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The effect of combined fig-Walnut syrup on functional constipation in pregnant women: a randomized controlled trial

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Abstract

Background Constipation is one of the most common gastrointestinal complaints during pregnancy. Consuming fruits and vegetables is often the first line of treatment due to their fiber content. Therefore, the purpose of the present study was to determine the effect of combined fig-walnut syrup on functional constipation (FC) and quality of life (QoL) in pregnant women.

Methods In this double-blind, randomized controlled clinical trial, 90 pregnant women with FC were randomly assigned to receive combined fig-walnut syrup, fig syrup, or placebo ($n = 30$ in each group) using block randomization. Participants received 15 ml of syrup once daily at night, half an hour before bedtime, for 14 days and were followed up for 2 weeks after the end of the intervention. The FC, quality of life-gravidity (QOL-GRAV), and food frequency questionnaires (FFQ) were used to collect data. The questionnaires were completed once before the intervention and then the FC questionnaire was completed once a week for four weeks and the QoL questionnaire was completed at the end of the fourth week. To compare the outcomes among the study groups, one-way ANOVA, ANCOVA, Mann-Whitney U test, and Kruskal-Wallis test were used.

Results Following the intervention, although there was no statistically significant difference in the number of defecations between the combined fig-walnut syrup group and the fig syrup group ($P > 0.05$) at every four weeks, there was a statistically significant difference compared to the placebo ($P < 0.05$). Combined fig-walnut syrup (adjusted mean difference (AMD): -3.4; 95% confidence interval: -0.7 to -6.1; $P = 0.008$) and fig syrup (AMD: -5.8; 95% CI: -3.1 to -8.6; $P < 0.001$) improved QoL compared to the placebo group and there was no statistically significant difference between the combined fig-walnut and fig syrup (AMD: 2.4; 95% CI: 5.2 to -0.3; $P = 0.104$).

Conclusion The consumption of fig-walnut syrup and fig syrup may help improve constipation symptoms and enhance QoL during pregnancy. Further studies are needed to reach a conclusive determination.

Trial registration Iranian Registry of Clinical Trials (IRCT): IRCT2012071801032N79. Date of registration: 07.12.2023.

Keywords Functional constipation, Walnut, Juglans, Fig, Ficus carica, Rome IV criteria

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Background

Gestation is a period that can have both positive and negative effects on women, influencing their quality of life (QoL) [1]. The World Health Organization (WHO) defines QoL as “*individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns*” [2]. It has been reported that pregnant women who experience intestinal problems have a lower QoL [3]. One of these common gastrointestinal complaints for some pregnant women is functional constipation (FC), which occurs due to anatomical and physiological changes [4]. If medical advice and appropriate interventions are not provided, it can become chronic and significantly reduce QoL [5] by affecting both physical and mental aspects of health [6]. In other words, those suffering from constipation are more likely to report poor general health, poor physical functioning, reduced vitality, and poorer social functioning [7].

In addition to affecting QoL, FC can cause hemorrhoids and distress for pregnant women [8]. Two-thirds of pregnant women experience anal symptoms such as hemorrhoids and anal fissures during pregnancy and postpartum, with constipation being the most important risk factor [9]. Constipation with straining weakens the pelvic floor muscles, damaging the pudendal nerve [10]. The results of a prospective cohort study revealed that inadequate fiber and fluid consumption increased the risk of constipation during pregnancy. Specifically, low fiber intake was linked to an increased risk of various adverse outcomes, including cesarean delivery, premature birth, and small for gestational age (SGA). Adequate intake of fiber and fluids may serve as a protective factor against constipation related to pregnancy and could be associated with better overall pregnancy outcomes [11].

The global prevalence of FC is 10.1% [12], while it is 40% in pregnant women, which is 2–3 times higher than in non-pregnant women [13]. The term FC has been defined by the Rome Foundation to help standardize the diagnosis of constipation in the absence of physiological abnormalities, where symptoms of difficult, infrequent, or incomplete defecation predominate [14].

There are several factors that can contribute to the development of FC in the pregnant women, including dietary alterations (reduced fiber and water intake, increased fluid loss by vomiting), decreased physical activity, medications (oral iron, antiemetics), mechanical factors (compression by the uterus, pelvic floor dyssynergia), maternal gut microbiota changes (influenced by diet, disease, sleep, hormones, weight, motility, medication), rectal outlet pain (hemorrhoids, anal fissure), metabolic effects (thyroid disorders, diabetes), and hormonal effects (progesterone > estrogen which reduces motilin and increases relaxin, leading to increased colon water

absorption, delayed transit, and decreased contractility) [15–18]. As a further explanation regarding the hormones, female sex hormones regulate GI homeostasis via specific receptors [19]. Generally, steroidogenesis increases throughout gestation to support different physiological demands that guarantee pregnancy success [20]. Progesterone maintains pregnancy by inhibiting uterine contractions [21], but it exerts an inhibitory role on gut smooth muscle cells in part by elevating nitric oxide synthesis which induces relaxation in smooth muscle [22]. Additionally, estrogen significantly prolongs colon transit and inhibits GI hypermotility [23].

The type and severity of symptoms can vary among individuals, and since the effects of drugs and other treatments on fetal development are often not widely studied, this makes treatment a challenge for healthcare providers, especially when caring for pregnant women [24]. The first line of therapy for constipation includes increasing dietary fiber and water intake along with moderate amounts of daily exercise as non-pharmacological treatment. If these are ineffective, pharmacological drugs (laxatives) are considered the second line of therapy [25, 26]. According to the current recommendations, laxatives include bulking agents, osmotic laxatives, stimulant laxatives, suppositories, stool softeners, and enemas. However, side effects such as abdominal pain, diarrhea, hypomagnesemia, and hastening the contraction of smooth muscles of the uterus, limit their use [8, 27, 28].

It is accepted that low fiber intake reduces intestinal motility [29]. Fiber supplements, preferably those containing a mix of soluble and insoluble fiber, or sufficient consumption of fruits and vegetables are the first-line recommendations for the treatment of constipation [30]. Soluble fiber dissolves in water and forms a gel-like substance in the large intestine which is then fermented by bacteria and insoluble fiber increases the volume of stool, helping it move faster through the intestine [31]. Fermentation of dietary fiber in the colon reduces the colon transit time by bulking the stool, which is not only useful in relieving and preventing constipation, but also in reducing the effects of toxic compounds such as hydrogen sulfide, nitrogen, and carcinogenic compounds [32].

Gut dysbiosis occurs in FC in pregnancy, marked by a diminished presence of bacteria that produce short-chain fatty acids (SCFAs), such as Faecalibacterium, alongside an increase in various opportunistic bacteria, including Escherichia-Shigella [33]. Targeting treatments for the dysbiosis of constipation by probiotics may be a new option [34]. Fibers have an effect in increasing the proliferation of certain probiotics, for this reason they are also called microbiota-accessible carbohydrates (MACs) or prebiotics [35]. Prebiotics increase the proportion of microbiota that produce short-chain fatty acids (SCFAs) including acetate, propionate, and butyrate, such as

Bifidobacterium and Bacteroidetes [36]. They are an important source of energy for intestinal epithelial cells that have an indirect effect on gut motility by promoting the release of serotonin (5-hydroxytryptamine; [5-HT] (to accelerate intestinal peristalsis [37] or it directly affects cholinergic neurons in the myenteric plexus [38]. Also, SCFAs are metabolized in the intestinal epithelium where they act as regulators of cell growth and division. They lower the pH of the intestine and thus enhance the growth and cell differentiation of intestinal epithelial cells and it has an effect on the formation of intestinal microflora [39].

