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The effects of regular consumption of short-chain fructo-oligosaccharides on digestive comfort of subjects with minor functional bowel disorders

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A comparative, randomised, double-blind trial was performed in the medical departments of five hospitals to study the effects of regular consumption of short-chain fructo-oligosaccharides (sc-FOS) on the digestive comfort of subjects with minor functional bowel disorders (FBD). In step 1, 2235 subjects were questioned to assess the incidence and intensity of digestive disorders. In step 2, 105 of these patients diagnosed with minor FBD were randomised into two groups to receive either 5 g sc-FOS or 5 g placebo (sucrose and maltodextrins) per d over a 6-week period. The incidence and intensity of digestive disorders were assessed at the end of the treatment period (day 43) using the step 1 questionnaires. A quality-of-life questionnaire was also completed at the start and end of the treatment period to assess potential effects on well-being and social performance. In step 1, 44 % of the subjects questioned presented FBD, of whom 57·1 % suffered from minor FBD. In step 2, on day 43, the intensity of digestive disorders decreased by 43·6 % in the sc-FOS group *v.* a 13·8 % increase in the placebo group ($P=0{\cdot}026$). Symptoms were experienced less frequently by 75·0 % of subjects in the sc-FOS group, while 53·8 % of controls experienced no change ($P=0{\cdot}064$). Using the functional digestive disorders quality of life questionnaire, the discomfort item scores increased in the sc-FOS group ($P=0{\cdot}031$). However, expressed as change in quality of life (improvement, worsening or unchanged), daily activities were significantly improved in the sc-FOS group ($P=0.022$). Regular consumption of sc-FOS may improve digestive comfort in a working population not undergoing medical treatment.

Short-chain fructo-oligosaccharides: Quality of life: Functional bowel disorders

Functional bowel disorders (FBD) are diagnosed on the basis of characteristic symptoms in the digestive system persisting for at least 12 weeks over the last 12 months in the absence of any structural or biochemical explanation[1]. The five main symptoms reported by patients are abdominal bloating, rumbling, transit disorders (occasional constipation and/or diarrhoea, possibly alternating), abdominal pains and flatulence. FBD have been reported as being chronic, non-life-threatening conditions, but having a marked impact on daily activities, wellbeing and social performance, even during symptom-free periods, mainly due to apprehension about impending pain[2–6].

These functional disorders, influenced by psychological and environmental factors[7], are common, with a reported prevalence of up to 61 % in the French population aged over 15 years[6]. Functional disorders thus lead to a high number of general medical and gastroenterology consultations, respectively accounting for 10 and 50 % of all medical consultations[4–6,8–11]. However, two-thirds of subjects with FBD never consult a doctor for their disorder. A nutritional approach therefore appears a good alternative to medication for subjects with minor FBD or individuals rejecting medical therapy. Amongst the few already well-established ingredients recognised as having an impact on the digestive system, short-chain fructo-oligosaccharides (sc-FOS) are known to be fully fermented by the colonic microflora and, above all, to increase colonic bifidobacteria[12–15] recognised as health

Abbreviations: FBD, functional bowel disorder; FDDQL, functional digestive disorders quality of life; sc-FOS, short-chain fructo-oligosaccharide.

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promoting[16,17]. Sc-FOS occur in numerous edible plants such as onions, garlic, asparagus, tomatoes and wheat. Bacterial fermentation of sc-FOS increases production of SCFA such as acetate, propionate and butyrate[18,19], whose ability to regulate ileal motility has been demonstrated by several studies[20–22]. As described by Hidaka[17], sc-FOS improve intestinal function with greater consistency and regularity in stool output.

Thus, while their impact on colonic health has been widely studied, little is as yet known about the impact of sc-FOS on the quality of life of subjects with FBD.

The present study was designed to test the efficacy of sc-FOS in improving digestive comfort among subjects with minor FBD.

Subjects and methods

Subjects

Subjects were recruited in the occupational medicine departments of five hospitals.

