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Original Article

Efficacy of non-pharmacological treatment for adult patients with chronic constipation

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Abstract: Background: Functional constipation is defined as a delay or difficulty in defecation that lasts two weeks or more which history and physical examination have ruled out its organic causes. In this study, we aimed to evaluate the efficacy of non-pharmacological treatments (dietary changes and increased physical activity) for adult patients with chronic constipation. Methods: This prospective randomized clinical trial was performed in 2020-2021 on 64 patients with functional constipation with the Iranian Registry of Clinical Trials (IRCT) code IRCT20200601047621N2 (https://en.irct.ir/trial/48798). The demographic data and constipation severity were collected by checklist. The diet was designed by a nutritionist containing 25 to 30 grams of fiber and eight glasses of water or liquids other than tea daily for 12 weeks. The amount of sufficient physical activity was defined as doing half an hour of brisk walking daily to increase the heart rate by 50%. All cases were visited during the study and the constipation severity questionnaire was completed at baseline and after 2, 4, 8 and 12 weeks after the beginning of the study. Results: Patients had significantly improved defecation frequencies after 12 weeks ($P = 0.03$ compared to baseline). We also observed that patients had improvements in having a hard stool ($P = 0.001$ compared to baseline), painful defecation ($P = 0.03$ compared to baseline), use of a finger to defecate ($P = 0.04$ compared to baseline), and straining while defecation ($P < 0.001$ compared to baseline). Patients with age groups 30-40 and 40-50 significantly improved defecation frequencies, painful defecation, and straining while defecating compared to other age groups. Conclusion: Non-pharmacological treatments could significantly improve functional constipation in patients. Significant improvements were observed in patients between 30-50 years of age.

Keywords: Functional constipation, management, constipation, non-pharmacological

Introduction

Functional constipation is a delay or difficulty in defecation that lasts two weeks or more and its organic causes have been ruled out by a history and physical examination [1]. According to Rome III, a diagnosis of functional constipation is made when at least two of the following criteria are met for the last three months with symptom onset at least six months before diagnosis: a) straining on > 25% of defecations; b) lumpy or hard stools on > 25% of defecations; c) sensation of incomplete evacuation on > 25% of defecations; d) sensation of anorectal obstruction/blockage on > 25% of defecations; e) manual maneuvers on > 25% of defecations; and f) less than three defecations per week [2-4]. Functional constipation is one of the functional diseases of the gastrointestinal tract, which is defined by straining, hard defecation, feeling of incomplete defecation, feeling of obstruction, and defecation less than three times a week; in a way that does not meet the criteria for irritable bowel syndrome (IBS) [3, 5, 6]. Functional constipation may occur due to disordered movement through the sigmoid colon and/or anorectum [6].

Studies in the United States and Europe have shown that functional constipation is more common in people over 60-70 years old [7]. Various studies at the community level show that its prevalence in adults in Western and Asian countries is about 10 to 20% and in children, between 0.7 to 29.6%. The prevalence of constipation in the Americas was between 2.27 and 2.9 percent and in Europe, it was between 15.3 and 17.1 percent [1, 8]. The prevalence of

constipation in Iran ranged from 1.4-37%, and the prevalence of functional constipation was reported to be 2.4-11.2% [9].

Different treatments for functional constipation have been prescribed, including topical drugs such as laxatives, probiotics, traditional therapies, and non-pharmacological treatments [10]. Physicians and patients have increasingly considered non-pharmacological therapies. The main reason for this issue is that these therapies are mainly cheap, safe and have no side effects, and could also contribute to improving other illnesses [11].

Diet modification and increased physical activity are the most crucial element of non-pharmacological therapies. Nutrition modification and diet, especially diet containing fiber and fluids, have long been considered by physicians to treat constipation. Studies have also shown that adjusting your diet to a diet rich in fiber and more fluids can help treat constipation. Increased physical activity has also been considered in various studies as one of the essential pillars of constipation treatment in non-pharmacological treatments and it has been shown that increased physical activity is associated with improved gastrointestinal function [12, 13].

However, so far, no study has been conducted to scientifically evaluate the effect of this type of treatment in patients with functional constipation in our region. Therefore, due to the relatively high prevalence of functional constipation and costs and its negative impact on patient's quality of life, as well as the existence of various treatments and the possible positive effect of non-pharmacological treatments on constipation, in this study, we aimed to evaluate the impacts of non-pharmacological therapies in patients with functional constipation.

Methods and material

Study design

This prospective randomized clinical trial was performed in 2020-2021 in Khorshid hospital affiliated to Isfahan University of Medical Science. The current study was conducted on patients with functional constipation. The study protocol was approved by the Research Committee of Isfahan University of Medical Sciences and the Ethics committee has confirmed it (Ethics code: IR.MUI.MED.REC.1399.106, Iranian Registry of Clinical Trials (IRCT) code: IRCT20200601047621N2).