According to the united states department of agriculture (USDA) nutrient database, 100 g of walnuts contain 6.7 g [40] and figs have 2.9 g dietary fiber [41]. Fig (*Ficus carica L.*) is indigenous to Southwest Asia and the eastern Mediterranean area, and it is classified within the Moraceae family [42]. Fig fruit is one of the richest plant-based sources of calcium, both soluble and insoluble fibers [43, 44] and polyphenols [45]. Walnut (*Juglans regia L.*) is a part of the Mediterranean diet [46] that contains both soluble [47] and insoluble fiber [48]. It increases microbiome diversity and the relative abundance of beneficial microbes such as Firmicutes species in butyrate-producing Clostridium clusters, including Faecalibacterium and Roseburia, which in turn elevates the concentrations of SCFAs [49, 50]. Also, walnut has the highest total polyphenols [51]. At the colon lumen, polyphenols are deglycosylated and generate absorbable bioactive metabolites particularly SCFAs [52].

Some studies have shown the positive effects of dietary fiber supplements in the improvement of constipation. In a study on pregnant women with FC, consuming dietary fiber and lactulose increased stool frequency compared to the placebo while digestive discomfort was higher in the lactulose group [53]. In another study, daily soluble fiber supplements until delivery decreased the need for medication for gestational constipation [54]. Also, insoluble dietary fiber from walnut alleviated the symptoms of loperamide-induced FC in an animal model [55]. The results of another study showed that fig paste for eight weeks on participants with FC reduces colon transit time and improves stool type and abdominal discomfort compared with the placebo [56].

In a literature search performed, dietary fibers have been used in studies but their composition was different from the product of our study [53, 54]. Figs have been used in studies for constipation, but they were in the form of a paste [56, 57]. Only one study has investigated the effectiveness of combined fig-walnut syrup in the treatment of constipation in the elderly with irritable bowel syndrome with constipation (IBS-C) [58], and there is no randomized controlled trial in the form of combined syrup regarding pregnant women. Given the

significant prevalence of constipation during pregnancy [13] and its potential serious complications [5–10], along with existing evidence regarding the impact of fruits on the digestive system of human [30, 31], this randomized controlled clinical trial was conducted. This study aimed to assess the effects of combined fig-walnut syrup in comparison to the fig syrup and placebo on FC and QoL in pregnant women.

Methods

Design and setting of the study

This study was a double-blinded (participants, outcome evaluators, and statistical analysts were blind), superiority, randomized controlled clinical trial with three parallel arms. Eligible pregnant women were recruited from the obstetrics clinics of Taleghani and Al-Zahra Medical Research and Training Hospitals and health centers in Tabriz, Iran, from September 2023 to late April 2024. Before enrollment, informed consent was obtained from the participants. Before the intervention, demographic data, constipation status, QoL, and food intake was collected from participants. The research received approval from the ethics committee at Tabriz University of Medical Sciences (ethical code: IR.TBZMED.REC.1402.492) and has been registered with the Iranian Registry of Clinical Trials (IRCT code: IRCT2012071801032N79).

Primary and secondary outcomes

The primary outcomes were the comparison of the mean number of defecations each week during a 2-week intervention and a 2-week follow-up period, as well as the comparison of the mean QoL score after the intervention in the three groups while controlling for baseline scores. Secondary outcomes included the comparison of straining, sensation of incomplete evacuation, sensation of anorectal obstruction or blockage, manual maneuvers, the amount of magnesium hydroxide used, and satisfaction with syrups among the three groups.

Sample size

According to previous studies, based on the variable of frequency of defecation) $M1=2.3$, $M2=3.45$, $SD1=SD2=0.7$, Two-sided $\alpha=0.05$, Power=95%), 11 people were calculated [59]. Regarding the QoL variable ($M1=5.98$, $M2=7.47$, $SD1=SD2=1.64$, Two-sided $\alpha=0.05$, Power=95%), 27 people were calculated [60]. Considering that the sample size calculated based on the QoL was larger and accounting for a dropout of 10%, 30 people were considered in each group.

Participants

Based on the sample size calculation, 90 pregnant women with FC (30 in each group) were recruited, all of whom met the criteria for FC as defined by the Rome IV

diagnostic guidelines [14]. The inclusion criteria were as follows: (1) Healthy and singleton pregnant women; (2) Gestational age below 32 weeks; (3) Diagnosed with FC based on the Rome IV criteria; (4) Being literate in reading and writing to fill out the questionnaires. Exclusion criteria included: (1) Receiving medication for constipation less than one week before the study; (2) Endocrine disorders (hypothyroidism, diabetes mellitus); (3) Colon disease (Hirschsprung); intestinal obstruction (colon cancer, hernia or intestinal stricture); inflammatory bowel disease; previous gastrointestinal surgery; spinal abnormalities; and anorectal injuries such as fistula; (4) Having an addiction to drugs and smoking; (5) Having an allergy to figs or walnuts; (6) Central nervous system (CNS) disorders (Parkinson's disease, Epilepsy, Migraines, multiple sclerosis (MS)); (7) Having a high-risk pregnancy (diabetes, preeclampsia, chronic diseases affecting pregnancy such as heart disease, lung disease, etc.); and (8) Use of medications known to contribute to constipation (opiates, tricyclic antidepressants, anticholinergics, calcium channel blockers (CCB), antipsychotics, antacids).

Randomization and blinding

Pregnant women were divided into three groups (combined fig-walnut syrup, fig syrup and placebo syrup) through a computerized random number generator utilizing block randomization with block sizes of 6 and 9, with an allocation ratio of 1:1:1. The allocation sequence was generated by an individual who was not involved in the sampling or data analysis processes. The syrups were matched for taste, color, and consistency, and then prepared in similar opaque bottles, sequentially numbered and distributed to participants in the order of their enrollment in the study. The placebo was composed of a blend of water, a sugar-free sweetener, and flavoring. They were boiled until thick and then flavoring and natural edible plant color were added to make them identical to the combined fig-walnut and fig syrups. To eliminate the osmotic effect of sweeteners on constipation, the amount of sugar in the syrups was equalized. To blind the analyst, when entering the data into the SPSS software, the letters A, B and C were used for the intervention and placebo groups.

