

Randomized Placebo-Controlled Trial of Psyllium Fiber in Functional Abdominal Pain Disorders in Children

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Abstract

Background: Functional abdominal pain disorders (FAPD) are common in children and there is heterogeneity in the available literature regarding the role of fibre in FAPD and none so far in functional abdominal pain-not otherwise (FAP-NOS).

Aim: The study aimed to evaluate the efficacy of psyllium fiber in pediatric FAPD including Irritable bowel syndrome (IBS) and FAP-NOS.

Methods: In this prospective randomized placebo-controlled trial, children (5-18 years) diagnosed as FAPD based on Rome IV criteria were randomized to psyllium fiber or placebo (maltodextrin) for 12 weeks. Post-treatment improvement of pain and quality of life (QoL) from baseline was compared between the two groups.

Results: The mean age of 109 children (FAP-NOS: 85%; psyllium fiber 57, placebo 52) was 11.8 ± 3.9 years (58% boys). There was a significant difference in pain improvement in terms of reduction in scores for intensity (5.5 vs. 3.2), frequency (6.0 vs. 3.2), duration (5.3 vs. 3.3), and QoL (4.4 vs. 2.3) between the psyllium and placebo group ($P < 0.001$ in all). Responders ($>50\%$ reduction in pain) were seen in 86% of the psyllium as compared to 60% in the placebo group ($P = 0.001$). On multivariate analysis, use of psyllium fiber was the only factor predictive of response ($OR: 5.49$, 95% $CI: 2.05-14.72$, $P < 0.001$). After discontinuation of psyllium fiber, 81% had sustained response over a mean follow-up of 6.7 ± 4.0 months.

Conclusions: A 12-week trial of psyllium fiber improves pain in most and gives sustained relief in three-fourths of children with FAP-NOS and IBS.

Trial registration: CTRI/2023/08/056772; Clinical trial registry website: <http://ctri.nic.in>

Introduction

Functional abdominal pain disorders (FAPD), now commonly referred to as disorders of gut-brain interaction, are quite common in children. The estimated global pooled prevalence of FAPDs is 11.7%.¹ FAPD in children consists of functional dyspepsia (FD), irritable bowel syndrome (IBS), functional abdominal pain-not otherwise specified (FAP-NOS), and abdominal migraine (AM).² Children with FAPDs have lower health-related quality of life (HR-QoL).³

The pathophysiology of these disorders are multifactorial and include altered motility, visceral hypersensitivity, and gut-brain interactions.⁴ Inadequate fiber intake is a potential dietary risk factor for FAPDs.⁵

There is a lot of heterogeneity in the available literature regarding the role of fiber in FAPD in pediatric patients. Though some previous studies showed its role in recurrent abdominal pain (RAP), recent

studies are mainly in IBS. In our setting, we see predominantly FAP-NOS, and the role of psyllium fiber in this subset (FAP-NOS) has not been studied so-far. Thus, in this prospective, randomized placebo-controlled trial, we aimed to evaluate the efficacy of psyllium fiber in children with FAPD (FAP-NOS and IBS).

Methods

Ethical Statement

The study was conducted after obtaining ethical approval from the institutional ethics committee and was registered with the Clinical Trial Registry of India (CTRI: CTRI/2023/08/056772). This is a single blinded trial conducted in accordance with the principles of Good Clinical Practice, the Declaration of Helsinki, and the recommendations of the Rome foundation pediatric subcommittee for pharmacological clinical trials in children with FAPD. Written informed consent from the parents and assent from the children were obtained before enrolment.

Study population: From September 2023 to May 2025, children (5 to 18 years), diagnosed with FAPD (FAP-NOS and IBS) as per Rome IV criteria, were enrolled consecutively from the Pediatric Gastroenterology outpatient services of Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, India, a tertiary health care centre.

Study design: The study consisted of a baseline observation period of 4-week followed by 12-week treatment period after randomisation to either the psyllium fiber or placebo group.