An initial questionnaire designed to assess the incidence and intensity of digestive disorders as well as the number of subjects presenting FBD was completed by 2235 subjects (Fig. 1).

This questionnaire was then analysed by a doctor at each study centre. Of the 2235 patients, 983 were presenting digestive disorders, of whom 57·1 % had minor symptoms. A total of 186 subjects met all of the following inclusion criteria: age >18 years, presenting at least two minor FBD symptoms according to the Rome II criteria[23] for at least 12 weeks over the last 12 months, a total intensity score of ≤ 25 for the symptoms included in the initial questionnaire, an intensity score of ≤ 5 for 'discomfort or abdominal pain', as well as relief following defecation, no major digestive disease and no previous consultation or medication for FBD.

A total of 105 subjects (fifteen men and ninety women; mean age 38·3 years) agreed to take part in the study. All subjects provided written informed consent to participate after the study procedures had been explained to them.

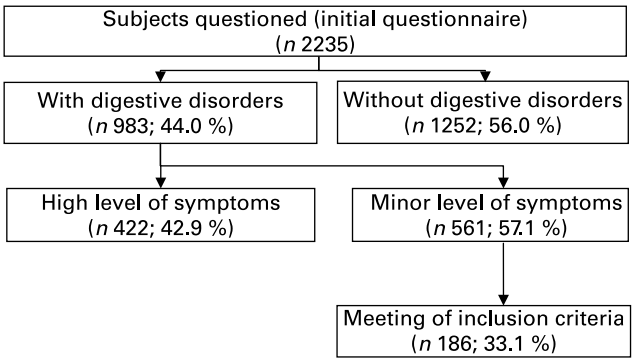

Fig. 1. Distribution of subjects (number and frequency) from initial respondents to the selected population meeting the inclusion criteria, i.e. presenting minor functional digestive disorders (according to the initial questionnaire based on the Rome II criteria[23]: at least two symptoms experienced for at least 3 months over the previous 12 months, abdominal pain intensity score ≤ 5 and global score ≤ 25). Those with a high level of symptoms had a severity score for 'discomfort or abdominal pain' >5, or total severity score >25, or frequency of digestive disorders $>$ once a week, or number of symptoms >5.

The study was approved by the ethics committee of Saint-Germain-en-Laye (France, no. 03 046) and was performed in accordance with the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the principles laid down in the current version of the Declaration of Helsinki.

Questionnaires

Initial questionnaire. The prevalence and general frequency of digestive symptoms based on the Rome II criteria were recorded in the initial questionnaire[1,23,24]. Subjects were asked to indicate which symptoms they were presenting. For five of the symptoms (abdominal discomfort or pain; abdominal fullness, bloating or swelling; feeling of incomplete bowel movement; urgency, i.e. an imperious urge to pass stool; straining at stool), subjects also indicated intensity on a scale from 1 to 10 (10 being the maximum intensity level). The initial questionnaire was used for inclusion and then at the end of the study to determine changes in intensity of symptoms.

Consultation questionnaire. A questionnaire designed to assess the frequency of digestive symptoms and stool quality for the last 4 weeks preceding the study was given by the study doctor to subjects meeting all inclusion criteria. This questionnaire was given again at the end of the study to determine the effects of sc-FOS.

Functional digestive disorders quality of life questionnaire. The quality of life of subjects was assessed using the validated French language functional digestive disorders quality of life (FDDQL) questionnaire[25]. Subjects completed the FDDQL questionnaire alone on the day of inclusion (day 0) and on the last day of the study (day 43) and changes in individual item scores were calculated.

Short-chain fructo-oligosaccharides studied

The sc-FOS studied were FOS Actilight® 950P (Béghin Meiji, Marckolsheim, France), comprising 37 ± 6 % 1-kestose (GF2), 53 ± 6 % nystose (GF3) and 10 ± 6 % 1F-β-fructofuranosyl nystose (GF4). The placebo consisted of a mixture of 50 % microcrystalline sucrose 120 (Béghin-Say; Tereos, Lille, France) and 50 % maltodextrin Glucidex® IT6 (Roquette, Lestrem, France).

