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Functional gastrointestinal disorders: real-life results of a multidisciplinary non-pharmacological approach based on group-consultations

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ABSTRACT

Introduction

Functional gastrointestinal disorders are prevalent and resource consuming. The use of group-consultations in these diseases is limited. No specific multidisciplinary programmes have been developed.

Methods

A multidisciplinary approach was used in patients with diverse functional gastrointestinal disorders attending group-consultations (Group A). Five 2-hour sessions were scheduled over a 4 month period. Sessions consisted on a theoretical introduction (Pathophysiology; Low fodmap diet; Over the counter medications; Mediterranean diet; Laughter therapy workshop) followed by relaxation techniques. This group was compared to a similar group of patients who received written information covering the topics treated during the group-consultations (Group B). Severity of digestive and

psychological symptoms, use of drugs and adherence to the diet were the main outcomes measured.

Results

Mean age of participants was 43 (± 1.38) years. 78% were women. 73% had at least 2 functional gastrointestinal disorders. 62 patients were included in Group A, 17 in Group B. The severity of gastrointestinal and psychological symptoms at baseline was similar between both groups. Globally, there was an improvement in all symptoms in both groups. The proportion of participants with severe baseline gastrointestinal symptoms or pathologic anxiety scores that showed improvement was significantly higher in Group A (74% vs 23%, p=0.005; 47% vs 8%, p=0.02; respectively). Symptoms were reassessed at 6 and 12 months after the intervention among those participants in Group A who attended ≥ 80% sessions, and sustained response was observed.

Conclusions

Group-consultations are useful and efficient to alleviate gastrointestinal and psychological symptoms in patients with functional gastrointestinal disorders.

Keywords

Functional gastrointestinal disorders; dyspepsia; irritable bowel syndrome; group-consultations; multidisciplinary; non-pharmacological treatment

Abbreviations

Functional gastrointestinal disorders (FGIDs); Irritable Bowel Syndrome (IBS); IBS-Severity Scoring System (IBS-SSS); Hospital Anxiety and Depression Scale (HADS).

INTRODUCTION

Functional gastrointestinal disorders (FGIDs), better defined as disorders of brain-gut interaction (1), are highly prevalent in Western countries (40%) (2). Up to 50% of patients suffering from FGID seek medical attention. This increases medical care costs (3,4).

FGIDs include a number of conditions where there is a similar underlying pathophisiology: altered motility, visceral hypersensitivity, low-grade mucosal inflammation, dysbiosis of the gut microbiota, and abnormal central pain processing (5,6). A biopsychosocial model helps explain the relationship between gastrointestinal symptoms and environmental factors or psychiatric disorders (7). A multidimensional approach to these issues could lead to an improvement in symptom control, and a reduction of drug use and diagnostic tests (8).

In the traditional clinical setting there is limited time to educate these patients in non-pharmacological life-style changes and stress management.

Group-consultations have proven to be an effective tool to reduce waiting times and costs, and to improve patient experience (9). This format has been used in different settings such as diabetes mellitus or chronic lung or heart diseases (10-15). Group education has been used in Irritable Bowel Syndrome (IBS) by some groups (16, 17), but no specific programs have been developed for other FGIDs, and there are no reported outcomes of such an intervention in standard practice.

We recently implemented a multidisciplinary educational program at our institution, based on non-pharmacological interventions imparted in group-consultations. The aim is to empower patients to better control their symptoms. The main objective of this study is to assess the efficacy of such measures in patients with FGIDs and their impact on a secondary care setting.

MATERIAL AND METHODS

Study design and Participants

This was a prospective single centre study.

An educational program for participants with FGIDs was introduced, as part of our routine clinical practice, in September 2017. This programme focuses on non-pharmacological interventions to improve gastrointestinal and psychological symptoms. The inclusion criteria for this program included participants between the ages of 18 and 65 who had been diagnosed in our gastroenterology clinic with any of the following FGIDs according to ROME criteria: IBS, functional diarrhoea, functional abdominal pain and functional dyspepsia. Comorbidities such as celiac disease, thyroid pathology or inflammatory bowel disease had been ruled out. No exclusion criteria were established.

