	SD	P-value	
Eating habits	Before	1.73	0.72	0.774	1.64	0.55	<0.0001	0.670
	After	1.74	0.73		3.73	0.28		<0.0001
	Difference	0.02	0.21		2.09	0.56		<0.0001
Drinking habits	Before	1.75	0.79	0.155	1.82	0.77	<0.0001	0.784
	After	1.94	0.90		3.79	0.37		<0.0001
	Difference	0.19	0.50		1.97	0.75		<0.0001
Sleeping habits	Before	1.77	0.71	0.843	1.99	0.59	<0.0001	0.301
	After	1.79	0.53		2.96	0.70		<0.0001
	Difference	0.02	0.41		0.97	0.75		<0.0001
Sexual activity	Before	2.88	1.00	0.191	2.79	1.02	0.001	0.834
	After	2.75	0.92		3.68	0.66		<0.0001
	Difference	-0.13	0.31		0.88	0.84		0.0002
Total score	Before	1.89	0.56	0.141	1.88	0.37	<0.0001	0.969
	After	1.92	0.64		3.61	0.27		<0.0001
	Difference	0.06	0.14		1.62	0.32		<0.0001

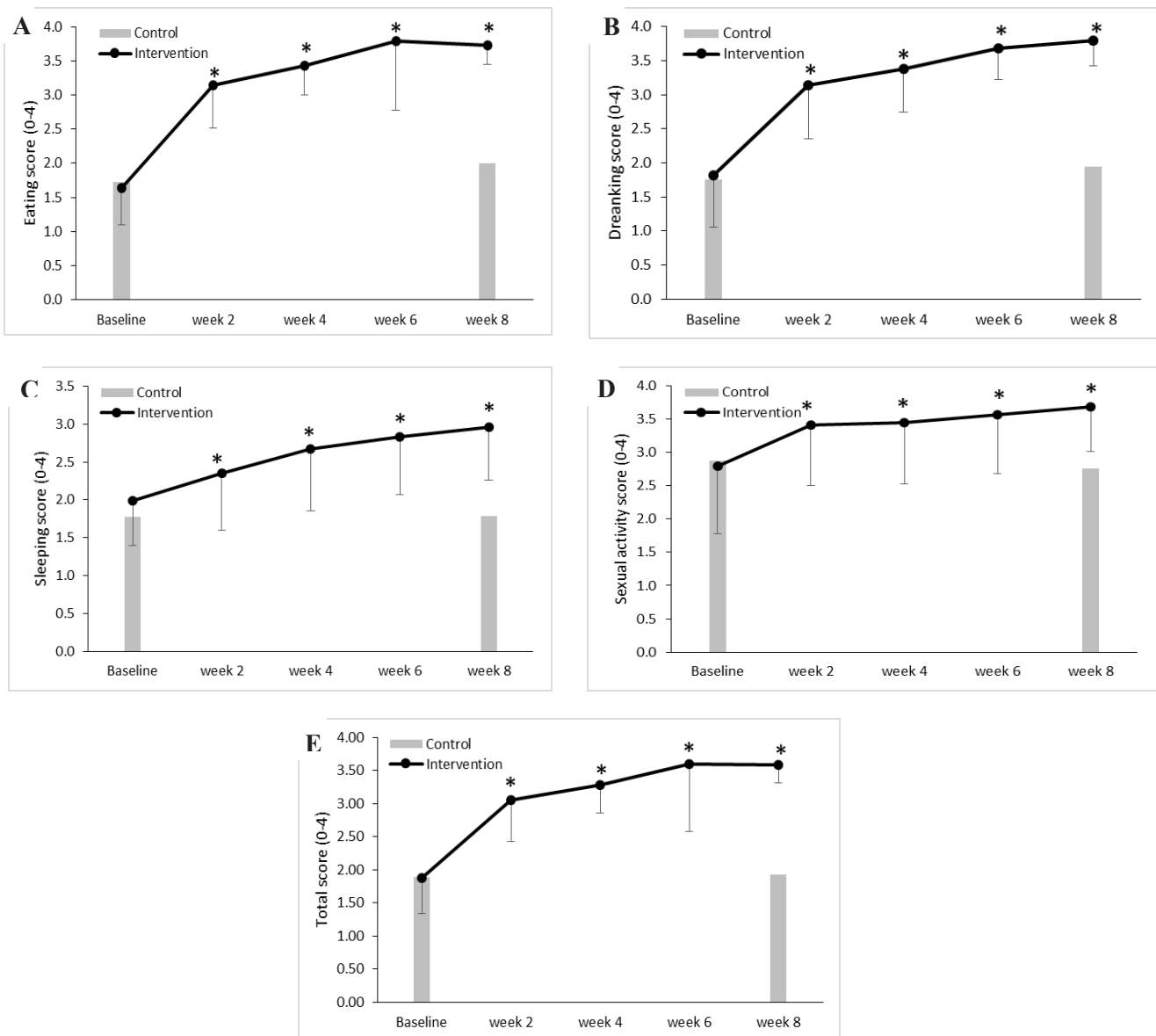


Figure 2. The compliance score with different domains of Persian Medicine Questionnaire on bloating in the study groups during the intervention. Telephone monitoring of the intervention group led to a boost in the total score of the questionnaire and its four domains of eating, drinking, sleeping, and sexual activity.