Exclusion criteria: Children were excluded if there was suspected/proven organic disease (screened with hemogram, total protein, albumin, erythrocyte sedimentation rate, c-reactive protein in all patients and celiac screening in patients with IBS-Diarrhoea), functional dyspepsia and abdominal migraine as their pathophysiology is different, already on fiber therapy in any form or psychiatric disorder and if they were on anticonvulsants or antipsychotic medications. Children on laxatives such as Polyethylene glycol (PEG), a washout period of 4 weeks (off laxative) was given before being included in the study.

Baseline assessment: Once the diagnosis was made, stressors, if any, were identified, and parents and the child were individually counselled about the pathogenesis of the disease, keeping the brain–gut axis in mind. There was no further counselling session during the trial.

Sample size: Taking study conducted by Menon et al.⁶ as reference study and assuming the lower effect-size in our study (Cohen-d: 0.8) for the difference among the two groups, at minimum two-sided 95% confidence-interval and 95% power of the study, estimated sample size in each group was 42. Sample size was estimated using software G*Power version 3.1.9.2.

Randomisation and intervention: Children recruited in the study were randomized by a computer-generated random number table in the ratio of 1:1. The participants were blinded. Psyllium fiber

(Telephone brand, Sidhpur Sat-Isabgol Factory Private Limited, Patan, Gujarat, India) and placebo (Maltodextrin) were given (5g in 5-11 years old and 10 g in 12-18 years old) once a day for 12 weeks in powder form after mixing with plain water (100 ml), followed by one glass of water (100 ml). Both powders were provided in the form of opaque sachets, with each sachet containing 5 g of either of the materials, to ensure patient blinding. Only intervention (psyllium or placebo) or analgesics (oral acetaminophen or parenteral analgesic after physician's advice) were allowed during the trial. Drug therapy compliance was monitored monthly via telephone check-ins and verified through sachet counts or diary reviews after 12 weeks of intervention.

Outcome assessment: The primary aim was to assess the efficacy of psyllium fiber in terms of pain relief in children with FAPD. Pain assessment was done using the pain score table, which assessed duration, frequency, and intensity of pain. The same score has been used in our previously published study and shown to be useful.⁷ Parent/child (>12 years) were trained to document each episode, its duration and pain intensity for 4 weeks at baseline (before randomisation) and for 12 weeks after randomisation. Visual analogue scale was used to describe the intensity of pain which ranged from 0 for no pain to 10 for unbearable pain. A scale of 0-10 was also used each for pain frequency (number of episodes of pain lasting for at least 10 minutes) and pain duration in hours. Thus, total score was calculated out of 30 at baseline and at the end of intervention after 12 weeks (supplementary information, S1). The outcome scores were documented and assessed by a single assessor (MK) throughout the study. Responder is defined as the reduction in total pain scores of > 50% of baseline values following intervention. The secondary outcomes were Quality of life (QoL) and occasions requiring analgesics (oral/parenteral) during pain episodes. QoL assessment was done by the American Chronic Pain Association QoL rating scale just before randomisation (2nd visit) and after 12 weeks of treatment (3rd visit) and scores were noted (supplementary information, S2).⁸ The adverse events (AEs) were noted after 12 weeks of treatment. Missing drug for more than 10% of days (>9 days in 12 weeks of treatment) was labelled as poor compliance and was excluded from the per-protocol analysis (PPA).

Post-intervention follow-up: At the end of the trial period, the intervention and the placebo were discontinued in patients with a complete response, and the patients were followed-up. Cases were allowed to continue psyllium fiber based on the willingness of the parents. Control patients with no response to placebo who came for follow-up were also started on psyllium fiber. After the treatment was stopped, pain status was assessed by either direct interviewing at follow-up or through telephone and the pain status was categorized as either sustained response if the condition remained the same or improved compared with the status while on treatment, or relapse if there was worsening of pain or if there was a recurrence of pain after at least 3 months of asymptomatic period.

Statistical analysis: The study employed both an intention-to-treat (ITT) and a per-protocol analysis (PPA) to evaluate the primary outcomes. Normality of the continuous variables were tested and a variable was considered normally distributed when Z-score of the variables were ranged between ± 3.29 . Continuous variables were presented as mean and standard deviation (SD), and categorical variables as number (percentage). For the comparison between means of two paired groups/ unpaired groups, paired

samples t-test / Independent samples t-test was used as appropriate. Chi-square test/ Fisher's exact test was used to compare the proportions/ test the association between two categorical variables. Binary logistic regression analysis was applied to identify the independent predictors for responders. All the results were considered as statistically significant on P -value <0.05 . Statistical analysis was performed using Statistical package for social sciences version -23 (SPSS-23, IBM, Chicago, IL, USA).