Table 1 Nutritional value of syrups

	Combined fig-walnut syrup	fig syrup
Each 100 ml contains		
Fiber (g)	2.9	1.4
Total phenolic (mg GAE/g [*])	500	80
Water (ml)	70	70

^{*}Milligrams of Gallic acid equivalent per gram of dry extract

Intervention

After randomization, each participant received a bottle containing combined fig-walnut syrup, fig syrup, or placebo syrup, administered orally once at night, 15 ml half an hour before bedtime for 14 days. It was emphasized to all participants not to use any laxatives, and in case of constipation, to use only 30 ml of milk of magnesium syrup (MOM) with a glass of water. Before the intervention food intake was evaluated through the use of a food frequency questionnaire (FFQ) to evaluate carbohydrates, fat, protein, and fiber consumed by the participants. Furthermore, all participants were asked to maintain their prior dietary habits and lifestyle and do not use any intestinal motility agent during the intervention. If a serious adverse event occurs during the study, the intervention will be unmasked and the physician can assess whether the product was indeed the cause. Participants retained the right to withdraw from the study at any time upon request, or they could be removed at any point at the investigator's discretion for safety considerations.

After 14 days, a 2-week follow-up was conducted without administering syrups. A text message or phone call was sent every three days to monitor treatment progress and to remind participants to complete the FC questionnaire and diaries.

Syrup preparation

To prepare study syrups, figs and walnuts in equal proportions were washed with water at 18 °C and chopped into smaller pieces. Then, using the maceration method, they were soaked in distilled water as a solvent with a solid-liquid ratio of 1:10 at a temperature of 80 °C for 4 h, stirring during the process. Only fig fruit was used in the fig syrup. The extract was filtered by centrifugation for 5 min at 4000 rpm and then standardized to a ratio of 5%. In every 5 ml of the combined syrup, 200 mg of figs and 200 mg of walnuts were used, and in the fig syrup, 400 mg of figs was used. The content of the syrups in bottles consists of 5% fruit extract, 0.5% stevia, 1% gelatin powder, and water. Estimated nutritional values for 100 ml of the syrups are shown in Table 1.

Data collection and measurements

Data collection was conducted using sociodemographic and obstetric characteristics, FC and QoL questionnaires, syrup consumption, number of defecations, MOM consumption, the level of participants' satisfaction, and side effects diaries.

The demographic and obstetrics characteristics questionnaire included inquiries regarding age, occupation, economic status, educational attainment, educational background of the husband, body mass index (BMI), and gravida, all of which were filled out before the intervention took place. The validity of this questionnaire was

confirmed by experts in midwifery and reproductive health.

The FC questionnaire [61] is developed in accordance with the Rome IV criteria and serves as a standardized tool for evaluating constipation. This questionnaire includes: (a) The occurrence of 2 or more of the following criteria for at least 3 months in more than 25% of instances: Small, hard, pebble-like stools, straining during defecations, the feeling of incomplete evacuation, sensation of anorectal blockage or cramp, manual maneuvers to facilitate excretion, and experiencing fewer than three spontaneous bowel movements per week; (b) loose stools are infrequently observed in the absence of laxative use and (c) Insufficient criteria for IBS such as bloating or abdominal pain. The onset of symptoms must occur at least 6 months prior to the diagnosis, and symptoms should be evident during the preceding three months. This questionnaire was completed before the intervention and once every week in 2-week intervention and 2-week follow-up period by participants.

The quality of life-gravidity (QOL-GRAV) [62] is a 9-item questionnaire, three of which (items 7, 8, and 9) are scored in reverse. The items are formatted using a 5-point Likert scale, where a rating of 1 indicates the highest QoL and a rating of 5 signifies the lowest. Consequently, lower average scores indicate a higher QoL, while higher scores suggest a diminished QoL. It covers physical health, psychological state, social relations, and relationship with important elements of the environment of the participants. The developers have classified the QoL into several categories: excellent, indicated by a mean score ranging from 9 to 18; very good, with a mean score between 19 and 27 points; good, corresponding to a mean score of 28 to 36 points; and not very good, which is represented by a mean score from 37 to 45 points. The QoL-GRAV's validity and reliability have been established by Mirghafourvand et al. (2016) [63] with a Cronbach's alpha of 0.796 and an ICC of 0.86. Participants completed this questionnaire prior to the intervention and at the end of the fourth week.

Food Frequency Questionnaire (FFQ) [64] is dietary assessment tool investigating the relationship between dietary intake and disease or risk factors. The FFQ, consisting of 168 items, serves as a checklist for various foods and beverages. It includes a section for frequency responses, allowing participants to indicate how often they consumed each item during a designated time frame. Reliability and relative validity of FFQ has been confirmed by Mirmiran et al. [65]. Food intake was assessed before the intervention to evaluate carbohydrates, protein, fat, and fibers consumed. Consumption of water were also questioned as confounding factor in constipation.

Statistical analysis

Data were analyzed using SPSS-Ver 24.0 software. The normality of the data was appraised using the Kolmogorov-Smirnov test. Mean and standard deviation (SD) were used for data that followed a normal distribution, while median and interquartile ranges (IQR) were employed for data that exhibited an abnormal distribution. One-way ANOVA, chi-square test, chi-square for trend, and Fisher's exact test were used to assess the homogeneity of the study groups concerning sociodemographic and obstetric characteristics.

To compare the mean number of defecations among the three groups before the intervention, one way ANOVA test and after the intervention, Kruskal-Wallis test was used. To compare each group with each other in terms of the mean number of defecations, Mann-Whitney U test was used. The mean score of QoL before the intervention was assessed using one way ANOVA and ANCOVA test was used to compare the mean score of QoL among the three groups with the control of the baseline score. The Kruskal-Wallis test was used to compare secondary outcomes between the three groups, and the Mann-Whitney U test was used for pairwise comparisons between groups. In order to prevent entering wrong data in the SPSS, two persons were checked them and also some questionnaires were selected randomly and matched with the data entered in SPSS. The intention-to-treat analysis were used and $P < 0.05$ was considered statistically significant.

Result

Description of study process

The participants were recruited from September 2023 to late April 2024. The follow-up ended in May 2024. A total of 640 individuals were assessed; among these, 350 had no constipation, 120 did not meet the basic eligibility criteria, 50 did not enter the study due to long distance, and 30 were unwilling to participate. Ninety eligible women were randomly assigned to three groups following their signing of the informed consent, and they subsequently received the interventions. During the study, 28 women in the combined fig-walnut group, 27 women in the fig syrup group and 29 women in the placebo group completed the treatment process. Four women were lost to follow-up (one in the combined fig-walnut group and three in the fig group), and two women did not continue the intervention after one week (one in the combined fig-walnut group and one in the placebo group). A total of 84 women underwent re-examined after a period of 4 weeks (Fig. 1). Participants' adherence to the syrups under investigation was estimated to be almost 90%.