Experimental design

This multicentre, double-blind, randomised, controlled study was performed in five study centres to assess the effects of regular sc-FOS consumption on the quality of life and digestive comfort of subjects with minor FBD.

A total of 105 volunteers were randomised to two groups consuming either 5 g sc-FOS/d or 5 g placebo/d over a 6-week period (Fig. 2). Subjects were instructed not to change their eating habits; in order to check normal consumption of pre- and probiotics during the experimental period, they were asked on day 0 to evaluate their intake of foods containing pre- and probiotics or enriched in fibres such as some yoghurts, milk, sweets and biscuits.

Treatments were allocated in the form of two packets containing either 2·5 g sc-FOS or a blend of 1·25 g maltodextrin

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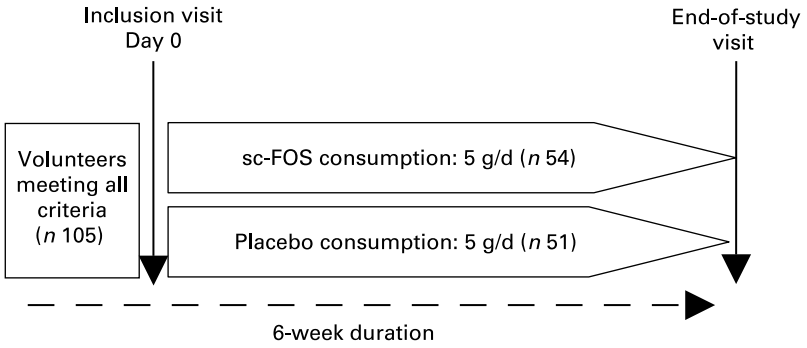

Fig. 2. Study design. sc-FOS, short-chain fructo-oligosaccharides.

and 1·25 g sucrose (tolerance ± 4 %), depending on the randomisation group. Two packets per d were to be consumed, one at breakfast and one at dinner, either sprinkled over a dessert or diluted in a drink.

Compliance was checked using a form on which subjects kept a daily record of the number of packets consumed and the time of intake. All unused packets were to be returned by the subjects to the investigators at the end of the study.

Statistics

All statistical analyses were conducted using the SAS statistical program (version 8.2; SAS Institute Inc., Cary, NC, USA). All tests comparing the two groups (sc-FOS *v.* placebo) were two-tailed with type 1 error set at 0·05, taking into account the two-arm parallel design.

Qualitative variables were expressed in terms of degree and percentage. Both groups were compared for non-ordered qualitative variables using a χ^2 test, or Fisher's exact test where size was too small (<5). For ordered qualitative variables, both groups were compared using the Wilcoxon–Mann–Whitney rank-sum test. Quantitative variables were expressed in terms of mean values, standard deviations and ranges. Depending on the results of the normality test (Shapiro–Wilk), the two groups were compared using a Student or Wilcoxon–Mann–Whitney rank-sum test.

Efficacy analysis. Changes in score between days 0 and 43 for each of the eight FDDQL questionnaire items were compared between the two groups using Student's test. The eight scores were summed and the global scores for days 0 and 43 were compared using Student's test. The intensity and frequency of symptoms as well as change in these parameters were also compared between the two groups using a Wilcoxon–Mann–Whitney test. Subject satisfaction was analysed using a χ^2 test or Fisher's exact test.

Safety analysis. A global analysis was performed for the observed frequencies and the intensity of symptoms occurring during the treatment period.

Results

Step 1

A total of 2235 subjects completed the initial questionnaire. Age ranged from 16 to 75 years (age 36·8 (SD 10·9) years), and 75·7 % of subjects were women. Of these, 983 subjects were presenting digestive disorders, 57·1 % of whom had minor symptoms (i.e. 25·1 % of subjects questioned). According to the symptoms reported, 36·9 % of all subjects questioned presented abdominal discomfort (women, 40·8 %; men, 24·3 %), 25·6 % presented constipation (women, 28·9 %; men, 15·3 %) and 21·9 % presented diarrhoea (women, 22·4 %; men, 20·3 %). Only 186 subjects, mainly presenting abdominal discomfort (96·8 %) or constipation (79·6 %), met all inclusion criteria during checks by the study doctors. Of the ten representative symptoms of FBD, the average number actually presented was 5·1 (SD 1·9), with a global mean intensity of 11·5 (SD 5·9).