The measurement of compliance with the principles of Persian medicine in the control group was assessed only twice (beginning and end of the study), A. The eating habit score of the questionnaire, B. The drinking habit score of the questionnaire, C. The sleeping habit score of the questionnaire, D. The sexual activity habit score of the questionnaire, E. The total score of the questionnaire. (*) Indicates a significant statistical difference from the baseline.

Evaluation of the severity of clinical CAFB in intervention and control groups during the study

According to Table 5, there are no significant differences between clinical CAFB in the study

groups at baseline. The educational intervention significantly reduced the severity of all clinical CAFB by 21.45% ($P < 0.0001$). However, no significant difference was found in the control

group. At the end of the study, the mean severity of all clinical CAFBs in the intervention group (19.95 ± 8.14 %) was significantly ($P < 0.0001$) lower than the control group (38.69 ± 12.85 %). The severity of every clinical CAFB was shown in Table 5 before and after the study in control and intervention groups. To eliminate the con-

founding effects of age, gender, BMI, marital status, monthly income, and Occupation on decreasing the severity of clinical CAFB, linear regression was used. The findings indicated that the severity of all clinical CAFBs was substantially decreased, with the exception of post-meal nausea.

Table 5. Mean severity of clinical CAFB in control and intervention groups, before and after educational intervention

Sign	stage	Control (n = 16)			Intervention (n = 24)			P-value	Adj. P-value*
		Mean	SD	P-value	Mean	SD	P-value		
The amount of epigastric distension after the usual meal	Before	33.13	30.71	0.751	49.17	27.49	<0.0001	0.093	0.001
	After Difference	32.81 -0.31	29.78 3.85		24.17 -25	17.11 20.48		<0.0001	
The amount of distension and bulging in the lower abdomen	Before	39.38	24.89	0.270	51.25	28.18	<0.0001	0.180	0.002
	After Difference	37.50 -1.87	25.17 6.55		26.46 -24.79	16.32 21.84		<0.0001	
The intensity of rectal gas (flatulence)	Before	66.56	19.72	0.252	68.75	21.12	<0.0001	0.744	<0.0001
	After Difference	64.69 -1.87	19.28 6.29		28.54 -40.20	14.26 17.47		<0.0001	
The amount of burping (eructation)	Before	37.50	24.08	0.609	40.21	27.21	<0.0001	0.749	<0.0001
	After Difference	36.88 -0.62	25.16 4.78		15.83 -24.37	13.88 24.15		<0.0001	
The intensity of abdominal rumbling	Before	41.88	31.46	0.204	35.83	24.79	<0.0001	0.502	<0.0001
	After Difference	39.38 -2.5	28.57 7.52		13.33 -22.5	14.94 16.01		<0.0001	
The intensity of early satiety in eating (The inability to finish the usual meal)	Before	31.25	25.53	0.411	30.42	30.43	0.003	0.929	0.007
	After Difference	30.00 -1.25	23.87 5.91		19.79 -10.62	22.38 15.62		<0.0001	
The severity of post-prandial fullness after a typical meal	Before	49.38	26.70	0.054	57.50	26.42	<0.0001	0.349	<0.0001
	After Difference	45.63 -3.75	23.66 7.18		27.50 -30	20.69 21.86		<0.0001	
The intensity of bloating after bloatable food eating	Before	74.38	17.11	0.580	75.83	19.09	<0.0001	0.807	<0.0001
	After Difference	75.00 0.62	16.73 4.42		43.33 -32.50	20.36 17.99		<0.0001	

The intensity of bloating in hunger and without food	Before	40.00	26.08	0.164	41.67	28.99	<0.0001	0.854	<0.0001
	After Difference	38.75 -1.25	25.00 3.41		21.46 -20.20	14.71 19.58		<0.0001	
The intensity of bloating during menstruation	Before	42.86	39.88	0.999	49.00	33.48	0.017	0.735	0.048
	After Difference	42.86 0	39.88 0		28.00 -21	27.41 22.82		0.03	
The intensity of nausea after eating	Before	21.88	27.13	0.555	7.92	10.21	0.019	0.065	0.109
	After Difference	24.69 2.81	26.55 18.16		3.54 -4.37	5.61 8.50		0.007	
The intensity of nausea in hunger and without food	Before	34.06	32.93	0.245	23.13	25.78	0.005	0.247	0.001
	After Difference	30.63 -3.43	31.67 11.36		9.79 -13.33	10.68 20.78		0.002	
The intensity of retching	Before	15.31	19.10	0.835	18.13	23.81	0.015	0.695	0.046
	After Difference	15.63 0.31	22.13 5.90		7.71 -10.41	12.51 19.44		0.021	
The intensity of epigastric pain	Before	33.75	26.86	0.164	36.67	30.92	<0.0001	0.760	<0.0001
	After Difference	32.50 -1.25	26.77 3.41		14.79 -21.87	19.64 22.10		<0.0001	
Total score	Before	39.73	13.81		41.40	12.80		0.698	<0.0001
	After Difference	38.69 -1.03	12.85 2.90		19.95 -21.44	8.14 11.42		<0.0001	

* Adj. P-value: Adjusted by Age, Gender, BMI, Marital status, Monthly income, and Occupation using linear regression analysis.

