



# The Effect of Honey and Diet Education on Symptoms of Functional Dyspepsia: A Randomized Clinical Trial

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## Abstract

**Background:** Functional dyspepsia is one of the most common and disturbing symptoms that affect many patients visiting health care centers.

**Objectives:** This study was intended to examine the efficacy of honey and diet education in functional dyspepsia symptoms.

**Methods:** This randomized clinical trial was conducted on 60 patients with functional dyspepsia symptoms in two groups. Patients from both groups received necessary education provided by a gastroenterology subspecialist for modifying their dietary patterns. Experimental group patients also received a teaspoon of honey per day, 30 minutes before each meal for 30 days. The severity of each symptom was measured using the Visual Analogue Scale.

**Results:** A total of 30 patients in each group were assessed. Patients' mean age was  $35.07 \pm 12.24$  and  $40.22 \pm 11.43$  years in the experimental and control groups, respectively. There was no significant difference between the groups in terms of demographic characteristics ( $P \geq 0.05$ ). There were significant differences in the signs of functional dyspepsia before and after the intervention in both groups ( $P < 0.05$ ). Mann-Whitney U test showed no significant differences between the experimental and control groups in any of the symptoms after the intervention ( $P \geq 0.05$ ).

**Conclusions:** The consumption of honey alone was unable to affect gastrointestinal factors in patients with functional dyspepsia. However, the improvement of symptoms in both groups due to the dietary pattern education is worth considering.

**Keywords:** Diet, Dyspepsia, Education, Functional, Gastroenterology, Honey

## 1. Background

Dyspepsia is a disorder of the upper gastrointestinal system that includes symptoms such as epigastric pain while eating, heartburn, belching, nausea and vomiting, bloating, and early satiety (1). Functional dyspepsia, defined as dyspepsia without structural disorders in diagnostic examinations, affects 60% of such patients. Functional dyspepsia is observed in 25% of the general population, and it constitutes a large number of referrals to health centers (2). Risk factors associated with dyspepsia include smoking, non-steroidal anti-inflammatory medications, anxiety, and history of digestive problems (3). Another cause of functional dyspepsia is the dietary pattern. Nutrition is regarded as one of the causes of digestive disorders. As the consumption of nutrients can moderate the sensors of the upper gastrointestinal tract movement, changes in diet can probably improve the symp-

toms of functional dyspepsia (4). Pharmaceutical therapies for dyspepsia include antacids (5), H<sub>2</sub> receptor antagonists (6), anti-depressants and anxiolytics (7), and pro-kinetic agents including Plasil, Cisapride, and Domperidone (8). Psychotherapy was used in a study to improve the symptoms (9). Alternative and complementary medicine has also been proposed as a practical treatment for dyspepsia. Red chilies were used in a study to improve the digestive symptoms (10). Another substance used for treating this disorder is honey, which is economical and has a short treatment period (11). Many old sources have reported the use of honey for preventing stomach ulcers, gastritis, and gastroenteritis (12-14). Honey has a stimulating effect on the stomach nerves (15), which may be due to the antioxidant activity of honey (16). According to a study, the consumption of honey reduces the acidic activity of the stomach by 56% (17). Another study showed the effect

of honey on the improved blood supply of stomach microscopic capillaries and it helped in the repair of ulcers (18). The symptoms of functional dyspepsia can also be improved through diet education. In various studies, most people have reported the onset or exacerbation of dyspepsia symptoms after eating (19). Unhealthy nutritional behaviors can exacerbate the symptoms of functional dyspepsia (20). The majority of studies have not investigated the effect of diet education on functional dyspepsia symptoms in interventional studies. In addition, many people are currently turning to natural products for the treatment of gastrointestinal disorders. Honey is one of these products. Honey is easily available and has the least side effects. In addition, the improved nutrition style can be also beneficial in abating symptoms in these patients.

## 2. Objectives

Given the high number of dyspepsia cases and its high financial, physical, and psychological costs, the present study was designed and conducted with the aim of determining the effects of honey and diet education on dyspepsia symptoms.