Step 2

A total of 105 subjects agreed to participate in the study and were randomised to the sc-FOS (fifty-four subjects) and placebo (fifty-one subjects) groups (Fig. 2).

Characteristics at inclusion. Demographic factors were similar between both groups (Table 1). Women accounted respectively for 83·3 and 85·7 % of subjects in the sc-FOS and placebo groups. The item scores and global score on the FDDQL questionnaire completed at inclusion were comparable for the two groups.

Treatment: compliance and concomitant medication. Treatment compliance was judged satisfactory when the product (two packets of treatment per d) was consumed as instructed throughout the study period (consumption for at least 30 d, consumption of the entire daily dose for at least 27 d and no interruption in intake for more than 4 consecutive days). In terms of these criteria, no significant differences were found in treatment compliance between the two groups ($P=0·83$). To qualify for inclusion in the per protocol analyses, the date of the final visit also had to be within 10 d of the theoretical date (i.e. between 43 and 53 d after the start of study product intake).

Compliance was good for fifty subjects (consumption during respectively 40·9 (SD 1·9) d in the sc-FOS group (twenty-four subjects) and 41·3 (SD 1·4) d in the placebo group (twenty-six subjects)), but less satisfactory for the other forty-seven subjects. Eight subjects (four in each group) dropped out before the final medical visit.

As regards concomitant medication, nine subjects took a treatment having a potential minor influence on FBD (respectively four and five subjects in the sc-FOS and placebo groups).

Table 1. Characteristics of patients in the intent-to-treat group with baseline intensity of symptoms related to minor functional bowel disorders (FBD)

(Mean values and standard deviations)

	sc-FOS group (*n* 48)		Placebo group (*n* 49)		
Characteristic	Mean	SD	Mean	SD	*P*
Age (years)	39·5	11·9	37·6	10·9	0·397
Age range (years)	20–59		20–55		
Females (*n*)	40		42		0·746
Symptoms related to minor FBD (*n*)*	5·6	1·8	5·5	1·8	0·898
Symptoms related to minor FBD range (*n*)*	2–9		2–10		
Intensity of symptoms related to minor FBD					
Abdominal pain†	3·6	1·8	3·4	2·1	0·566
Abdominal fullness†	3·7	2·4	4·0	2·1	0·528
Feeling of incomplete bowel movement†	1·7	2·4	1·6	2·2	0·800
Urgency†	1·8	2·6	2·1	2·7	0·628
Straining at stool†	2·9	3·1	3·1	2·9	0·694
Global intensity of symptoms†	13·4	7·0	13·7	6·9	0·857
Item scores on FDDQL for day 0 questionnaire					
Activities‡	80·9	14·7	80·5	17·3	0·723
Anxiety‡	64·3	24·4	67·3	24·1	0·454
Diet‡	64·2	17·2	64·5	21·7	0·628
Sleep‡	78·5	18·3	71·8	20·9	0·125
Discomfort‡	46·1	15·2	44·2	19·9	0·694
Coping with disease‡	71·5	14·9	70·0	17·2	0·645
Control of disease‡	56·7	24·9	48·5	26·3	0·118
Impact of stress‡	32·8	27·4	30·8	23·8	0·890
Global score on FDDQL for day 0 questionnaire‡	66·0	9·4	63·8	13·8	0·700

sc-FOS, short-chain fructo-oligosaccharides; FDDQL, functional digestive disorders quality of life.
* Number of symptoms between 1 and 11 experienced during the previous 12 months.
† On a scale of 1–10.
‡ On a scale of 0–100, where 0 = poor quality of life and 100 = excellent quality of life.