Inclusion and exclusion criteria

The inclusion criteria were age more than 18 years, diagnosis of functional constipation based on Rome III criteria, and signing the written informed consent to participate in this study. Patients with the following criteria did not enter the survey: any history of chronic inflammatory disease or structural disease of the gastrointestinal tract, any serious physical problems or illnesses such as malignancy, any physical problem that prevents physical activity, addiction to drugs or analgesics or sedatives, history of chronic diseases such as diabetes, using any laxatives during the study or two weeks before the survey, and the patients consuming enough amount of fiber and liquid. The exclusion criteria were the patient's will to exit the study, not following the study protocol and any symptoms or acute gastrointestinal problems such as nausea, vomiting and diarrhea.

Disease diagnosis

The sampling method of our study was a non-random, easy (available) process and eligible patients were recruited based on the criteria to complete the sample size. All eligible patients were added using the census method. An expert gastroenterologist diagnosed functional constipation according to Rome III criteria [14]. The items evaluated were defecation times, hard stool, painful defecation, anal obstruction sensation, using a finger to defecate, straining while defecating, and incomplete elimination.

Data collection

After obtaining permission from the research and ethics committee, patients demographic data, including age and gender, were collected using a checklist. We collected data regarding the defecation and constipation severity in patients. This questionnaire was according to the Rome III criteria [14]. These data were as follows: defecation times (per week), having hard stool, painful defecation, anal obstruction sensation, use of a finger to defecate, straining during defecation and incomplete defecation. Each of these items was scored from 1 (never,

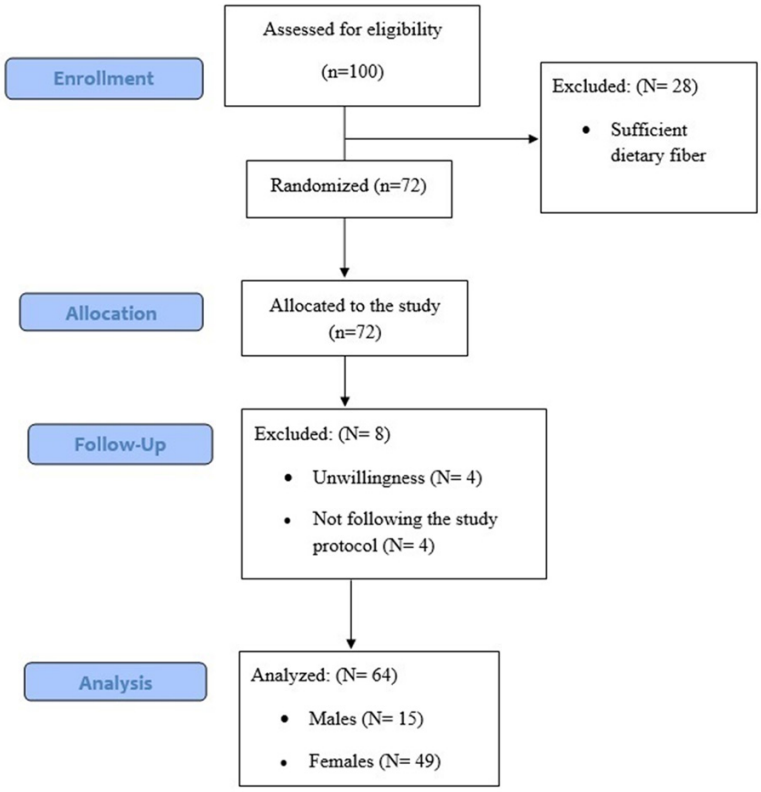

Figure 1. The CONSORT flow chart of the study.

very seldom) to 4 (always). The validity and reliability of this questionnaire have been proven in Iranian studies and has been studied in the Iranian population [15].

Interventions and assessments

Patients were first asked to explain their diet with what they had consumed in the past two weeks, and those who did not consume enough fiber and fluids were included in the study. Patients underwent a 12-week program for diet adjustment and increasing physical activity. The diet was adjusted by a nutritionist containing 25 to 30 grams of fiber and eight glasses of water or liquids other than tea daily by a nutrition consultant and also according to the daily needs of each individual. The amount of sufficient physical activity was defined as doing half an hour of brisk walking daily to increase the heart rate by 50%.

All cases were visited during the study and the constipation severity questionnaire was completed at baseline and after 2, 4, 8 and 12 weeks after the beginning of the study.

Statistical analysis

The obtained data were entered into the Statistical Package for Social Sciences (SPSS) (version 24, SPSS Inc., Chicago, IL). Quantitative data were reported as mean ± standard deviation and qualitative data as frequency distribution (percentage). Independent t-test and Chi-square tests were used to analyze the data. *P*-value < 0.05 was considered a significance threshold.