## 3. Methods

In the present controlled clinical trial, a 1:1 parallel design was used. The present study was registered at the Iran's clinical trials registration center after obtaining permission from the Ethics Committee of Mazandaran University of Medical Sciences and registered under IRCT201610297494N25 at the Iranian Registry of Clinical Trials.

### 3.1. Sample Collections

Of all patients visiting the endoscopy center of Imam Hospital of Sari, Iran, between April 2016 and May 2017, 18-65-year-old patients with symptoms of functional dyspepsia were assessed. Endoscopy was performed for patients by a gastroenterologist, and then their eligibility for inclusion in the study was checked. A total of 267 patients were assessed for the inclusion criteria. The inclusion criteria were the lack of any kind of gastrointestinal ulcers, inflammatory intestinal diseases, diabetes, pregnancy, cancer, gastrointestinal tract surgery, alcohol use (21), smoking, and the use of neuropsychiatric medications. Using the before and after results of a pilot study conducted on 10 patients from the experimental group, giving 80% power, 95% confidence level, and means and standard deviations of  $19.49 \pm 6.16$  and  $10.7 \pm 4.3$ , the sample size was determined as 12 people, which increased to 30 people per group

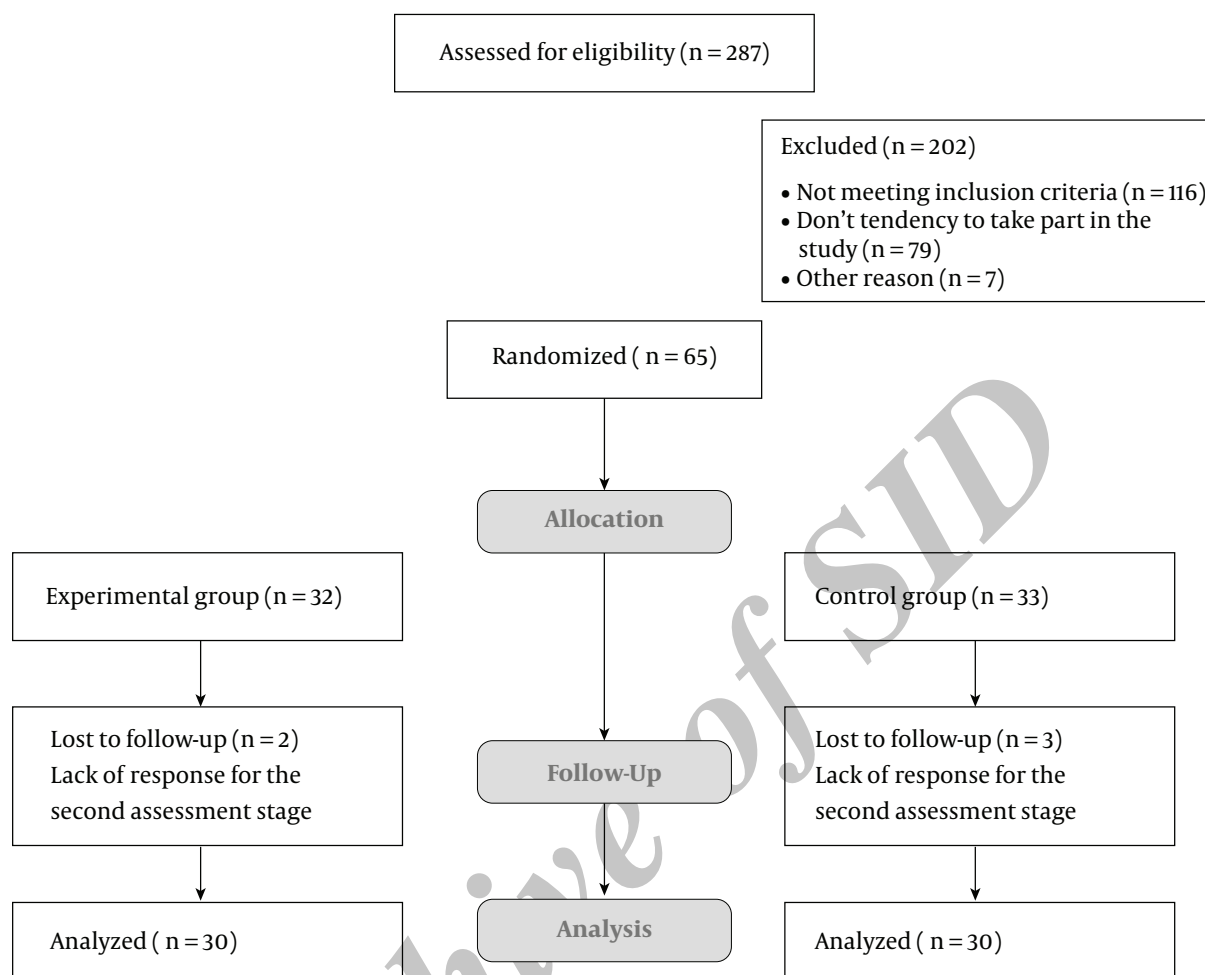
in order to enhance the study rigor and account for possible withdrawals. Given the study inclusion and exclusion criteria, a total of 65 people were assigned to the experimental and control groups (Figure 1). Using a randomization list, eligible patients were placed into two groups. The randomization list was prepared using Excel RANDBETWEEN function. A total of 60 opaque envelopes were designed and according to the random numbers, cards A (experimental group) and B (control group) were placed in them. After the initial assessment of an eligible patient, necessary explanations about the study were provided and written consent was obtained. Then, envelope one was opened and based on the card containing, the patient was assigned by simple randomization to either experimental or control groups.