Furthermore, the occurrence of gastroenteritis in one subject may have had a minor effect on FBD.

Safety analysis

In the ninety-seven subjects in the intent-to-treat group, twenty-seven adverse events were seen, concerning respectively eleven (22·9 %) and sixteen (32·6 %) subjects in the sc-FOS and placebo groups. Severity of these adverse events was distributed as follows: nine were reported as light (two under sc-FOS *v.* seven under placebo), fifteen as mild (seven sc-FOS *v.* eight placebo) and three as severe (two sc-FOS *v.* one placebo). Five adverse events comprised infectious diseases such as angina, bronchitis, sinusitis or gastroenteritis (two sc-FOS *v.* three placebo), ten comprised gastrointestinal symptoms such as diarrhoea, constipation, abdominal pain, vomiting or nausea (six sc-FOS *v.* four placebo), twelve comprised painful symptoms including headache or lower back pain (five sc-FOS *v.* seven placebo) and six comprised other symptoms (for example, anxiety, weight loss). Of the three adverse events reported as severe, respectively two (abdominal pain and nausea (same subject), spots on the chest, back and arms) and one (unwarranted anxiety) were seen in the sc-FOS and placebo groups. Two patients had symptoms diagnosed as linked to sc-FOS consumption (possible or probable association); these were diarrhoea, and abdominal pain and nausea (same subject). Eight subjects definitively stopped consuming the product after the occurrence of an adverse event.

Change in symptom intensity (initial questionnaire)

At the beginning of the study, the sc-FOS and placebo groups showed similar intensity of digestive disorders (sc-FOS, 3·6 (SD 1·8); placebo, 3·4 (SD 2·1); $P=0·565$). Sc-FOS ingestion for 6 weeks significantly reduced symptom intensity by 43·6 % (−1·6 (SD 2·1); $P=0·026$, FOS *v.* placebo); the placebo group experienced a 13·8 % increase (see Fig. 3 and Table 2).

Change in frequency of digestive disorders (consultation questionnaire)

The frequency of digestive disorders was assessed over the 4 weeks before the start of the study and at the end of the study. Over the 4 weeks preceding the start of the study (day 0), the various symptoms of digestive disorders occurred once per week in both groups (per protocol population) (Table 3): 41·7 and 38·5 % of subjects in the sc-FOS and placebo groups, respectively. On day 43, a reduced frequency was noted in the sc-FOS group, with 20·8 % for the mixed items 'more than once per week' and 'every day', whereas the frequency in the placebo group remained higher, at 42·3 % for the same mixed items. None of these changes were statistically significant.

At 6 weeks later, symptoms were experienced less frequently by 75·0 % of subjects in the sc-FOS group (29·2 % much less frequently; 45·8 % rather less frequently) compared with control subjects, 53·8 % of whom experienced no change, as shown in Fig. 4 ($P=0·064$).

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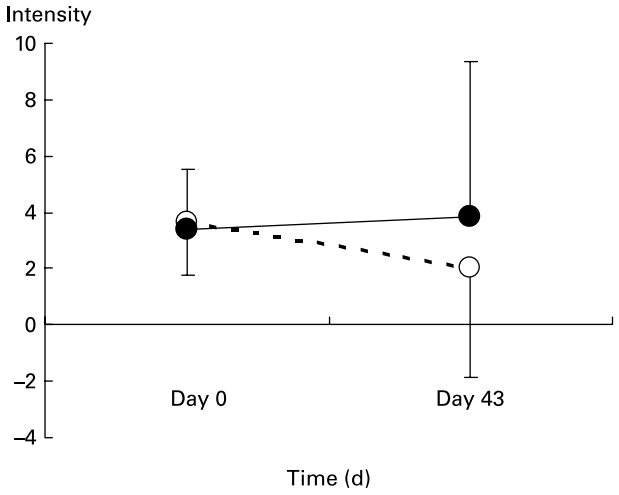