The mean (SD) age of participants was 32.8 (6.5) years in the combined fig-walnut group, 31.3 (7.4) years in the fig group and 29.3 (7.4) years in the placebo group. The

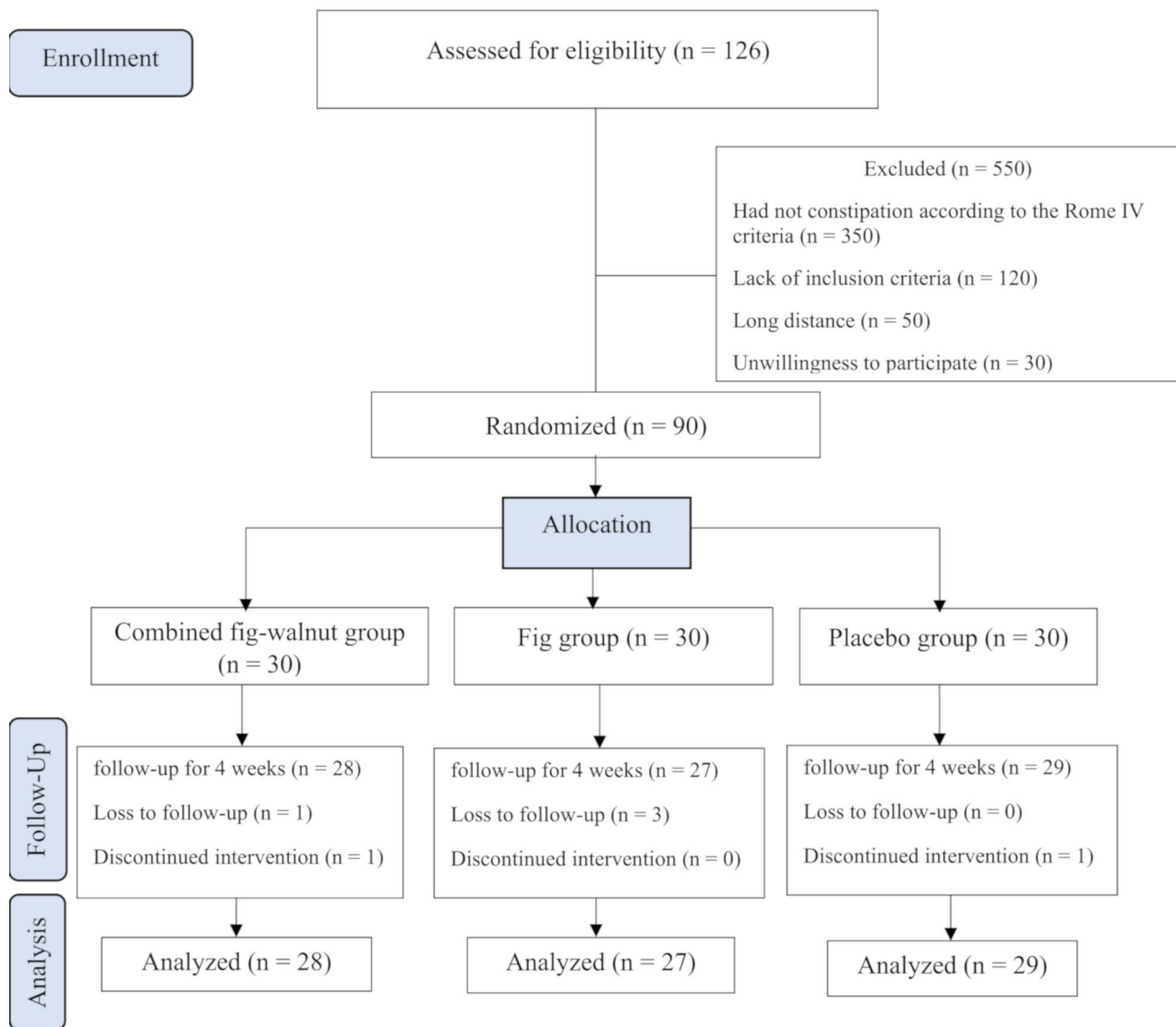


Fig. 1 Flow chart of the study

mean (SD) gestational age of the participants was 20.0 (8.5) weeks in the combined fig-walnut group, 19.7 (7.5) weeks in the fig group and 20.2 (8.3) weeks in the placebo group. The mean (SD) BMI score was 25.8 (3.8) in the combined fig-walnut group, 25.9 (5.3) in the fig group and 26.0 (5.6) kg/m² in the placebo group. Most of the participants were housewives (83.3% in the combined fig-walnut group, 90% in the fig group, and 96.7% in the placebo group). The majority of participants indicated that their income was nearly adequate to cover their living expenses (56.7% in the combined fig-walnut group, 73.3% in the fig group and 80% in the placebo group). Most of the participants were nulliparous or had one child. There was no significant statistical difference among the groups regarding socio-demographic and obstetric characteristics ($P > 0.05$). Additionally, the analysis revealed

no statistically significant differences among the three groups concerning the consumption of nutrients, including energy, carbohydrates, protein, fat, dietary fiber, and water intake (Table 2).

Primary outcomes

At the baseline, the frequency of defecations per week did not show a statistically significant difference between the groups ($P = 0.963$). The median (25th–75th percentile) score of the frequency of defecations during the first week of the intervention was 10.0 (4.5–12.5) in the combined fig-walnut syrup group, 8.0 (7.0–11.0) in the fig group and 5.0 (4.0–8.5) in the placebo group. The results indicated a statistically significant difference among the study groups ($P = 0.016$). The median (25th–75th percentile) score of the frequency of defecations during the

Table 2 Baseline characteristics of the women by the groups

Characteristic	Combined fig-walnut (n = 30)	Fig (n = 30)	Placebo (n = 30)	P-value
	Mean (SD [*])	Mean (SD [*])	Mean (SD [*])	
Age (year)	32.8 (6.5)	31.3 (7.4)	29.3 (7.4)	0.173 [†]
Gestational age (week)	20 (8.5)	19.7 (7.5)	20.2 (8.3)	0.974 [†]
BMI (Kg.m ²)	25.8 (3.8)	25.9 (5.3)	26.0 (5.6)	0.984 [†]
Energy (Kcal/day)	2531.7 (1203.5)	2317.2 (619.4)	2695.0 (1081.8)	0.345 [†]
Carbohydrate (Gram/day)	401.3 (229.6)	363.8 (115.3)	424.0 (188.2)	0.443 [†]
Protein (Gram/day)	77.8 (38.7)	71.0 (23.6)	83.3 (31.2)	0.325 [†]
Fat (Gram/day)	74.3 (41.2)	70.4 (27.6)	80.5 (42.1)	0.578 [†]
Dietary fiber (Gram/day)	25.7 (11.3)	26.5 (10.0)	25.2 (7.0)	0.877 [†]
Water (glass)	4.8 (1.8)	4.5 (1.7)	5.0 (1.9)	0.550 [†]
	Number (Percent)	Number (Percent)	Number (Percent)	
Number of defecations				0.963 [‡]
< 3	17 (56.7)	18 (60.0)	19 (63.3)	
≥ 3	13 (43.3)	12 (40.0)	11 (36.7)	
Education				0.375 [‡]
Primary school	5 (16.7)	4 (13.3)	0 (0)	
Secondary school	4 (13.3)	5 (16.7)	6 (20.0)	
High school	13 (43.3)	15 (50.0)	19 (63.3)	
University	8 (26.7)	6 (20.0)	5 (16.7)	
Husband education				0.796 [‡]
illiterate	1 (3.3)	0 (0)	0 (0)	
Primary school	1 (3.3)	6 (20.0)	3 (10.0)	
Secondary school	4 (13.3)	4 (13.3)	8 (26.7)	
High school	12 (40.0)	11 (36.7)	14 (46.7)	
University	12 (40.0)	9 (30.0)	5 (16.7)	
Job				0.340 [§]
Housewife	25 (83.3)	27 (90.0)	29 (96.7)	
Working outside	3 (10.0)	3 (10.0)	1 (3.3)	
Working at home	2 (6.7)	0 (0)	0 (0)	
Income sufficiency				0.277 [‡]
Not sufficient	13 (43.3)	8 (26.7)	5 (16.7)	
Somewhat sufficient	17 (56.7)	22 (73.3)	24 (80.0)	
Completely sufficient	0 (0)	0 (0)	1 (3.3)	
Gravida				0.913 [‡]
1	8 (26.7)	8 (26.7)	10 (33.3)	
2	9 (30.0)	8 (26.7)	6 (20.0)	
≥ 3	13 (43.3)	14 (46.7)	14 (46.7)	
Parity				1.000 [‡]
0	10 (33.3)	11 (36.7)	11 (36.7)	
1	13 (43.3)	13 (43.3)	13 (43.3)	
≥ 2	7 (23.3)	6 (20.0)	6 (20.0)	
Number of children				0.953 [‡]
0	11 (36.7)	12 (40.0)	11 (36.7)	
1	13 (43.3)	11 (36.7)	14 (46.7)	
≥ 2	6 (20.0)	7 (23.3)	5 (16.7)	
Abortion				0.795 [‡]
0	19 (63.3)	20 (66.7)	17 (56.7)	
≥ 1	11 (36.7)	10 (33.3)	13 (43.3)	
IUFD				1.000 [§]
0	30 (100.0)	29 (96.7)	29 (96.7)	
≥ 1	0 (0)	1 (3.3)	1 (3.3)	
Death				1.000 [§]