On the basis of these criteria, two groups were defined: Group A, conformed by those participants who accepted to participate in the program, and Group B, conformed by those who could not attend or refused to attend the group sessions.

The study was approved by the Regional Ethics Board at the Fundación Jiménez Díaz Research Institute (PIC 105/2017_HIE) before the implementation of the program, and is compliant with the ethical principles expressed in the Helsinki declaration (1975) and its further updates (18). Written informed consent was obtained from all the participants included in this study.

Recruitment into the program started in September 2017 and it was ongoing at the time of submitting this publication. The results reported here are from the participants recruited in the initial 17 months.

Interventions

The educational program is built around the explanation of the physiopathological basis of FGIDs and the life-style changes that have shown to improve symptoms in these diseases (19-21).

Group A received the education via group-sessions. A new group (8-15 participants per group) was planned to start each month. Each group had five 2-hour sessions scheduled over a 4 month period (2 on the first month, then once a month). Each session consisted on a theoretical introduction followed by an open discussion, finishing with relaxation techniques (muscle relaxation and visualization techniques, abdominal breathing exercises)(16, 22-24). The content of the sessions was as follows: 1) Getting to know FGIDs (gastroenterologist), 2) Low fodmap diet (dietitian), 3) Over the counter medications and myths in FGIDs (gastroenterologist), 4) Mediterranean diet (dietitian), 5) Laughter therapy workshop (volunteer laughter therapist) (25). Mental health specialists supervised the relaxation techniques used during the program. The gastroenterologists and dietitians implicated in the program were experts in FGIDs and group consultations.

Participants in Group B were given written information summarizing the same topics discussed in group-consultations with Group A.

Data collection and Endpoints

The efficacy of the intervention was assessed using the following variables:

a) Primary outcomes:

1.- Gastrointestinal symptoms:

-FGID diagnosis was established by a gastroenterologist in clinic. Afterwards, patients' symptoms were recorded using a self-designed questionnaire based on ROME III and IV criteria. We decided to use both sets of criteria to increase the number of patients who could benefit from the program (2, 26, 27).

-Severity of gastrointestinal symptoms was evaluated using the IBS-Severity Scoring System (IBS-SSS) (28). This tool classifies symptoms into severe (≥300 points), moderate (175-299), mild (75-174) or remission (<75). License to use this tool was obtained from the ROME foundation. This score was literally translated from the original score (28). IBS-SSS was specifically designed to assess symptoms in IBS, and not in other FGIDs. We consider that, since each patient is his own control (paired data collection), this does not affect the validity of the results.

-Bloating was assessed measuring the waist circumference (WC).The dietitian measured WC with an anthropometric flexible tape before the second and fourth session. Participants were asked to stay relaxed, standing with their arms at their side and their feet together. Measurements were made at the umbilicus level with the abdominal muscles relaxed at the end of a normal expiration (29, 30).

2.- Adherence to low fodmap diet:

The number of high fodmap portions consumed per day by each patient at was recorded by means of a dietary journal. All patients were instructed to follow a low fodmap diet during which a probiotic product was recommended (31), followed by a reintroduction phase. The dietary journals were completed at baseline and after the exclusion phase (Group A), but not after the reintroduction phase. This diet has proven its efficacy in IBS; there are no studies assessing its use with other FGIDs. As there appears to be a degree of overlap between the mechanisms implicated in many FGIDs with those of IBS, we decided to explore its use in this setting (32-34).

3.- Psychological symptoms:

Severity of anxiety and depression was evaluated using the Hospital Anxiety and Depression Scale (HADS) (21). Symptoms were considered pathologic (11-21 points), borderline (8-10) or normal (0-7).

4.- Drug use:

The number of drug groups used by each patient in the 6 months prior to the intervention was recorded. Drug prescription was performed in the Gastroenterology clinic as per medical criteria, by a different physician to the one imparting the group clinics.