Results

From September 2023 to May 2025, a total 109 children with FAPD (FAP-NOS 93 and IBS 16 [IBS-Constipation (8); IBS-Diarrhoea (5); IBS-Mixed (3)]) were recruited in the study. Their mean age was 11.8 ± 3.9 years, with a male-to-female ratio of 63:46. Of the 109 randomized children, 57 were randomized to the psyllium fiber group and 52 to the placebo, of which 47 from the fiber group and 49 from the placebo group completed the study (Fig 1).

Baseline characteristics

The baseline characteristics are shown in Table 1. There was no statistically significant difference in haematological parameters and inflammatory markers between the groups. The most common site of pain was periumbilical ($n=86$, 79%), followed by multiple sites or diffuse pain ($n=16$, 14.6%) and epigastric pain ($n=7$, 6%). Family history of functional gastrointestinal disorder, migraine, anxiety, or depression was present in 17% ($n=18$; psyllium, 10; placebo, 8) of patients. History of stressors such as academic pressure, death of a family member, parental conflicts, change of school or residence, etc., was found in 14% ($n=15$; psyllium, 7; placebo, 8) of patients.

Primary efficacy variables.

The efficacy outcome (primary and secondary) in the psyllium fiber group and the placebo group is shown in Table 2. Assuming the same baseline scores in the post-treatment period for those children who were lost to follow-up, ITT analysis was done in 109 children, and pain scores at baseline and post 12-week intervention were compared (Table 2). The mean pain score reduction was much greater in the psyllium group than in the placebo group (15.7 vs. 9.4, $P=0.048$). Also, the effect size was more in psyllium group as compared to the placebo (Cohen-d [calculated using mean difference with respect to pooled SD]: 2.9 vs 1.4, $P<0.001$) (Figure 2). PPA also showed a significant reduction in pain scores (16.8 vs. 9.7, $P < 0.001$) in the psyllium group as compared with the placebo (Table 3).

Pain scores showed significant improvement for IBS and FAP-NOS in the fiber group as compared with placebo (Table 4). Significantly higher proportion of patients responded to therapy ($>50\%$ reduction of pain) with the psyllium as compared with the placebo [86% ($n=49$) vs. 60% ($n=31$), $P=0.001$]. Complete relief of pain was also significantly more in the psyllium group as compared with the placebo group ($n=20$, 36% vs. $n=6$, 11%; $P=0.006$). Non-responders ($<20\%$ pain reduction) were fewer in number in the psyllium group as compared with the placebo group, however, the difference was not statistically significant ($n=5$, 9% vs. $n=11$, 21%, $P = 0.06$). On multivariate binary logistic regression analysis to assess

the parameters predicting responders, the only parameter that was predictive of pain response was the use of psyllium fiber (adjusted OR: 5.49, 95% CI: 2.05-14.72, $P<0.001$) (Table 5).

Post-intervention outcomes in psyllium fiber are shown as a flow chart (Figure 3). After discontinuation of psyllium fiber, 81.6% had sustained response over a mean follow-up of 6.7 months. Of the remaining 7 patients (18.4%) who had relapse of symptoms, 5 had mild symptoms without a need for analgesics or any treatment, and 2 were seeking medical advice from elsewhere and were still on intermittent analgesics. Of 20 patients who did not respond to the placebo, psyllium fiber was given to 11 patients who came for follow-up and response was seen in 7 of them. Of 4 patients who did not show response to fiber, 2 were treated with amitriptyline, with positive response.