Table 2 (continued)

Characteristic	Combined fig-walnut (n = 30)	Fig (n = 30)	Placebo (n = 30)	P-value
	Mean (SD)*	Mean (SD)*	Mean (SD) [†]	
0	30 (100.0)	29 (96.7)	30 (100.0)	
≥ 1	0 (0)	1 (3.3)	0 (0)	

Standard Deviation; [†] One way ANOVA; ^{}Chi-square for trend; [‡]Fisher's Exact Test; [§]Chi-square

second week of the intervention was 10.5 (7.3–12.0) in the combined fig-walnut syrup group, 10.0 (7.0–11.0) in the fig syrup group, and 5.0 (4.0–7.5) in the placebo group. There was a statistically significant difference between the study groups ($P < 0.001$). The median (25th–75th percentile) score of the frequency of defecations during the first week of follow-up (third week) was 7.5 (6.0–10.0) in the combined fig-walnut syrup group, 7.0 (6.0–9.0) in the fig syrup group and 6.0 (4.0–8.0) in the placebo group. The results indicated a statistically significant difference among the study groups ($P = 0.032$). The median (25th–75th percentile) score of the frequency of defecations during the second week of follow-up (fourth week) was 7.5 (6.0–9.8) in the combined fig-walnut syrup group, 7.0 (6.0–9.0) in the fig syrup group and 5.0 (4.5–7.0) in the placebo group. The results indicated a statistically significant difference among the study groups ($P = 0.007$) (Table 3).

There was no statistically difference between the combined fig-walnut and fig syrup group in the mean number of defecations during the first week of the intervention ($P = 0.723$), the second week of the intervention ($P = 0.406$), the first week of the follow-up ($P = 0.825$), and the second week of the follow-up ($P = 0.786$) while there was statistically difference between the combined fig-walnut syrup and placebo and also, fig syrup group compared to the placebo in the mean number of defecations ($P < 0.05$) (Table 3).

Before the intervention, the mean (SD) score of the QoL was 25.8 (7.4) in the combined fig-walnut group, 25.7 (4.3) in the fig group and 24.8 (4.9) in the placebo group. There was no statistically significant difference between the groups ($P = 0.719$). After the intervention, the mean (SD) score of the QoL was 23.0 (6.5), 20.7 (3.9), and 25.8 (6.6), in the combined fig-walnut, fig, and placebo groups, respectively. There was a statistically significant difference between the groups ($P < 0.001$). The inter-group comparison results showed that there was no statistically significant difference between the combined fig-walnut group and the fig group (adjusted mean difference (AMD): 2.4; 95% confidence interval (CI): 5.2 to -0.3; $P = 0.104$). There was a statistically significant difference between the combined fig-walnut and placebo groups (AMD: -3.4; 95% CI: -0.7 to -6.1; $P = 0.008$) and between the fig and placebo groups (AMD: -5.8; 95% CI: -3.1 to -8.6; $P < 0.001$) (Table 4).

Secondary outcomes

Before the intervention, there was no statistically significant difference between the three groups regarding constipation symptoms including the amount of defecation ($P = 0.855$), consistency of stool ($P = 0.591$), straining ($P = 0.671$), sensation of incomplete evacuation ($P = 0.880$), sensation of anorectal blockage ($P = 0.345$), and manipulation to facilitate defecation ($P = 0.800$).

After the intervention, results indicated a statistically significant difference among the three groups regarding constipation symptoms, including the amount of stool, stool consistency, straining, and the sensation of incomplete evacuation ($P < 0.05$). There was no statistically significant difference observed among the three groups regarding the sensation of anorectal blockage and the need for manipulation to facilitate defecation ($P > 0.05$). The results indicated that there was no statistically significant difference in the other constipation symptoms between the combined fig-walnut group and the fig syrup group ($P > 0.05$), but there was statistically difference between the combined fig-walnut syrup and placebo and also, fig syrup group compared to the placebo in the other symptoms of constipation ($P < 0.05$) except for the sensation of anorectal blockage and the need for manipulation to facilitate defecation ($P > 0.05$) (Table 5).

In the first week of the intervention, one participant (3.7%) in the fig syrup group used MOM syrup. In the second and third weeks of the intervention, one person (3.3%) in the placebo group used MOM syrup. In the fourth week, none of the participants used MOM syrup. There was no statistically significant difference between the study groups during the first week of the intervention ($P < 0.314$), the second week of the intervention ($P = 1.000$), and the first week of the follow-up ($P = 1.000$).

There was a statistically significant difference in the level of satisfaction with the syrup across all weeks between the groups ($P < 0.05$). In the first and second weeks, most participants in the combined fig-walnut syrup group and the fig syrup group were very satisfied with the intervention received compared to the placebo group. In the third and fourth weeks, most individuals in the combined syrup group reported high satisfaction, while those in the fig syrup and placebo groups reported moderate satisfaction.