The IBS-SSS, HADS and drug use were assess at baseline (all participants), at the end of the educational program (all participants) and at 6 and 12 months after the intervention (only those participants in Group A who completed ≥ 80% program). The questionnaires were self-administered (Fig 1).

b) Secondary outcomes:

1.- *Motivation* was assessed among participants in Group A to see whether it was determinant to clinical improvement. Motivation is generally assessed with a number of surveys or structured interviews, but the available tools are inconsistent within the literature. We decided to study the following variables as surrogates for motivation:

- Adherence to assigned tasks (ie, filling out dietary journals).

-Length of follow-up in the gastroenterology clinic prior to inclusion in the program.

-Number of sessions attended.

2.- *Impact on daily clinical practice* of the implementation of the program was measured by the following indicators:

-Number of discharges from clinic after the inclusion in the program.

-Number of endoscopic exams performed outside of clinical guidelines recommendations. We compared the number of endoscopic procedures performed in participants under the age of 50 included in Group A at the beginning of the program with the number of examinations requested 18 months after implementation of the program, in participants within the same age range newly included in the program (36-38).

Data analysis and statistics

Statistical analyses were performed using SPSS for Windows version 19 (SPSS Inc, Chicago, Illinois, USA). Categorical variables are summarised as percentages and

compared using the Chi-square or Fischer's exact tests. Continuous variables are summarised as mean (SEM) or median (IQR), and compared using the Student's t-test or the Mann-Whitney's test in case of non-normal distributions. To test for a difference between three or more groups, analysis of variance was used. Lineal regression was used to study the relationship between two continuous variables. p values less than 0.05 are considered statistically significant.

RESULTS

Participants

The program was offered to 114 participants between September 2017 and January 2019 (Fig 1). Baseline characteristics can be found in Table 1. Patients in Group A were older and consumed more drugs at baseline.

100% of participants included in Group A attended at least one educational session (18% one, 21% two, 11% three, 23% four and 27% five sessions). The reason adduced by 84% of the participants who did not attend at least 80% of the sessions was the impossibility to reconcile the timing of the sessions with their professional or personal life.

Median follow up at the time of writing this manuscript was 332 days (IQR: 311 to 374) for Group A and 241 days (IQR: 214 to 276) for Group B.

Gastrointestinal symptoms and low fodmap diet adherence

The severity of gastrointestinal symptoms at baseline was similar between Groups A and B: 61% and 44% of the participants had severe symptoms, respectively (N. S.), 33% and 38% moderate (N. S.), 5% and 19% mild (N. S.). No participants in either group were in remission.

There was a correlation between initial gastrointestinal symptom severity and baseline anxiety levels (R^2=0.22, p<0.0005).

Globally, there was an improvement in gastrointestinal symptoms in both groups (Fig 2) (decrease by 78 ± 14 points in Group A vs 51 ± 34 in Group B, N. S.). The proportion of participants with severe baseline symptoms that showed improvement was significantly higher in Group A (74% vs 23%, p=0.005).

Adherence to low fodmap diet was assessed in Group A: a reduction in the number of high fodmap portions per day was observed in those participants who filled the dietary

journals (9.7 ± 1.1 at baseline vs 1.6 ± 0.4 after the exlusion phase, p<0.0005). This was associated with a reduction in waist circumference (93.3 ± 1.8 cm vs 91.5 ± 2.6 cm respectively, p=0.03), which, in the absence of changes in the body mass index, was interpreted as an improvement in bloating. This information was not collected in Group B for logistic reasons.

Psychological symptoms

Mean baseline scores for anxiety and depression were similar between Groups A and B (Table 2). However, in Group A there was a higher proportion of participants with scores above 7 (borderline-pathologic), both for anxiety (78% vs 53%, p=0.05) and depression (37% vs 12%, p=0.05).

Globally, there was an improvement in psychological symptoms in both groups (Fig 3). The anxiety score decreased 1.9 ± 0.5 points in Group A vs 2.2 ± 0.6 in Group B (N. S.). The depression score decreased 1.2 ± 0.5 points vs 0.7 ± 1.0 respectively (N. S.). The proportion of participants with baseline scores above 7 that showed improvement was significantly higher in Group A (47% vs 8%, p=0.02).