Results

Study population

The present study assessed 100 patients with functional constipation for eligibility. All cases were assessed for amounts of fiber and liquid in their diet. Initial evaluations showed that 28 patients had sufficient dietary fiber (more than 25 grams daily) and were excluded from the study. Of the 72 entered patients, four patients were excluded due to unwillingness, four other patients were excluded due to not following the study protocol. In the end, data of 64 patients were analyzed. The CONSORT flow diagram of patients is shown in **Figure 1**.

The study population consisted of 15 males (23.4%) and 49 females (76.6%) with a mean age of 45.01 ± 14.19 years. The ratio of men to women was 0.306. Assessments of different factors related to the patient's constipation in patients indicated significantly improved conditions after 12 weeks of interventions.

Data assessments

As indicated in **Table 1**, patients had significantly improved defecation frequencies after 12 weeks (P = 0.03 compared to baseline). We also observed that patients had improvements in having a hard stool (P = 0.001 compared to baseline), painful defecation (P = 0.03 compared to baseline), use of a finger to defecate (P = 0.04 compared to baseline), and straining

Table 1. Evaluation of different variables in patients during the study

Variable	Before treatment	After 2 weeks	After 4 weeks	After 8 weeks	After 12 weeks
Defecation times (per week) (Mean ± SD)	3.63 ± 1.12	3.84 ± 2.44[a]	5.27 ± 1.50[b]	5.67 ± 1.49[a]	6.12 ± 1.72[b]
Hard stool (N (%))	59 (92.2%)	57 (98%)[a]	45 (70.3%)[b]	37 (57.8%)[b]	32 (50%)[a]
Painful defecation (N (%))	56 (87.5%)	41 (64.1%)[b]	33 (51.6%)[b]	28 (43.8%)[b]	25 (39.1%)[a]
Anal obstruction sensation (N (%))	50 (78.2%)	53 (82.8%)[a]	51 (79.7%)[a]	50 (78.2%)[a]	52 (78.2%)[a]
Use of finger to defecate (N (%))	32 (50%)	18 (28.1%)[b]	19 (29.7%)[a]	12 (18.7%)[b]	11 (17.1%)[a]
Straining while defecation (N (%))	61 (95.3%)	42 (65.6%)[b]	28 (43.7%)[b]	21 (32.8%)[a]	13 (20.3%)[b]
Incomplete defecation (N (%))	41 (64.1%)	43 (67.2%)[a]	42 (65.6%)[a]	40 (62.5%)[a]	41 (64.1%)[a]

a: paired samples t-test in comparison with previous time of the evaluation was not significant (P > 0.05). b: paired samples t-test in comparison with previous time of the evaluation was significant (P < 0.05).

Table 2. Mean of each clinical sign in patients based on different age groups

Variable	Under 30 (N = 8)	30-40 (N = 14)	40-50 (N = 20)	50-60 (N = 16)	Above 60 (N = 6)	*P* value[a]
Defecation times (per week) (mean ± SD)	5.24 ± 2.20	6.67 ± 2.57	5.98 ± 1.12	5.11 ± 2.71	5.07 ± 1.39	0.018
Hard stool (per week) (mean ± SD)	4.78 ± 2.60	4.50 ± 1.68	4.13 ± 2.44	4.55 ± 2.91	4.25 ± 2.15	0.336
Painful defecation (per week) (mean ± SD)	2.58 ± 1.20	1.69 ± 0.91	2.14 ± 1.24	3.17 ± 1.72	3.29 ± 1.65	0.03
Anal obstruction sensation (per week) (mean ± SD)	6.19 ± 3.06	6.26 ± 2.66	6.96 ± 2.27	6.36 ± 3.18	6.64 ± 2.07	0.617
Use of finger to defecate (per week) (mean ± SD)	2.66 ± 1.12	2.37 ± 1.26	2.53 ± 1.07	2.66 ± 1.25	2.45 ± 1.78	0.244
Straining while defecation (per week) (mean ± SD)	4.22 ± 2.17	3.31 ± 2.45	3.49 ± 1.85	4.51 ± 2.07	4.39 ± 2.77	0.04
Incomplete defecation (per week) (mean ± SD)	6.33 ± 2.01	6.27 ± 2.44	6.67 ± 3.12	6.35 ± 2.14	6.68 ± 3.11	0.575

a: paired samples t-test in comparison with previous time of the evaluation not significant (P > 0.05).

while defecation (P < 0.001 compared to baseline).

The frequencies of anal obstruction sensation and incomplete defecation did not change significantly in patients compared to baseline (P = 0.26 and P = 0.33, respectively). We summarized the frequencies of patients with these issues and improvements compared to the previous measured times in **Table 1**.