Secondary efficacy variables

Quality of life (QoL) scores following treatment showed a significant improvement in the psyllium group as compared with the placebo group in PPA (4.4 vs. 2.3, $P<0.001$) (Table 3). Most children (psyllium: 98.3% and placebo: 96.5%) required analgesics at least once (either oral or parenteral) during the baseline observation period. However, only 26.3% of children in the psyllium group and 58.2% of children in the placebo group required analgesics during the intervention period. There was significantly more reduction in analgesic requirement in psyllium group compared to the placebo group (35.8% vs. 21.9%, $P=0.0001$). Subgroup analysis of pain scores and QoL was done in the placebo group to look for the placebo effect. There was a significant reduction in the mean pain scores (20.5 vs. 11.1, $P<0.001$) and improvement in QoL (3.9 vs. 1.8, $P<0.001$) in the placebo group as well from baseline to the end of therapy. The requirement of analgesics was also significantly lower during intervention in the placebo group (36.1 vs. 14.1, $P<0.001$).

Adverse events

There were no major adverse events. The incidence of minor adverse events was more in psyllium group compared to placebo (11% vs. 2%, respectively, $P=0.055$). Adverse events ($n=6$) noted in the psyllium fiber group were bloating ($n=2$), nausea ($n=3$) and vomiting ($n=1$). Discontinuation of therapy due to adverse events (nausea) was reported in 2 cases after 2 weeks of starting therapy. None had an exacerbation of pain in the psyllium group. Three children found it difficult to take psyllium, of whom 2 cases stopped medication after 4-week duration, after having a response. In the placebo group, one child had minor adverse effect in the form of nausea and the medicine was discontinued.

Discussion

In this prospective, randomized, single-blinded, placebo-controlled trial, we found that there was a significant reduction in pain scores with 12-week trial of psyllium as compared with placebo (16.8 vs. 9.7, $P<0.001$). Also, the proportion of responders was significantly higher in the psyllium group (86% vs. 60%; $P=0.001$). Though, there was significant reduction in mean pain scores and improvement in QoL scores in the placebo group at the end of study as compared to the baseline scores, however, the effect-

size was more in psyllium group as compared to the placebo (Cohen-d: 2.9 vs 1.4, $P<0.001$). On multivariate binary logistic regression analysis, the use of psyllium fiber was the only parameter predictive of pain response. The role of fiber in IBS is well known both in adult and pediatric studies.^{6,9-11} Our study included patients with FAP-NOS as the majority. The role of fiber in this subset of FAPD has never been described before.

In a recent meta-analysis of the epidemiological data on FAPD, IBS was found to be the most predominant type.¹ On the contrary, FAP-NOS constituted the majority (63%) followed by IBS (17.4%) in a recent Indian study.¹² A similar spectrum was seen in our study with FAP-NOS diagnosed more frequently than IBS (85% vs 15%). FAP-NOS was more common in younger age as compared to IBS (10.4 years vs 14.9 years, $P=0.003$).

Psyllium, a soluble fiber, increases bulk of stool and its fermentation generates short-chain fatty acid such as butyrate which provides energy to colonic epithelial cells and act as an anti-inflammatory agent.¹³ RCTs done by Shulman et al. including 84 children of IBS (psyllium fiber: 37 and placebo [maltodextrin]: 47 for 6 weeks) and Menon et al in 81 children of IBS (psyllium, $n=43$ and placebo [maltodextrin], $n=38$ for 4 weeks) have shown a significant reduction of pain frequency (8.2 vs. 4.1, $P=0.03$) and total IBS-severity score system (IBS-SSS) [75 vs. 225; $P<0.001$] in the psyllium group respectively.^{6,9} Previous studies by Jalihal et al and Prior et al failed to show any significant response in pain relief.^{14,15} On the contrary, our study found significant pain reduction in the fiber group as compared to the placebo in IBS. A recent meta-analysis in children with FAPDs, including 5 RCTs (predominantly IBS) found beneficial effects of soluble fibers, in particular psyllium.¹¹

The effectiveness of fiber in children with FAP-NOS remains uncertain due to a lack of substantial evidence.¹⁴ Our cohort was different from other studies as it was constituted by FAP-NOS as the majority (85%). Feldman et al. in an RCT of fiber in 52 RAP children showed a significant reduction of pain attacks (50% reduction was twice more in fiber than in placebo).¹⁶ In RCTs of 89 children of abdominal pain-predominant FGID by Hovarth et al. (glucmannan with placebo) and 31 children with RAP by Christensen et al. (ispaghula husks versus placebo) did not find any difference in the pain frequency between the groups.^{17,18} On the contrary, our study showed statistically significant reduction in pain in terms of number of episodes, intensity of pain, duration and total pain scores in the fiber group ($P<0.001$ in all). Also, majority (89/93, 96%) of children in FAP-NOS group had normal stool pattern at baseline (Bristol type 3 and 4). Four children who had abnormal Bristol (type 2: 1, type 5: 3) were equally distributed in psyllium and placebo group. To our knowledge, this is the first study to discuss the role of fiber in pediatric FAP-NOS.