Drug use

The number of drug groups used in the 6 months prior to inclusion in the program in Group A was higher compared to Group B (2.3 ± 0.2 vs 0.7 ± 0.3, p=0.001), so was the reduction in drug use after the intervention (number of drug groups decreased by 1.1 ± 0.2 vs 0.1 ± 0.3 respectively, p=0.02).

Drug use was reassessed at 6 and 12 months after the intervention among those participants in Group A who attended at least 80% of the sessions, and sustained response was seen.

Motivation analysis

Those participants who filled out both of the journals showed a trend to improve gastrointestinal and psychological symptoms (Table 2). The number of patients who did

not attend at least 80% of sessions was also lower (0% if two journals completed vs 30% if one journal completed vs 81% if no journals completed, p<0.0005).

The time the participants had been under follow-up in the general gastroenterology clinic prior to their inclusion in the program also seemed to influence adherence: 57% of participants with a follow-up under 3 years attended less than 80% of sessions vs 31% of those with longer follow-ups (p=0.08).

The number of sessions attended did not significantly change the degree of improvement.

Impact on daily clinical practice analysis

The percentage of discharges from clinic showed a trend to be higher in Group A compared to Group B (47% vs 24%, p=0.085). Within Group A, the proportion of discharges was higher among those participants who attended at least 80% of sessions compared to those who did not (65% vs 29%, p=0.005).

The implementation of this program has resulted in a reduction of unnecessary colonoscopies by 25% in participants under the age of 50 (p=0.05).

DISCUSSION

This study proves that a multidisciplinary educational intervention delivered via group-consultations provides sustained improvement of gastrointestinal and psychological symptoms in patients with FGIDs.

This is the first reported experience where different FGIDs are addressed simultaneously in our country. This is an advantage, as there is a high prevalence of coexisting FGIDs.

Ringstrom et al published a similar multidisciplinary group education program, directed only to patients with IBS (17). It consisted of 5 six-weekly 2-hour sessions given by different healthcare professionals. They also demonstrated that the intervention was as effective if delivered by the specialist nurse alone (39). In our approach, we aimed at five 2-hour sessions over 4 months. Our multidisciplinary team was formed by a gastroenterologist and a dietitian. The dietitian's expertise was essential to explain the exclusion and reintroduction phase of the low fodmap diet in an adequate manner to prevent long term nutritional deficits, and ensure a healthy and balanced diet on an individual basis. We opted for five sessions to resolve any questions over time and give

participants an opportunity to share their experiences, which was perceived as positive by them. Our results are comparable to those of the Swedish group.

Some studies have shown symptomatic improvement of IBS patients who received written information (40, 41), but these findings were not supported by some clinical trials that show that structured patient education (either in person (group-sessions) or through on-line sessions) is superior to written information in the management of patients with IBS (42, 43). In our experience, participants in Group B improved, but not as much as those in Group A. This difference was particularly relevant, and statistically significant, in those with more severe symptoms. This suggests that this type of intervention could be tailored to only such patients, after an initial intervention in clinic has failed. They are likely to benefit from an intensive educational program and reinforcement of life-style changes.

Our results point towards a reduction in frequent attendance, drug use and invasive diagnostic tests. This will likely result in cost and waiting time reductions.

The main strength of our study is that it is the first reported real-life intervention on different FGIDs simultaneously. This model is feasible in a small hospital daily practice and useful for different types of FGIDs, with sustained benefits over time.

There is clearly an unmet need for patients with FGIDs, as shown by the fact that 85% of those who are offered the program initially accept. Later on, only 64% of them attend at least one session, and there is a progressive adherence loss. Many patients could not reconcile the timing of the sessions with their personal life, and some times, there was a delay between inclusion and the first session scheduled. This could compromise the efficiency of the program. From our experience, several proposals could improve the expected outcomes of such an intervention: overbooking of the groups could balance the high lost to follow up rate, flexibility in schedules and catch-up sessions for patients who miss some of them could improve adherence to the program, and the explanation by the recruiters of the importance of lifestyle changes towards symptomatic improvement may help patients understand the usefulness of this intervention. As an alternative to these face-to-face meetings, on-line therapy or educational videos could also be considered.