The incidence of side effects included one case of diarrhea in each of the combined fig-walnut syrup and fig

Table 3 Comparison of the frequency of defecations among study groups

Variable	Combined fig-walnut (n = 30) Median (per *25–75)	Fig (n = 30) Median (per *25–75)	Placebo (n = 30) Median (per *25–75)	Three groups P-value †	Combined fig-walnut with fig P-value ‡	Combined fig-walnut with placebo P-value ‡	Fig with placebo P-value ‡
Frequency of defecations							
Week 1	10.0 (4.5–12.5)	8.0 (7.0–11.0)	5.0 (4.0–8.5)	0.016	0.723	0.038	0.004
Week 2	10.5 (7.3–12.0)	10.0 (7.0–11.0)	5.0 (4.0–7.5)	<0.001	0.406	<0.001	0.001
Week 3	7.5 (6.0–10.0)	7.0 (6.0–9.0)	6.0 (4.0–8.0)	0.032	0.825	0.031	0.018
Week 4	7.5 (6.0–9.8)	7.0 (6.0–9.0)	5.0 (4.5–7.0)	0.007	0.786	0.006	0.007

*Percentile; †Kruskal-Wallis test; ‡Mann-Whitney U

syrup groups. Two participants in the placebo group reported mild nausea and one reported severe nausea.

Discussion

According to the study results, administering both combined fig-walnut syrup and fig syrup for two weeks had beneficial effects on increasing the frequency of defecation and improving QoL and other FC symptoms, except for the sensation of anorectal blockage and the need for manual maneuvers to facilitate defecation. The effect of these syrups lasted at least two weeks after the cessation of their ingestion. No study has evaluated the effect of combined fig-walnut syrup for constipation during pregnancy.

The present study showed the positive effect of both combined fig-walnut syrup and fig syrup on the number of defecations compared to the placebo group. There was no significant difference between combined fig-walnut and fig syrups. Figs and walnuts are high in both soluble and insoluble dietary fiber. Dietary fibers are a group of carbohydrates that are not digested or absorbed in the human body due to not being hydrolyzed by human enzymes [66]. Similar to our findings, Lee et al. [57], examined the effects of fig paste for four weeks on loperamide-induced constipation in a rat model. Results showed that fecal number, weight, and water content, and histological parameters such as thickness and mucin areas in the distal colon were improved. The gut serotonin binds to the 5-HT₄ receptor in colon smooth muscle and accelerates colon motility [67]. Lalitha et al. [68], conducted a study on rats that showed the ethanolic extract of fig enhances peristaltic movement in the intestine by increasing the levels of serotonin in the gut. The results of another study conducted by Kim et al., [69], showed that after two weeks of treatment with fig, the total colonic transit time have been shortened and the number of bowel movements increased. Also, walnuts improve bowel movements by activating serotonergic synapses due to their insoluble fiber content [55]. Compared with previous studies, the participants in our study were pregnant women with FC, while most of the previous studies were conducted on participants who were not pregnant or were animal models. Our findings align with those of earlier research, demonstrating that figs and walnuts have positive effects on alleviating constipation.

Based on our findings, both the combined fig-walnut and fig syrups improved FC symptoms such as the consistency of stool, straining, and sensation of incomplete evacuation, while they did not improve the sensation of anorectal blockage and the need for manual maneuvers. There was no significant difference between combined fig-walnut and fig syrups. The human gastrointestinal tract contains the largest microbial community. These microbes metabolize the dietary fibers and produce

Table 4 Comparison of the mean score of quality of life among study groups

Variable	Combined fig-walnut (n = 30) Mean (SD)*	Fig (n = 30) Mean (SD)*	Placebo (n = 30) Mean (SD)*	P-value
Quality of Life (score range: 9 to 45)				
Before the intervention	25.8 (7.4)	25.7 (4.3)	24.8 (4.9)	0.719 [†]
After 4 weeks	23.0 (6.5)	20.7 (3.9)	25.8 (6.6)	<0.001 [‡]
Mean difference between groups	Combined fig-walnut with Placebo	Fig with Placebo	Combined fig-walnut with Fig	
	AMD (95% CI)[§]; P	AMD (95% CI)[§]; P	AMD (95% CI)[§]; P	
Before the intervention	1.0 (3.9 to -1.9); 0.498	1.1 (4.0 to -1.9); 0.470	-0.1 (2.9 to -3.0); 0.964	
After 4 weeks	-3.4 (-0.7 to -6.1); 0.008	-5.8 (-3.1 to -8.6); <0.001	2.4 (5.2 to -0.3); 0.104	

*Standard Deviation; [†]One way ANOVA; [‡]ANCOVA test adjusted for the baseline score; [§]Adjusted mean difference (95% Confidence Interval)

SCFAs. Fiber intake can alter the microbiota and increase SCFAs concentrations. In one study, the gut microbiota was improved after intragastric administration of walnut oil to mice [70]. Yang et al., [55] showed that walnut insoluble dietary fiber could effectively alleviate the symptoms of loperamide-induced FC in mice, including shortening the defecation time and increasing the water content of feces, which improves stool consistency. A randomized, double-blind clinical trial was conducted by Sadri et al. [71], on 40 patients with multiple sclerosis. Participants with constipation (according to ROME III criteria) were divided into two groups to receive 10 g of fig paste or placebo three times a day for three months. Consistent with our work, the results showed a significant increase in the frequency of spontaneous bowel movements, and a reduction in straining during defecation, but the results regarding the reduction in the need for manual maneuvers to facilitate defecation and sensation of incomplete evacuation per week were inconsistent. The mean reductions in the frequency of hard stools in the intervention group showed no significant difference compared to the value in the placebo group, while our study results showed that combined fig-walnut syrup and fig syrup improve stool consistency. Yoen et al. [72] conducted a double-blind case-control study with three groups: placebo, low-dose dietary fiber group, and high-dose dietary fiber group on participants with FC. Both low-dose and high-dose fiber groups had significant improvement in straining and sense of incomplete evacuation that is consistent with our findings. Also, the high-dose group improved colon transit time. Baek et al. [56], reported that supplementation with fig paste for eight weeks was associated with a significant reduction in colon transit time and a significant improvement in stool type and abdominal discomfort compared with the placebo in participants with FC. However, fig paste had no significant treatment effects on constipation-related symptom parameters, which is inconsistent with our finding. According to the differences in participants in our study and the above studies (nonpregnant or animal models), as well as the type of product, which in our

study is a combination and in the form of a syrup, this could be the cause of some inconsistencies in the results.

In the present work, the mean score of post-intervention QoL in both the combined fig-walnut syrup and fig syrup groups was significantly higher than that in the placebo group but there was no significant difference between them. Our study results are consistent with the findings of a clinical trial conducted by Pourmasoumi [73] on 150 participants with IBS-C who were randomly assigned to three groups and received flaxseed, fig, or placebo. The findings indicated that the intake of flaxseed or fig, in contrast to the placebo group, led to a notable enhancement in symptoms associated with IBS-C, such as pain frequency, abdominal distention, bowel movement frequency, and the consistency of stools and significantly improved QoL. The effect of constipation on QoL is considerable and can be likened to that of other prevalent chronic conditions [74]. It is reported that constipation affects the QoL of pregnant women in all trimesters so that it encompasses the quality of life in all dimensions, including physical, psychological, and social [75]. Yüksesol et al. [76], showed that pregnant women's QoL improved after they were trained on how to overcome their constipation. It can be concluded that walnuts and figs can increase the QoL due to their role in relieving constipation. Also, it has been shown in a study that a high-fiber, fruit, and vegetable-enriched eating plan can have a positive impact on QoL [77].