Fig. 3. Change in intensity of digestive disorders after 6 weeks' consumption of short-chain fructo-oligosaccharides (sc-FOS; ○) or placebo (●) in the per protocol population. The intensity scores were assessed by subjects on a scale from 1 to 10 (maximum intensity). Values are means, with their standard deviations represented by vertical bars. At baseline, there was no difference between the groups (sc-FOS, 3·6 (SD 1·8); placebo, 3·4 (SD 2·1); Wilcoxon–Mann–Whitney rank-sum test, $P=0·565$). On day 43, the mean intensity of digestive disorders between both groups was significantly different (sc-FOS, 2·1 (SD 3·9); placebo, 3·9 (SD 5·5); Wilcoxon–Mann–Whitney rank sum test, $P=0·026$).

Change in quality of life after 6 weeks of short-chain fructo-oligosaccharide consumption

The FDDQL questionnaire item scores were compared between day 0 and day 43 for both groups (Table 4). As regards the per protocol population, the discomfort item scores appeared to have significantly increased in the sc-FOS group after 6 weeks of consumption of the study product compared with the placebo (sc-FOS, 20·1 (SD 14·2); placebo, 12·1 (SD 19·6); $P=0·031$). The differences between the sc-FOS and placebo groups regarding the other item scores were not significant.

Change in quality of life was also analysed in terms of improvement (i.e. item score on day 43 > day 0), worsening (i.e. item score on day 43 < day 0) and no change in comfort (i.e. item score on day 43 = day 0). As shown in Fig. 5, digestive comfort tended to increase ($P=0·071$) and daily activities were significantly improved ($P=0·022$). These increases respectively concerned 95·8 and 83·3 % of subjects in the sc-FOS group.

Activity scores on day 43 also differed significantly between the sc-FOS and placebo groups (sc-FOS, 95·0 (SD 5·3); placebo, 82·7 (SD 19·7); $P=0·011$). Subjects consuming sc-FOS were therefore less disturbed by their digestive symptoms in performance of their daily activities.

Table 2. Change in intensity of symptoms related to minor functional bowel disorders (FBD) in the per protocol population (day 43 − day 0)
(Mean values and standard deviations)

	Change in intensity (day 43 − day 0)				
	sc-FOS group (*n* 24)		Placebo group (*n* 26)		
Minor FBD symptoms	Mean	SD	Mean	SD	*P*
Discomfort or abdominal pain	−1·6	2·1	+0·5	3·4	0·026
Abdominal fullness, bloating or swelling	−0·7	2·2	−0·4	2·5	0·828
Feeling of incomplete bowel movement	−0·4	2·7	0·0	2·6	0·491
Urgency	+0·2	3·4	+0·4	2·9	1·000
Straining at stool	−1·4	3·7	0·0	2·3	0·211

sc-FOS, short-chain fructo-oligosaccharides.

Table 3. Change in frequency of digestive disorders (%) in the last 4 weeks before day 0 and day 43 in the per protocol population

	sc-FOS group (*n* 24)		Placebo group (*n* 26)	
Frequency (%)	Day 0	Day 43	Day 0	Day 43
Less than once per month	0	20·8	0	15·4
Once per month	4·2	33·3	3·8	7·7
Once per week	41·7	25·0	38·5	30·8
More than once per week	45·8	8·3	46·1	23·1
Every day	8·3	12·5	11·5	19·2
Data missing	0	0	0	3·8

sc-FOS, short-chain fructo-oligosaccharides.

Discussion

The patients enrolled in the present study were screened using the Rome II criteria[24]. They are representative of the female population generally known to present FBD[26]. However, compared with previous FBD data for the French population[6], the prevalence detected in the present study was lower (44 *v.* 61 %), which could be due to a lower mean age in the present study, as well as different socio-cultural makeup of the populations. This last factor is a consequence of the method of recruiting the subjects, who were mainly hospital staff members. Age, socio-economic status and culture are indeed recognised as important factors that can have a bearing on FBD[26].