Our study has several limitations. It aims at assessing the impact of an educational program to improve care quality in a real-life setting. As the participation in the program

was voluntary, there was no randomization of the intervention, which could have induced a selection bias, compromising the comparability of both groups. Sample size for Group B is small, which may have limited the statistical power of the study. There is no control group that comprises individual regular follow-up in the outpatient clinic. The information on drug use obtained by our study is limited, as it does not include the frequency of use, the types of drugs that were withdrawn or the use of over the counter medications. Finally, a literal translation of the original IBS-SSS was used, as opposed to the existing validated translation to Spanish (44). All of the above should be taken into account in future studies to accurately establish the utility of group interventions.

In conclusion, multidisciplinary group-consultations are effective for the non-pharmacological management of FGIDs, improving both gastrointestinal and psychological symptoms, reducing frequent attendance and unnecessary invasive tests. It remains to be established the most appropriate format for such interventions. It is possible that tailored interventions can be offered to patients depending on their individual situation.

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DECLARATION OF CONFLICTING INTEREST

The authors declare that there is no conflict of interest.

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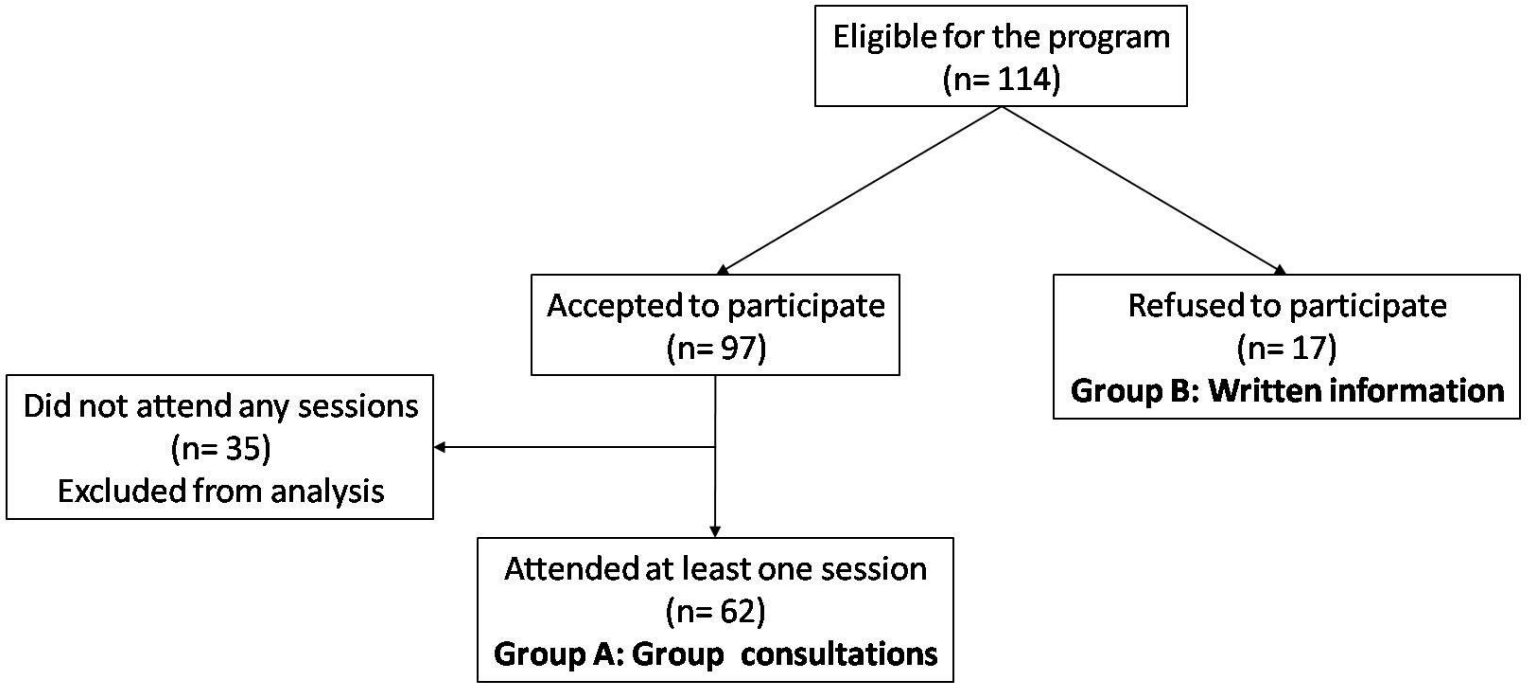
	GROUP A (n=62)	GROUP B (n=17)	p
Sex: male/female (n)	12/50	5/12	NS
Age years (mean ± SEM)	44 ± 1.5	37 ± 3.0	0.03
FGID diagnosis [n (%)]:			
IBS	1 (2)	0 (0)	
Functional diarrhea	0 (0)	1 (6)	
Functional abdominal distension	1 (2)	1 (6)	
Dyspepsia	5 (8)	2 (12)	NS
≥ 2 FGID:			
Dyspepsia+IBS	16 (26)	3 (18)	
Dyspepsia+diarrhea	11 (18)	3 (18)	
Dyspepsia+distension	22 (35)	4 (23)	
Doesn't fulfill ROME criteria	6 (10)	3 (18)	
IBS-SSS (mean ± SEM)	309 ± 11.5	278 ± 31.2	NS
HADS-Anxiety (mean ± SEM)	10.7 ± 0.6	8.7 ± 1.3	NS
HADS-Depression (mean ± SEM)	6.5 ± 0.6	4.3 ± 0.8	NS
Number of drug groups used[a] (mean ± SEM)	2.3 ± 0.2	0.7 ± 0.3	0.001