### 3.2. Ethical Consideration

Written consent was consequently obtained from eligible patients. All participants were informed that participation would be voluntary and they would be free to decline to answer any questions. All participants were informed that they would be free to withdraw from the study at any time.

### 3.3. Interventions

Patients in both groups received vitamin B1 tablets procured from Jalinous Co. (Registration No.: IRC.1228043321) as a placebo. This medication was chosen because it has no effect on the symptoms of functional dyspepsia and no side effects. In addition to placebo, the experimental group patients received a teaspoon of honey (undiluted) per day 30 minutes before each meal (breakfast, lunch, and dinner) (22) for 30 days (23). To prevent the dilution of honey and the reduction of its effectiveness, the patients were asked to refrain from drinking for 20 minutes after taking honey (23). We used spring honey procured from Gangineh Tabiat Company (registration No. 182567). This product was approved by the laboratory of Mazandaran University of Medical Sciences in terms of fructose (2.5%), pH (5.5), and absence of yeast and bacteria. Patients from both groups received necessary education provided by a gastroenterology subspecialist for modifying their dietary patterns (reducing the amount of food intake per meal, increasing the number of meals, complete chewing of food, taking no water during meals, not talking during meals, reducing the consumption of hot and spicy foods, refraining from drinking carbonated drinks and coffee, and avoiding eating at night), stress control, regular exercise, and avoiding the use of medications that exacerbated their symptoms. The control group patients were asked not to use honey in the course of the study.



**Figure 1.** Flowchart of the study's inclusion, allocation, and follow-up

### 3.4. Measurements

Patients' demographic data including age, gender, disease duration, and history of treatment were assessed using a demographic and medical checklist. Patients from both groups were examined for the symptoms of functional dyspepsia before and after the study. The symptoms of the disease were assessed using a medical detailed checklist, and variables assessed included postprandial fullness, bloating, epigastric discomfort, postprandial nausea, belching after meals, and vomiting. These variables were listed according to a study conducted by Talley et al. (24). In the present study, variables were measured only according to their severity. The severity of each symptom was measured using the Visual Analogue Scale (VAS), which is in the form of a horizontal ruler with a graded label on its back from 0 to 100 mm, where zero indicates the lowest level of the symptom and 100 shows its highest

level. The ruler was held in front of the patients to indicate the severity of their symptom, and the researcher read and noted the corresponding figure on the back.

### 3.5. Statistical Analysis

Data were analyzed using SPSS Statistical Software for Windows, version 16.0 (SPSS Inc., Chicago, ILL., USA) (<http://www-01.ibm.com/support/docview.wss?uid=swg214761974>). Quantitative data were summarized using mean and standard deviation, and the percentage was used for qualitative data. The normal distribution of variables of functional dyspepsia was assessed using the Shapiro-Wilk test. For non-normally distributed data, Mann-Whitney and Wilcoxon non-parametric tests were used in inter- and intra-group comparisons. Demographic variables

were analyzed using Chi-square and *t*-tests.  $P < 0.05$  was considered significant.