In our study, a placebo response was seen in 60% of the patients. In the previous studies and meta-analysis done in children with AP-FGID, placebo response was seen in 41%-58% of the patients.¹⁹⁻²¹ High placebo effect could be attributed to the concealment of group, high expectancy level of the children and their parents getting enrolled in a trial, strong family-doctor bond and parents' reassurance about the

tertiary care physician's knowledge and experience. The last statement can further be justified by the observation, that 45% of patients had no pain in the baseline period (Figure 1).²² We explored factors such as gender, age, FAPD subtype, stressor or family history of FGID by multivariate regression analysis and found no effect in predicting response to the placebo as shown in past studies.^{23,24} However, mean baseline pain scores in the placebo group were lower in responders as compared to non-responders (18.9 vs. 22.6, $P=0.023$). Despite a 60% response in the placebo group, our study showed significantly more response in the psyllium group as compared to the placebo. One may argue that, like the placebo group, responders in the psyllium group may also have lower mean baseline pain score as compared to the non-responders, however, it was not statistically different (21.2 vs. 22.3, $P=0.497$).

The strength of the study is its randomized design with blinding of patients. The majority of our cohort comprised FAP-NOS, and the role of psyllium in this subset in children has not been discussed in previous studies. The intervention duration was also longer in our study as compared to previous studies. Also, the children with FAPDs were meticulously characterised using Rome IV criteria, including FAPD subtype, family history and history of stressor, which we demonstrated were comparable between the groups and are therefore less likely to contribute significantly to the observed pain responses to psyllium. Notably, objective measurement of daily pain scores using diaries, which are shown to be more reliable in children than questionnaires, enhances the credibility of our data collection approach.²⁵

Our study has some limitations. The biggest limitation is the lack of double blinding and the assessment of response by a single assessor throughout the study. However, it has helped to maintain the uniformity in assessing responses, and also the objective pain score tables used in our study minimised the bias. Assessment was done only at baseline (4 week run-in before randomisation) and week 12 (post randomisation). The amount of dietary fiber was not pre-determined, and all patients were advised to follow a regular diet, so the possibility of more fiber intake in the placebo group cannot be ruled out. However, it applies to real-life scenarios. The associated symptoms, such as anxiety and depression, were not assessed, which could have affected the outcome. A recent systematic review by Almutairi et al. has questioned the validity of maltodextrin use as placebo in clinical trials as it induces various modifications in gut microbiota configurations, and immunological factors.²⁶ Also, it differs from psyllium in texture, however, use of opaque sachets ensured blinding in our study. Ours is a single-centre study, which raises the need for multicentric and blinded trials with a larger sample size to validate our results.

Conclusions

Psyllium fiber has similar efficacy in the FAP-NOS and IBS with no significant adverse effects. Proper counselling of parent-child dyad about the pathophysiology of FAPD along with placebo could improve pain in around half of children. A 12-week trial of psyllium fiber improves pain in most and gives sustained relief in three-fourths of children with FAP-NOS and IBS. However, there is a need of more randomized studies with double blinding to validate our results.

Declarations

Funding: The authors did not receive support from any organization for the submitted work.

Competing Interest (for all authors): The authors have no relevant financial or non-financial interests to disclose.

Clinical trial registration (22/08/2023): Clinical Trial Registry of India (CTRI: CTRI/2023/08/056772; Website URL - <http://ctri.nic.in>).

Data availability statement: The data about patient details are given in the tables and further information is available with the corresponding author. If required it can be made available on personal request.

Ethics approval statement: The study was conducted after obtaining ethical approval from the institutional ethics committee.

Consent to participate: Written informed consent from the parents and assent from the children were obtained before enrolment.