Table 1. Baseline characteristics of participants, both in Group A and B. aThe drug groups assessed included: prokinetics, antiflatulents, antispasmodic, laxatives, antidiarrhoeals. FGID: functional gastrointestinal disorder. IBS: irritable bowel síndrome. IBS-SSS: irritable bowel síndrome – severity scoring system. HADS: hospital anxiety and depression scale.

Table 2. Degree of symptomatic improvement depending on adherence to assigned tasks. Completion of dietary journals was used as a surrogate for participant's motivation. Analysis performed among those participants who attended ≥ 80% of sessions. *p=0.07 compared to No Dietetic Diary. IBS-SSS: irritable bowel síndrome – severity scoring system. HADS: hospital anxiety and depression scale.

	No Dietary Journal n=21	**One Dietary Journal n=15**	**Two Dietary Journals n=11**
Change in IBS-SSS (mean ± SEM)	62 ± 19	75 ± 24	110 ± 37
Change in A-HADS (mean ± SEM)	0.7 ± 0.8	2.7 ± 0.7*	2.8 ± 1.1
Change in D-HADS (mean ± SEM)	0.2 ± 0.6	2.2 ± 0.7*	1.8 ± 1.2



Intervention in Group A:

Month 1				Month 2		Month 3		Month 4	
Week 1	**Week 2**	**Week 3**	**Week 4**	**Week 1-3**	**Week 4**	**Week 1-3**	**Week 4**	**Week 1-3**	**Week 4**
Session 1 -ROME -IBS SSS -HADS -Dietary jl		**Session 2** -WC -Instructed to follow LFD			**Session 3**		**Session 4** -WC -Dietary jl -Instructed to reintroduction		**Session 5** -IBS SSS -HADS

Figure 1. Flow chart of the study and intervention in Group A. IBS SSS: irritable bowel syndrome severity scoring system. HADS: hospital anxiety and depression scale. Dietary jl: dietary journal. WC: waist circumference.