#### 4. Results

A total of 30 patients from each group were assessed. Patients' mean age was  $35.07 \pm 12.24$  years (range = 15 - 63) in the experimental group and  $40.22 \pm 11.43$  years (range = 18-65) in the control group. There was no significant difference between the groups in terms of demographic characteristics (Table 1). Shapiro-Wilk test showed the non-normal distribution of functional dyspepsia symptoms. Thus, non-parametric tests were used in inter- and intra-group comparisons. Mann-Whitney test showed no significant difference between the two groups before intervention in terms of functional dyspepsia symptoms ( $P > 0.05$ ). According to the Wilcoxon test, functional dyspepsia symptoms in the experimental group patients were significantly different before and after the intervention (Table 2). Wilcoxon test also showed significant differences in functional dyspepsia symptoms (except for one symptom) in the control group before and after the intervention (Table 3). Mann-Whitney U test showed no significant differences between the experimental and control groups in any of the symptoms after the intervention ( $P > 0.05$ ). Comparing differences in the scores of the two groups before and after the intervention in functional dyspepsia symptoms using Mann-Whitney U test showed no significant differences between the two groups in most symptoms ( $P > 0.05$ ) (Table 4).

#### 5. Discussion

The present study results showed that although the two groups were not significantly different in terms of the score of gastrointestinal symptoms after the intervention, both groups showed improvements in the scores of these symptoms after the study. These results showed that using honey did not improve gastrointestinal symptoms in the experimental group patients compared to the controls. Honey is known as a suitable medication for treating gastrointestinal disorders. It is also recognized as an antimicrobial agent (25). Few studies have been conducted on the digestive effects of honey. In their study, Mohtashami et al. investigated the effect of honey and black seed mixture compared to placebo on the symptoms of functional dyspepsia, by mixing equal proportions of honey, black seed, and water. Control group patients received placebo that mimicked the scent and color of the original mixture using laboratory techniques. The Hong Kong dyspepsia severity index was used to measure the symptoms of functional

dyspepsia. The results obtained showed a significant reduction in the score of functional dyspepsia in both groups at the 2nd, 4th, and 8th weeks of the study, but this reduction was more significant in the experimental group (26). In contrast to the present study, in their study, patients in the honey-receiving group showed greater recovery compared to the controls. In their study, honey and black seed mixture was used, which may explain the difference in the results.

In the present study, patients from both groups received education on changing diet style before the intervention. This can explain the improvement of gastrointestinal symptoms in both experimental and control groups. Few studies have been conducted on the effect of diet on the symptoms of functional dyspepsia. Functional dyspepsia is a heterogeneous disorder that can be caused by nutrition in different ways (27). In their study, Carvalho et al. investigated food intolerance, diet, and eating patterns in patients with functional dyspepsia. Their results showed that 30% of patients consumed certain foods. For instance, consuming chili and coffee can cause heartburn, or some foods cause a feeling of fullness. In their study, the dietary pattern was also referred to as a cause of stomach dysfunction. For example, eating at night exacerbated the symptoms of functional dyspepsia in these patients compared to the control group (28). In another study, Jiang et al. investigated food habits in patients with persistent functional dyspepsia. The results obtained showed that unhealthy nutritional behaviors, especially skipping meals, overeating, and preference for sweet and gas-producing foods can be associated with persistent functional dyspepsia (20). Pilichiewicz et al. compared the reports of daily food intake of 20 patients with functional dyspepsia, and 21 healthy people and found that patients received fewer meals, less energy, and higher amount of fat compared to the control group. Stomach fullness and belching were directly associated with the amount of fat received, while fullness showed an inverse association with the amount of carbohydrate intake (29). In a case-control study, 99 patients with functional dyspepsia were compared with 119 people in the control group. Both groups completed a 103-item questionnaire containing the type of food, food habits, and supplements. The results showed that patients with functional dyspepsia consumed more fat and fewer carbohydrates compared to the control group. No difference was found in the consumption of calories, fiber, protein, or micronutrients (30).