Discussion

Functional bloating is one of the most annoying signs that significantly affects the quality of life and can cause significant problems in working and participating in social activities and imposing a high financial burden on society. Numerous contributing factors such as intestinal hypersensitivity, disruption of intestinal gas passing, changes in intestinal microbial flora, and psychological factors have been effective in etiology and exacerbating functional bloating [2,4, 14,15]. The precise causality is unclear and

many current treatments for this disease face limitations. Unlike modern medicine, PM has a holistic view of human health and highlights all the factors affecting human well-being such as nutrition, environment, physical activities, emotional and psychological status, sleeping, and body intake-output balance in the treatment of diseases. Therefore, lifestyle in PM plays a fundamental role in the treatment of many diseases including functional bloating [16,17]. In the present study, the efficacy of PM lifestyle-based medical advice on the improvement

of clinical CAFB was investigated for the first time. Improving the lifestyle of patients with functional bloating significantly reduced the severity of clinical CAFB. The total severity of 14 clinical CAFB in women was 9.11% more than men ($p = 0.027$). Previous studies have also found a higher prevalence of functional bloating in young women with the single life, less education, less physical activity, and addiction [18-23]. These studies indicate that various aspects of life style affect functional bloating, especially in women.

According to the results, the implementation of PM recommendations by patients significantly reduced the clinical CAFB. The recommendations were in lifestyle modification and include four domains of eating pattern, drinking pattern, sleeping pattern, and sexual activity. According to the previous studies, the regularity of meal-time and the proper amount of meals are of the recommendations that, according to the previous studies, are effective in bloating prevention. Ohlsson and colleagues showed that irregular breakfast consumption is directly related to bloating [24]. Other lifestyle factors that are important in functional bloating have also been studied in previous studies. For example, Moding et al. declared that excessive consumption of beverages such as soda and tea could cause abdominal pain and functional bloating [25]. Takaoka and colleagues also found that employees with a high rate of fast food consumption were more likely to have bloat. In addition to the low nutritional content of fast food, several principles of PM are not observed. These principles include not drinking during eating,

avoiding eating different kinds of food in one meal, and avoiding eating fast [26]. Vakhshoori et al. have emphasized that adherence to certain eating habits, such as complete chewing of food and avoiding overeating, can reduce gastrointestinal complications [27]. Ice-cold water drinking is another factor associated with the eating and drinking aspects of life style, leading to worsening of CAFB. long-term ice-cold water drinking by activation of gastrointestinal thermoreceptors leads to gastrointestinal and reproductive dysfunction [28].

Meanwhile, studies have reported a direct relationship between sleep, anxiety-depression, and mental disorders, and physical activity, with gastrointestinal disorders including functional bloating [29]. For example, Takaoka et al. have shown that an airline's insomnia can cause multiple gastrointestinal disorders, including bloating and anorexia [26]. Physical activity is also likely to reduce the risk of most gastrointestinal abnormalities, including functional bloating, by reducing the passing time of foods through the gastrointestinal tract and gas clearance [30,31]. According to the previous studies, the rate of bloating in eastern countries was lower than in western countries, probably due to lifestyle differences. High fat and protein intake and low dietary fiber intake are among the major causes of higher Prevalence of functional bloating in western societies [32-35].

Today, lifestyle modification in the prevention of various diseases has received particular attention in health care systems. The effectiveness and prediction of probable side effects are evaluated by new methods such as artificial

intelligence, ontology-based side-effect prediction framework, and network embedding [36-38]. It seems that responsible authorities should increase general education of PM life style recommendations to promote health and improve diseases such as functional bloating. In present study was shown that telephone monitoring and clarifying patients' ambiguities about PM recommendations can cause to more implementation of PM principles and reduction of clinical CAFB. Unlike the intervention group, the telephone monitoring of control group was avoided. Because asking repetitive questions during the study most likely affected their lifestyle. Of course, the telephone monitoring of the intervention group may have had a psychological effect on the patients. This confounding factor is one of the limitations of the study, which was beyond the control of the researcher. Our study is much more comprehensive compared to the previous studies in the field and included more lifestyle factors. However, it is limited in other aspects such as failure to check exercise, job-related physical activity, diet habits, lactose intolerance conditions and the small sample size. It is also recommended that in the future studies the updated ROME IV criteria of functional bloating be used.

Conclusion

Lifestyle modification based on PM can be effective in improving the clinical complications of functional bloating. Regarding the generalizable nature of these training and it is safety, more studies with larger sizes and, more extended periods are recommended.

Conflict of Interest

The authors have no conflict of interest to declare.

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