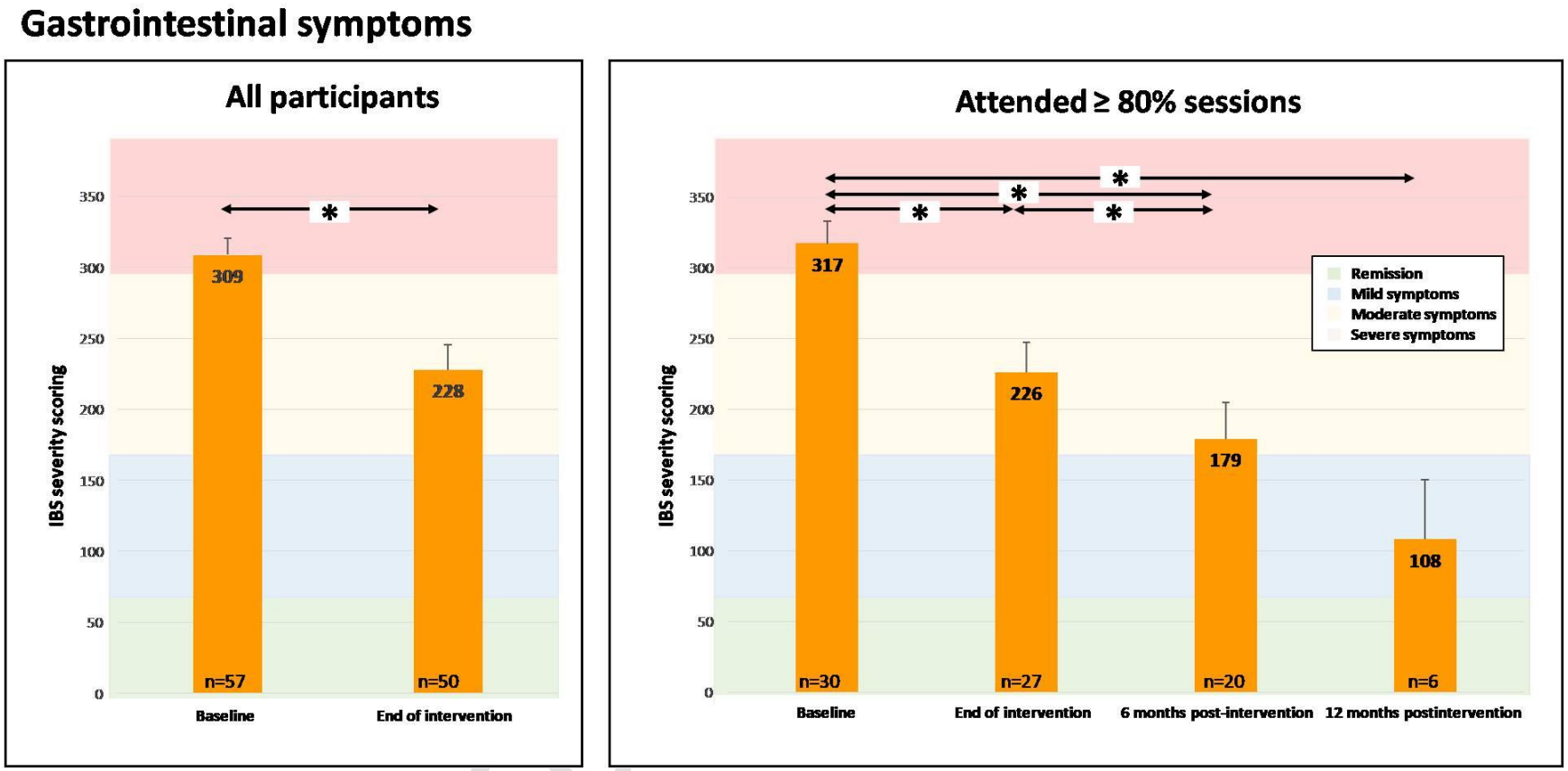


Figure 2. Gastrointestinal symptoms in Group A. Left panel: there is a significant improvement in gastrointestinal symptom severity in all of the participants, regardless of the number of sessions attended. Right panel: this improvement is sustained one year after the intervention in those patients who attend at least 80% of the sessions. The number at the base of each column refers to the number of patients with available data at each time point. *p<0.05. IBS: irritable bowel syndrome.