In studies, no side effects were reported [56, 58, 73]. In our study using syrup every night without proper spacing caused diarrhea in two participants in the combined fig-walnut and fig syrup groups.

Strengths and limitations

The strengths of the present study included adherence to the principles of controlled trials, such as blinding, random allocation, and allocation concealment, which effectively mitigated the risks of selection and performance biases. The pleasant taste, harmlessness, convenient use and the absence of chemical substances in combined fig-walnut syrup and being effective in relieving

Table 5 Comparison of constipation criteria among study groups

Variable	Combined fig-walnut (n = 30)	Fig (n = 30)	Placebo (n = 30)	Three groups P-value*	Combined fig-walnut with fig P-value [†]	Combined fig-walnut with placebo P-value [†]	Fig with placebo P-value [†]
	Number (Percent)	Number (Percent)	Number (Percent)				
Amount of stool							
Baseline				0.855	0.576	0.776	0.783
Low	22 (73.3)	20 (66.7)	21 (70.0)				
Moderate	8 (26.7)	10 (33.3)	9 (30.0)				
Week 1				0.001	0.175	0.008	<0.001
Low	5 (17.2)	3 (11.1)	15 (50.0)				
Moderate	19 (65.5)	15 (55.6)	13 (43.3)				
High	5 (17.2)	9 (33.3)	2 (6.7)				
Week 2				0.003	0.654	0.003	0.004
Low	4 (14.3)	3 (11.1)	13 (44.8)				
Moderate	13 (46.4)	16 (59.3)	13 (44.8)				
High	11 (39.3)	8 (29.6)	3 (10.0)				
Week 3				0.008	0.543	0.012	0.006
Low	6 (21.4)	6 (22.2)	15 (51.7)				
Moderate	18 (64.3)	14 (51.9)	13 (44.8)				
High	4 (14.3)	7 (25.9)	1 (3.4)				
Week 4				<0.001	0.304	0.004	<0.001
Low	6 (21.4)	4 (14.8)	17 (58.6)				
Moderate	21 (75.0)	20 (74.1)	12 (41.4)				
High	1 (3.6)	3 (11.1)	0 (0)				
Consistency of stool							
Baseline				0.591	0.466	0.801	0.328
Very hard	11 (36.7)	14 (46.7)	10 (33.3)				
Hard	18 (60.0)	15 (50.0)	19 (63.3)				
Soft	1 (3.3)	1 (3.3)	1 (3.3)				
Week 1				0.051	0.931	0.048	0.029
Very hard	2 (6.9)	0 (0)	2 (6.7)				
Hard	8 (27.6)	9 (33.3)	17 (56.7)				
Soft	17 (58.6)	18 (66.7)	10 (33.3)				
Watery	1 (3.4)	0 (0)	1 (3.3)				
Very watery	1 (3.4)	0 (0)	0 (0)				
Week 2				0.001	0.261	0.013	0.001
Very hard	0 (0)	0 (0)	1 (3.4)				
Hard	6 (21.4)	3 (11.1)	15 (51.7)				
Soft	21 (75.0)	22 (81.5)	12 (41.4)				
Watery	0 (0)	2 (7.4)	1 (3.4)				
Very watery	1 (3.6)	0 (0)	0 (0)				
Week 3				0.009	0.265	0.003	0.044
Very hard	0 (0)	0 (0)	1 (3.4)				
Hard	7 (25.0)	10 (37.0)	18 (62.1)				
Soft	20 (71.4)	17 (63.0)	9 (31.0)				
Watery	1 (3.6)	0 (0)	1 (3.4)				
Week 4				0.001	0.865	0.002	0.001
Very hard	0 (0)	0 (0)	1 (3.4)				
Hard	11 (39.3)	10 (37.0)	22 (75.9)				
Soft	17 (60.7)	17 (63.0)	6 (20.7)				
Straining during defecations							
Baseline				0.671	0.730	0.377	0.578
Every time	20 (66.7)	21 (70.0)	23 (76.7)				

Table 5 (continued)

Variable	Combined fig-walnut (n = 30)	Fig (n = 30)	Placebo (n = 30)	Three groups P-value*	Combined fig-walnut with fig P-value†	Combined fig-walnut with placebo P-value†	Fig with placebo P-value†
	Number (Percent)	Number (Percent)	Number (Percent)				
Usually	8 (26.7)	8 (26.7)	6 (20.0)				
Sometimes	2 (6.7)	1 (3.3)	1 (3.3)				
Week 1				0.001	0.334	0.016	<0.001
Every time	4 (13.8)	0 (0)	7 (23.3)				
Usually	6 (20.7)	7 (25.9)	13 (43.3)				
Sometimes	14 (48.3)	14 (51.9)	9 (30.0)				
Not at all	5 (17.2)	6 (22.2)	1 (3.3)				
Week 2				0.003	0.521	0.001	0.013
Every time	0 (0)	0 (0)	3 (10.3)				
Usually	1 (3.6)	4 (14.8)	8 (27.6)				
Sometimes	16 (57.1)	13 (48.1)	14 (48.3)				
Not at all	11 (39.3)	10 (37.0)	4 (13.8)				
Week 3				0.004	0.207	0.001	0.038
Every time	1 (3.6)	1 (3.7)	5 (17.2)				
Usually	1 (3.6)	6 (22.2)	10 (34.5)				
Sometimes	17 (60.7)	13 (48.1)	10 (34.5)				
Not at all	9 (32.1)	7 (25.9)	4 (13.8)				
Week 4				0.006	0.714	0.003	0.017
Every time	1 (3.6)	1 (3.7)	5 (17.2)				
Usually	3 (10.7)	7 (25.9)	12 (41.4)				
Sometimes	19 (67.9)	12 (44.5)	9 (31.0)				
Not at all	5 (17.5)	7 (25.9)	3 (10.3)				
Sensation of incomplete evacuation							
Baseline				0.880	0.898	0.605	0.749
Every time	10 (33.3)	12 (40.0)	12 (40.0)				
Usually	15 (50.0)	12 (40.0)	14 (46.7)				
Sometimes	4 (13.3)	2 (6.7)	2 (6.7)				
Not at all	1 (3.3)	4 (13.3)	2 (6.7)				
Week 1				0.041	0.881	0.019	0.049
Every time	1 (3.4)	0 (0)	5 (16.7)				
Usually	3 (10.3)	9 (33.3)	9 (30.0)				
Sometimes	14 (48.3)	5 (18.5)	9 (30.0)				
Not at all	11 (37.9)	13 (48.1)	7 (23.3)				
Week 2				0.005	0.410	0.003	0.016
Every time	1 (3.6)	0 (0)	4 (13.8)				
Usually	0 (0)	2 (7.4)	8 (27.6)				
Sometimes	11 (39.3)	12 (44.4)	9 (31.0)				
Not at all	16 (57.1)	13 (48.1)	8 (27.6)				
Week 3				0.012	0.408	0.007	0.027
Every time	1 (3.6)	0 (0)	3 (10.3)				
Usually	1 (3.6)	1 (3.8)	8 (27.6)				
Sometimes	9 (32.1)	12 (46.2)	9 (31.0)				
Not at all	17 (60.7)	13 (43.3)	9 (31.0)				
Week 4				0.002	0.997	0.005	0.002
Every time	1 (3.6)	0 (0)	4 (13.8)				
Usually	3 (10.7)	1 (3.7)	7 (24.1)				
Sometimes	6 (21.4)	10 (37.0)	10 (34.5)				
Not at all	18 (64.3)	16 (59.3)	8 (27.6)				
Sensation of anorectal blockage							