Author contribution statement:

MK: Methodology, Data curation, Writing- Original draft preparation, Visualisation. She has approved the final manuscript.

UP: Conceptualization, Visualisation, Investigation, Supervision, Validation, Writing- Reviewing and Editing. He has approved the final manuscript.

AS:Supervision, Writing- Reviewing and Editing. She has approved the final manuscript.

MSS:Supervision, Writing- Reviewing and Editing. He has approved the final manuscript.

PM: Data curation, Formal analysis. He has approved the final manuscript

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Figures

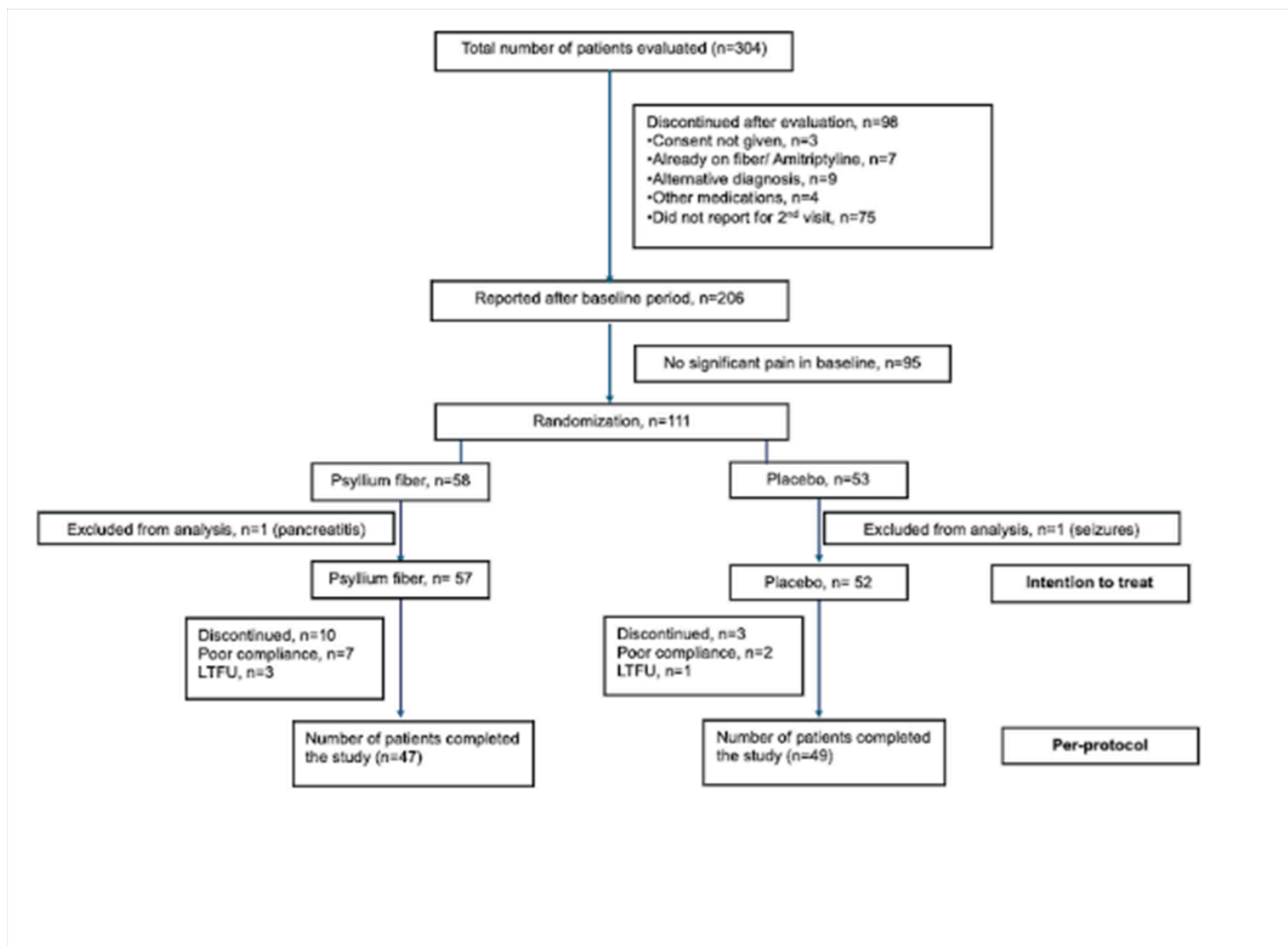


Figure 1

CONSORT flow diagram of enrolment, allocation, and completion of the study

Alternative diagnosis: Celiac disease (1), Functional constipation (4), Functional dyspepsia (3), Urinary tract infection (1); Other medicines: Antiepileptic (1); Antipsychotic (2), Anticholinergic (1). CONSORT, Consolidated Standards of Reporting Trials; LTFU, Lost to follow-up