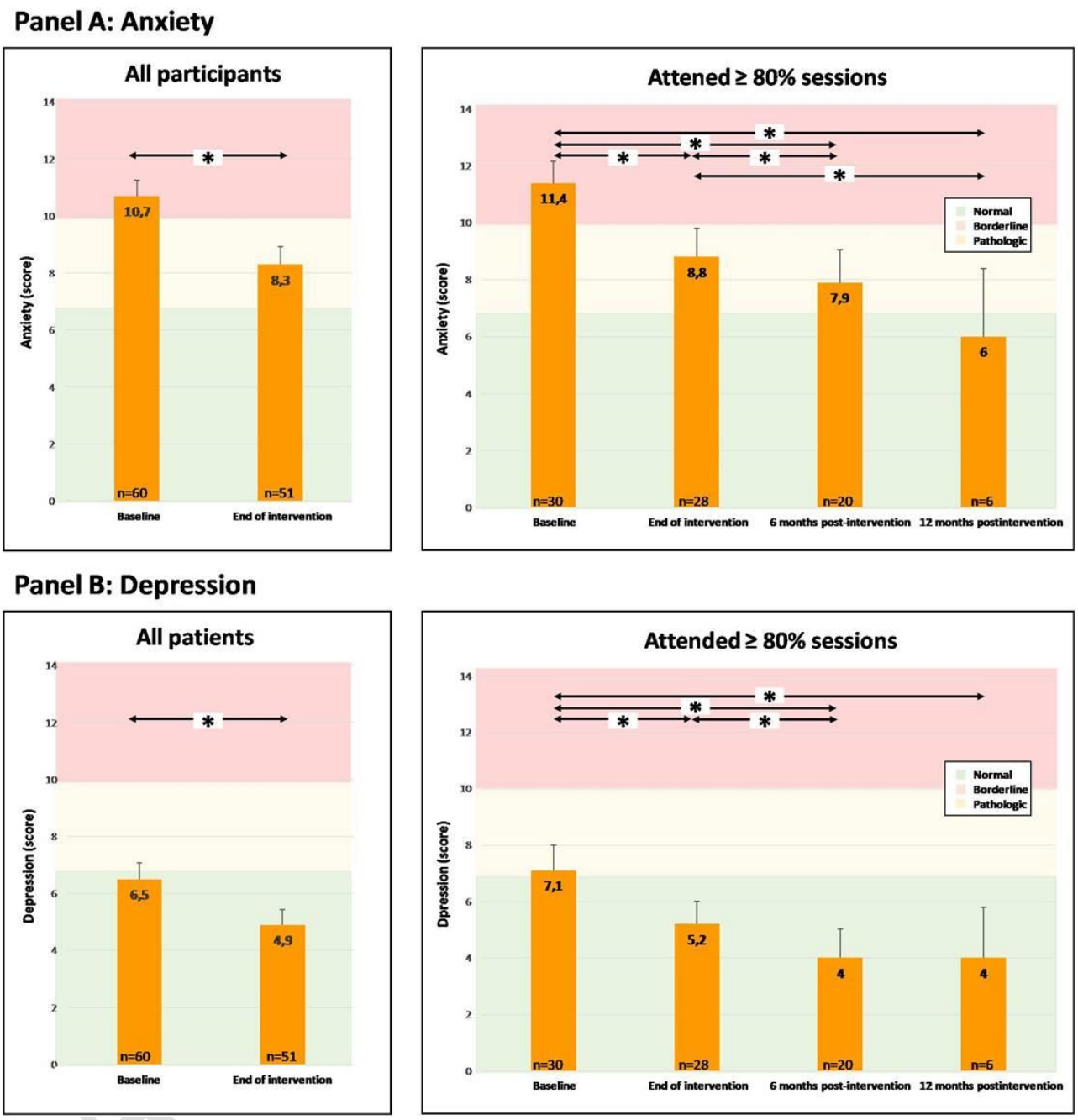


Figure 3. A and B: anxiety and depression in Group A. Left: there is a significant improvement in anxiety and depression levels in all of the participants, regardless of the number of sessions attended. Right: this improvement is sustained one year after the intervention in those patients who attended at least 80% of the sessions. The number at the base of each column refers to the number of patients with available data at each time point. *p<0.05. HADS: hospital anxiety and depression scale.