Beyond the prevalence of FBD, the study also provided information concerning the impact of FBD on quality of

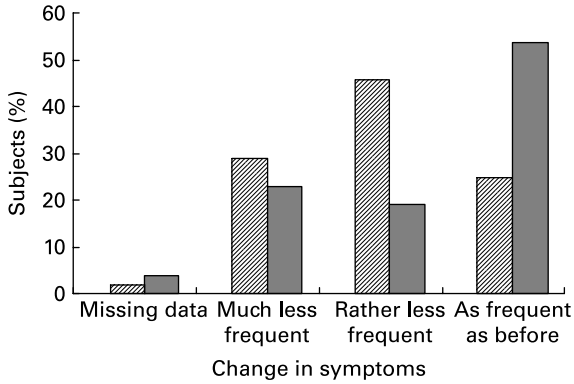

Fig. 4. Change in digestive disorder score after 6 weeks' consumption of short-chain fructo-oligosaccharides (sc-FOS; ▨) or placebo (■) in the per protocol population. Subjects were questioned about their perception of the frequency of digestive disorders during the 4 weeks before the end of the study. A χ^2 test was carried out to determine the difference between the sc-FOS and placebo groups ($P=0·064$).

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Table 4. Change in quality of life between day 0 and day 43 in the per protocol population (expressed as change in item score)*

(Mean values and standard deviations)

	Change in item score (day 43 − day 0)				
	Sc-FOS group (*n* 24)		Placebo group (*n* 26)		
Item	Mean	SD	Mean	SD	*P*
Activities	+10·3	10·5	+5·0	15·2	0·109
Anxiety	+15·3	18·5	+6·2	18·4	0·134
Diet	+10·2	17·9	+5·6	14·0	0·315
Sleep	+5·9	14·6	+14·7	17·2	0·057
Discomfort	+20·1	14·2	+12·1	19·6	0·031
Coping with disease	+2·4	12·0	+4·3	12·1	0·574
Control of disease	+7·6	31·7	+13·5	26·0	0·350
Impact of stress	+1·7	24·3	+4·8	31·7	0·704

sc-FOS, short-chain fructo-oligosaccharides.
* Measured with the functional digestive disorders quality of life questionnaire.

life. Contrary to previous studies[2,27–30], a specific quality-of-life questionnaire devoted to functional digestive disorders was used to assess each patient's own evaluation of his or her health status[25]. This is currently the most relevant, valid and responsive questionnaire available to assess the impact of FBD status on quality of life as perceived by the patient. Other questionnaires, such as the 'medical outcomes study 36-item short form', the sickness impact profile, and the psychological general wellbeing scale, are generic instruments designed to compare health status scores among subjects with various diseases but do not focus on the specific impact of a particular symptom on their quality of life. They were therefore less likely to detect small but clinically important changes induced by the treatment used during the present study[31,32]. For example, problems largely experienced by patients with irritable bowel syndrome such as abdominal pain or urgency would not be singled out by the above-mentioned questionnaires.