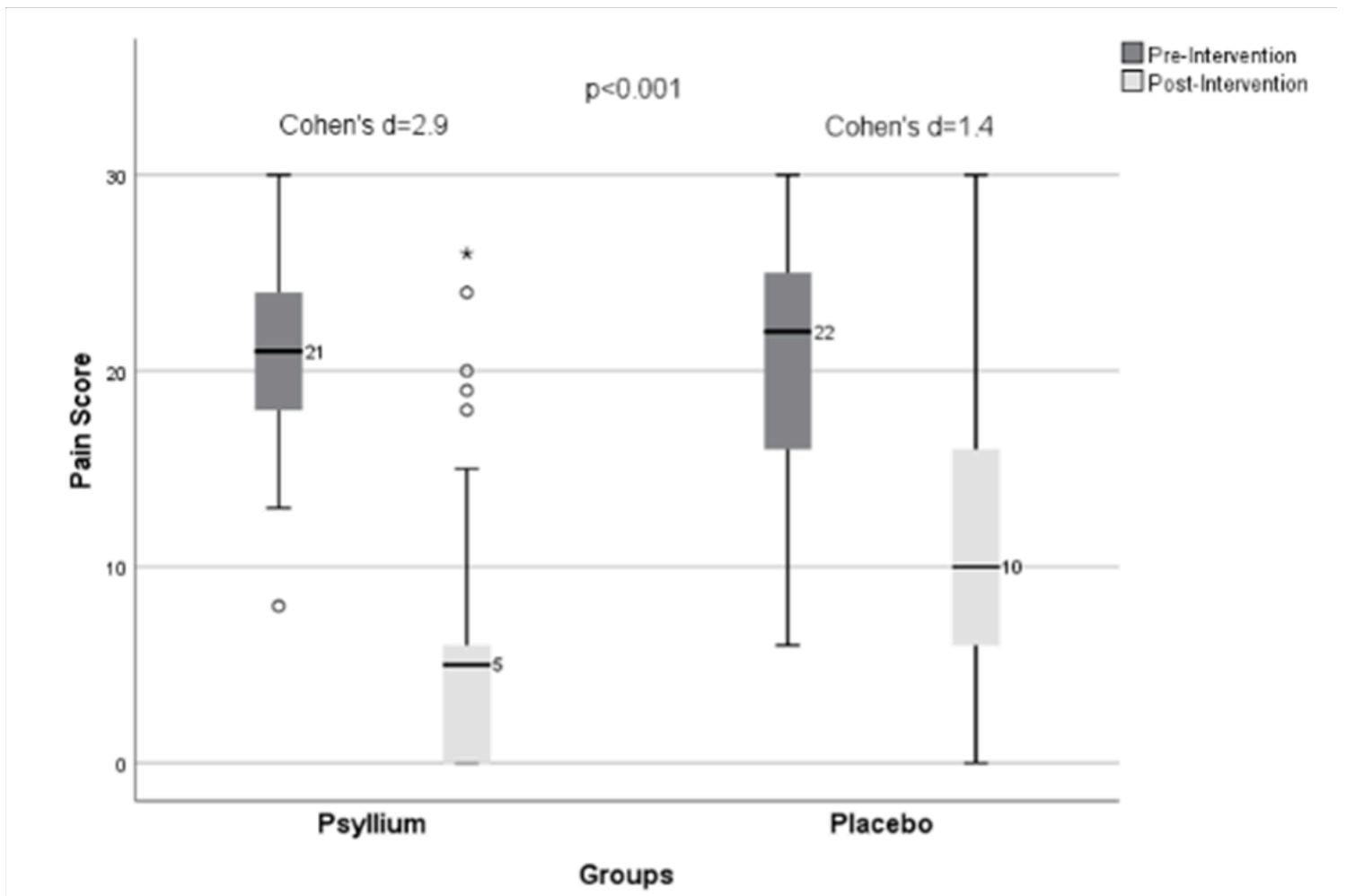
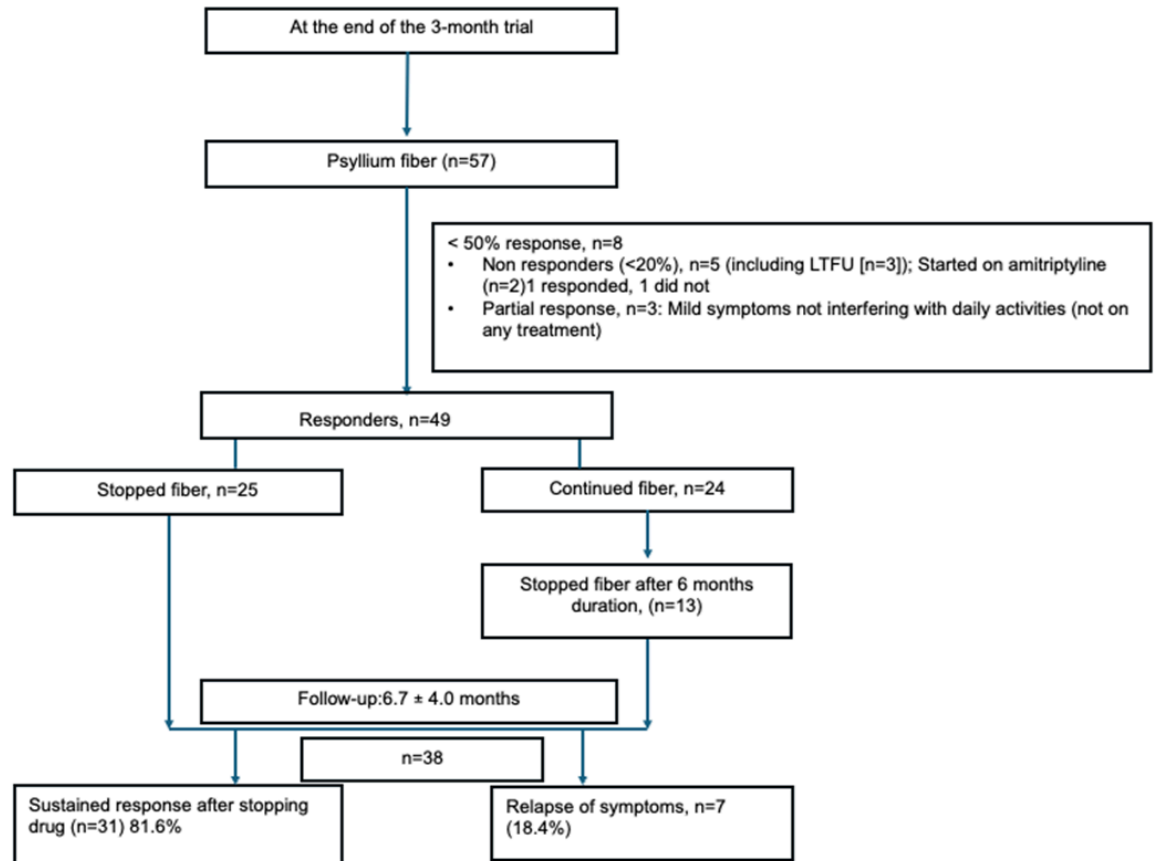


Figure 2

Box whisker plot illustrating post-intervention change in median pain score in psyllium and placebo group. The lower whisker is touching the 25th percentile, post- intervention in psyllium group



Flowchart showing treatment extension and follow-up in psyllium fiber group; LTFU, Lost to follow up

Figure 3

Flowchart showing treatment extension and follow-up in psyllium fiber group. LTFU, Lost to follow-up

Supplementary Files

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