In contrast, in a case-control study, Cuperus et al. compared 50 patients with functional dyspepsia to 50 people without and recorded the pattern of meals, intake of food groups and distribution over time for seven days. The results showed no difference between patients with

**Table 1.** Demographic and Medical Data of the Patients

Variable	Experimental Group (N = 30)	Control Group (N = 30)	P Value
Age	35.7 ± 12.24	40.22 ± 11.43	0.116
Disease duration (months)	34.96 ± 47.39	48.18 ± 58.58	0.366
Gender			0.272
Male	33.3%	22.2%	
Female	66.7%	77.8%	
History of treatment			0.383
Yes	74.1%	66.7%	
No	25.9%	33.3%	

**Table 2.** Signs of Functional Dyspepsia Before and After Intervention in the Experimental Group

Sign	Before Intervention, Mean Rank	After Intervention, Mean Rank	P Value <sup>a</sup>
Postprandial fullness	30.41	29.76	0.003
Early satiety	29.61	29.19	0.014
Bloating	29.57	28.59	0.000
Epigastric discomfort	30.72	31.59	0.000
Epigastric pain	31.39	28.98	0.000
Postprandial nausea	28.76	27.59	0.024
Belching after meals	31.33	27.63	0.000
Vomiting	29.37	27.52	0.017

<sup>a</sup> P-values based on Wilcoxon test. P < 0.05 was considered significant.

**Table 3.** Signs of Functional Dyspepsia Before and After Intervention in the Control Group

Sign	Before Intervention, Mean Rank	After Intervention, Mean Rank	P Value <sup>a</sup>
Postprandial fullness	24.59	24.13	0.001
Early satiety	25.39	25.81	0.028
Bloating	25.43	26.41	0.000
Epigastric discomfort	24.28	23.41	0.000
Epigastric pain	23.61	26.02	0.000
Postprandial nausea	26.24	27.41	0.038
Belching after meals	23.67	27.37	0.000
Vomiting	25.63	27.48	0.083

<sup>a</sup> P-values based on Wilcoxon test. P < 0.05 was considered significant.

and those without functional dyspepsia (31). This was also shown in Carvalho et al. study (28). Thus, further studies on the effect of nutrition on the symptoms of functional dyspepsia are necessary.

Recent functional dyspepsia treatments have generally overlooked the role of nutrition. Patients with functional dyspepsia may change their food habits to prevent symptoms. As part of the clinical assessment of patients with functional dyspepsia, a nutrition notebook can be signif-

icantly beneficial to the symptoms of functional dyspepsia and dietary pattern. Nutrition changes, such as fewer meals, reduced fat intake, and modification of nutrition style, can be a promising target for treating functional dyspepsia. However, only a few studies have been conducted in this area, and further studies are required.

According to the present study results, the consumption of honey alone was unable to affect gastrointestinal factors in patients with functional dyspepsia. However,



**Table 4.** Differences in the Scores Before and After Intervention on Functional Dyspepsia Symptoms in the Two Groups

Sign	Experimental Group	Control Group	P Value <sup>a</sup>
Postprandial fullness	29.10	30.93	0.668
Early satiety	28.32	32.68	0.284
Bloating	29.40	31.60	0.621
Epigastric discomfort	29.85	31.15	0.770
Epigastric pain	26.78	34.22	0.095
Postprandial nausea	31.20	29.80	0.024
Belching after meals	24.78	36.22	0.010
Vomiting	27.80	33.20	0.075

<sup>a</sup> P-values based on Mann-Whitney U test.

the improvement of symptoms in both groups due to the dietary pattern education is worth considering. Since a few studies have been conducted on these matters, further studies are recommended.

There were some limitations to this study. The lack of articles on the goal of the study led to the use of out of data references. In addition, this type of honey that was used in our study may not be found in other areas. This may limit the generalization of the study findings.

## Acknowledgments

This study was approved by Mazandaran University of Medical Sciences (approval number: 1041/1394).

## Footnote

**Conflict of Interests:** The authors have no conflict of interest to declare.

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