Data assessments based on age

The patient's data at the end of the study were also analyzed based on the age groups. Based on our data, patients in age groups 30-40 and 40-50 had more significant improvements in frequencies of defecation, painful defecation, and straining while defecation compared to other age groups. The advances in the 50-60 and 60-70 years were the lowest, respectively (P = 0.018). Similar results were observed for painful defecation and straining during defecation (P = 0.03 and P = 0.04, respectively). There were no significant differences between age groups regarding other variables. These data of summarized in **Table 2**.

Discussion

In the current study, we evaluated the effectiveness of non-pharmacological treatments (dietary changes and increased physical activity) in managing functional constipation in 64 adults.

It was also observed that patients with age groups 30-40 and 40-50 had more significant improvements in frequencies of defecation, painful defecation and straining while defecation compared to other age groups. These data indicate the importance and effectiveness of dietary changes and increased physical activity in managing functional constipation. In a recent study in 2020 by Dobarrio-Sanz and colleagues, the long-term results of non-pharmacological treatments in adults with functional constipation were evaluated. In this report, data from 7 studies and 657 patients were analyzed. The results of this study indicated that the patients had significant improvements in constipation symptoms and constipation-related quality of life.

Furthermore, it was reported that dietary changes could decrease the frequency of hard

stool and anal obstruction sensation [16]. Fenton and colleagues conducted another recent study in 2021 in New Zealand. By assessing different non-pharmacological treatments in patients with constipation, they reported that dietary soluble fiber, biofeedback training, and increasing physical activities could significantly improve constipation [17]. These results are in line with the findings of our study.

We compared different items related to functional constipation in patients and observed improvements in most things. However, we found that some items, such as anal obstruction sensation and incomplete defecation, did not change significantly in patients. This issue could be due to a lack of complete patient compliance with the study protocols or severe constipation. In another review study by Daniali and colleagues in 2020, they assessed the therapeutic strategies and options for functional constipation. They mentioned that there had been no completely accepted treatment method for functional constipation, and pharmacological and non-pharmacological treatments could be useful. Reviewing various studies showed that non-pharmacological methods are beneficial in most cases and that pharmacological treatment should be initiated in non-responsive cases. It was also declared that non-pharmacological treatments might not result in complete improvements but have significant results [18]. These data were also in line with the findings of our study.

We observed that after 12 weeks, patients had significantly improved constipation. Our results showed improved defecation times, hard stool, painful defecation, use of a finger to defecate, and strain while defecating. An essential point of our study was that we observed significant improvements in frequencies of defecation, painful defecation, and straining while defecation in patients with age groups 30-40 and 40-50 compared to other age groups. This issue also indicates higher patient compliance to non-pharmacological treatments in younger adults. Dobarrio-Sanz and colleagues' study mentioned that older adults might respond better to pharmacological therapies due to a lack of proper compliance [16]. This issue leads to decreased treatment responses. Selçuk and colleagues reported similar results in 2017 by assessing patients with hypertension [19].

In a study by Gungorduk and colleagues in 2021, they summarized the evidence on non-pharmacological interventions in impaired gastrointestinal motilities. This study also highlighted the use of dietary changes and increased physical activity for patients with constipation [20]. Further studies have reported the significant effects of this treatment strategy in patients with constipation due to IBS (2021) and functional constipation in pediatrics [21-23]. These data are consistent with the findings of our study, emphasizing the importance of non-pharmacological treatments for functional constipation.

In a systematic review by Rao and colleagues in 2015, the roles of dietary changes and increasing dietary fiber in the management of constipation were evaluated. Based on this study, fiber supplementation is beneficial in patients with moderate chronic constipation and these effects are increased when associated with physical activities [24]. In the present study, we recommended the patients consume high fiber-containing foods and more water based on nutrition consults and a daily program for physical activity was provided for every patient. The results of our study showed significant improvement in the constipation of patients. The critical point of our research was that this was one of the few studies in our region on patients with functional constipation.

On the other hand, it has been discussed that non-pharmacological treatments might not be effective in cases with severe constipation [25, 26]. Therefore, further studies should be conducted on the effect size of these types of treatments. The limitations of our study include a local study population and not comparing these effects with pharmacological therapies. However, we believe that non-pharmacological treatments have high clinical importance in patients with functional constipation.

Conclusion

Administration of non-pharmacological treatments, including dietary changes and increased physical activities for 12 weeks, improved conditions in patients with functional constipation. Our results showed enhanced defecation times, hard stool, painful defecation, using fingers to defecate, and straining while defecating. It was also observed that patients in age

groups 30-40 and 40-50 had more significant improvements in frequencies of defecation, painful defecation, and straining during defecation compared to other age groups.

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Disclosure of conflict of interest

None.

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