Table 5 (continued)

Variable	Combined fig-walnut (n = 30)	Fig (n = 30)	Placebo (n = 30)	Three groups P-value*	Combined fig-walnut with fig P-value†	Combined fig-walnut with placebo P-value†	Fig with placebo P-value†
	Number (Percent)	Number (Percent)	Number (Percent)				
Baseline				0.345	0.295	0.742	0.160
Every time	8 (26.7)	8 (26.7)	6 (20.0)				
Usually	5 (16.7)	9 (30.0)	7 (23.3)				
Sometimes	8 (26.7)	9 (30.0)	7 (23.3)				
Not at all	9 (30)	4 (13.3)	10 (33.3)				
Week 1				0.852	0.912	0.679	0.588
Usually	6 (20.7)	5 (18.5)	3 (10.0)				
Sometimes	6 (20.7)	7 (25.9)	9 (30.0)				
Not at all	17 (58.6)	15 (55.6)	18 (60.0)				
Week 2				0.985	0.863	0.924	0.937
Usually,	1 (3.6)	1 (3.7)	1 (3.4)				
Sometimes	9 (32.1)	8 (29.6)	9 (31.0)				
Not at all	18 (64.3)	18 (66.7)	19 (65.5)				
Week 3				0.459	0.216	0.391	0.728
Usually	1 (3.6)	2 (7.4)	3 (10.3)				
Sometimes	7 (25.0)	10 (37.0)	8 (27.6)				
Not at all	20 (71.4)	15 (55.6)	18 (62.1)				
Week 4				0.650	0.373	0.496	0.821
Usually	1 (3.6)	1 (3.7)	1 (3.4)				
Sometimes	8 (28.6)	11 (40.7)	11 (37.9)				
Not at all	19 (67.9)	15 (55.6)	17 (58.6)				
Manipulation to facilitate defecation							
Baseline				0.800	0.529	0.895	0.609
Every time	6 (20.0)	3 (10.0)	4 (13.3)				
Usually	2 (6.7)	4 (13.3)	4 (13.3)				
Sometimes	5 (16.7)	4 (13.3)	5 (16.7)				
Not at all	17 (56.7)	19 (63.3)	17 (56.7)				
Week 1				0.366	0.251	0.847	0.175
Every time	2 (6.9)	0 (0)	1 (3.3)				
Usually	1 (3.4)	1 (3.7)	3 (10.0)				
Sometimes	6 (20.7)	4 (14.8)	6 (20.0)				
Not at all	20 (69.0)	22 (81.5)	20 (66.7)				
Week 2				0.141	0.216	0.466	0.44
Every time	2 (7.1)	0 (0)	1 (3.4)				
Usually	1 (3.6)	0 (0)	2 (6.9)				
Sometimes	2 (7.1)	2 (7.4)	5 (17.2)				
Not at all	23 (82.1)	25 (92.6)	21 (72.4)				
Week 3				0.484	0.334	0.860	0.247
Every time	2 (7.1)	0 (0)	1 (3.4)				
Usually	0 (0)	1 (3.7)	1 (3.4)				
Sometimes	5 (17.9)	3 (11.1)	6 (20.7)				
Not at all	21 (75.0)	23 (85.2)	21 (72.4)				
Week 4				0.290	0.123	0.714	0.229
Every time	2 (7.1)	0 (0)	1 (3.4)				
Usually	1 (3.6)	1 (3.7)	2 (6.9)				
Sometimes	6 (21.4)	3 (11.1)	5 (17.2)				
Not at all	19 (67.9)	23 (85.2)	21 (72.4)				

*Kruskal-Wallis test; † Mann-Whitney U

constipation, were other strengths of this study. According to studies, fig fruit extract has antidiabetic properties. Also, the sugar in the syrups is prepared from the extract of the stevia plant and is sugar-free, low-calorie with very low glycemic index and allowed for diabetics.

The participants in our study were pregnant women who found their pregnancy to be a challenging period and were reluctant to increase their stress levels by participating in a scientific study, because they believed it might be harmful to their fetus. Due to the fact that constipation is related to the nutritional status, although we examined participants in terms of fiber consumption at the beginning of the study and advised them to continue their previous diet and physical activity, it is possible that women could increase the consumption of other dietary fibers such as fruits and vegetables in addition to consuming syrup which may have influenced the results.

Clinical recommendations

Natural products mentioned in this study, are rich in useful compounds such as antioxidants, fibers, vitamins and minerals, and in addition to the targeted treatment of desired disease, they may be having wide-ranging effects. For example, they may compensate for the deficiencies of the pregnant women's body, improve health conditions, prevent diseases and help the body's immunity. Considering the benefits mentioned for walnuts, it seems that the combination of figs and walnuts may be better than fig syrup alone. Hence, it may be the best alternative to conventional medicine for relieving constipation during pregnancy.

However, future studies with other ways to administer the syrup to reduce the incidence of diarrhea, long follow-up and other age groups such as children are recommended to see its effect and introduce as an effective herbal medicine for FC. Also, considering the benefits mentioned for walnuts, it is recommended to measure other consequences in future studies.

Conclusion

Regarding the findings indicating the positive effect of combination of fig and walnut in improving bowel performance especially increasing the frequency of defecations and improving QoL and decreasing straining without serious side effects in pregnant women, it is recommended that midwives and gynecologists could suggest the use of syrup to resolve FC in pregnant women.

Abbreviations

FC	Functional constipation
QoL	Quality of life
SCFAs	Short-chain fatty acids
IBS-C	Irritable bowel syndrome with constipation
MOM	Milk of Magnesium
FFQ	Food frequency questionnaires

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Author contributions

MM, SMAC, KH and RV contributed to the conception and design of the study and revised the manuscript. RV collected the data. MM and SMAC conducted statistical analysis. MAK helped to prepare syrups. RV drafted the manuscript under direct supervision of MM. The authors read and approved the final manuscript.

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Tabriz University of Medical Sciences provided funding and Sina Noandish Tabiat Company produced the syrups; however, they were not involved in the design, execution of the study, data analysis, manuscript preparation, or the submission for publication.

Data availability

The data that support the findings of this study are available from the corresponding author, MM, upon reasonable request.

Declarations

Ethical approval and consent to participate

This research was carried out in accordance with the principles outlined in the Helsinki Declaration and its subsequent amendments. This research received approval from the ethics committee of the Research and Technology Deputy at Tabriz University of Medical Sciences (IR.TBZMED.REC.1402.492). All participants gave their consent to take part in the study after receiving both verbal and written information regarding the objectives and procedures involved. All participants provided informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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