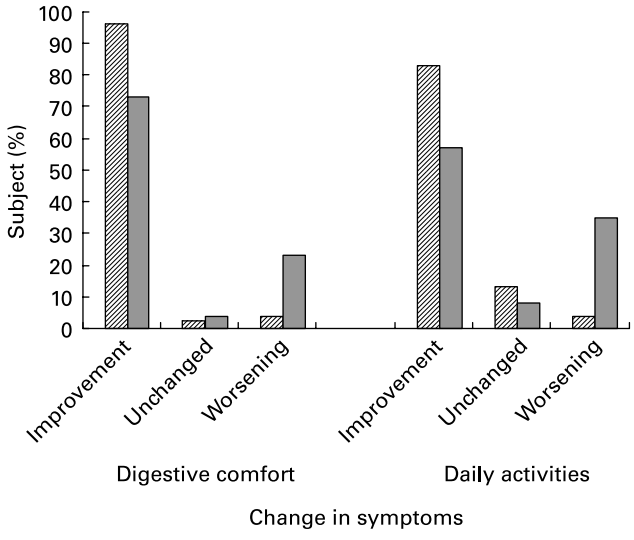

Fig. 5. Change in digestive comfort and degree of discomfort in daily activities after 6 weeks' consumption of short-chain fructo-oligosaccharides (sc-FOS; ▨) or placebo (■) in the per protocol population. Change was defined as follows: improvement = (item score on day 43 > item score on day 0); worsening = (item score on day 43 < item score on day 0); unchanged = (item score on day 43 = item score on day 0), with a higher score being associated with superior quality of life. Change in the item 'daily activities' was seen to differ significantly between the sc-FOS and placebo groups (Fisher's exact test; $P=0·022$), whereas change in the item 'digestive comfort' was close to significance (Fisher's exact test; $P=0·071$).

Furthermore, the present study is the first dealing with FBD to be carried out in a working population not undergoing medical treatment. To date, no randomised, placebo-controlled clinical trials have been performed introducing a dietary ingredient for the treatment of minor FBD symptoms and using relevant evaluation methods to quantify the results. For subjects presenting these symptoms, which while not severe cause discomfort in all daily activities, dietary change could have a significant impact on wellbeing as well as working capacity, and may thus have potential benefits for healthcare spending[2,29,30].

A recent study showed that sc-FOS are bifidogenic and well tolerated at doses ranging from 2·5 to 10 g/d with a dose–response relationship in healthy volunteers[33]. Studies with higher dosages of sc-FOS did not show any further increase in Bifidobacteria count but excessive flatus occurred in some cases[14]. In another threshold study evaluating symptomatic response to varying levels of sc-FOS ingested regularly by fourteen healthy volunteers, excessive flatus and borborygmus were recorded by about 10 % of volunteers at 10 g/d[34]. We therefore chose to test a 5 g/d dose rather than 10 g/d in our trial in subjects with FBD, particularly as subjects with irritable bowel syndrome are more sensitive and could present more pronounced gastrointestinal side effects than healthy subjects for a given dose[35].

An improvement in digestive comfort (close to significance) and in performance of daily activities (significant) was observed under sc-FOS compared with placebo. Other items related to quality of life (anxiety, diet, sleep, control of disease, coping with disease and stress) showed no significant change compared with placebo. No significant change in intensity of symptoms was noticed with sc-FOS consumption except for digestive disorders and abdominal pain, which were significantly lower compared with placebo. In the present study, the placebo effect appeared remarkably high. The influence of psychological and environmental factors on these symptoms[6] is well known, but this could also explain why several statistical tendencies were obtained rather than solid statistical effects.

This double-blind, placebo-controlled study was carried out to assess the effect of regular and moderate sc-FOS consumption on the quality of life of subjects presenting untreated minor FBD. It was initially assumed that these dietary fibres could reduce symptoms linked with FBD and therefore improve the quality of life of such subjects. Finally, we showed that 6 weeks' consumption of 5 g sc-FOS/d led to a significant decrease in the intensity of digestive disorders. Improvement was also noted in digestive comfort and in daily activities. On the basis of these findings, we conclude that regular consumption of 5 g sc-FOS/d may improve digestive comfort in subjects with minor FBD, thereby improving quality of life as well as social performance.

It would also be useful to study the effect of sc-FOS consumption on irritable bowel syndrome, a particular form of functional bowel disorder. Referring to the Rome III

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criteria[36], irritable bowel syndrome is in fact characterised by abdominal pain and discomfort associated with defecation disorders. Throughout the world, about 10–20 % of adults and adolescents have symptoms consistent with irritable bowel syndrome[37], which is slightly less than the level found in the subjects initially questioned in the present study (Fig. 1); these symptoms are frequently associated with impaired quality of life[38,39] and high healthcare costs[40]. The impact of sc-FOS on Crohn's disease is another interesting area for investigation. A recent study proved that 3 weeks' consumption of 15 g fructans/d reduces the activity of Crohn's disease[41]. Increased levels of faecal bifidobacteria, modification of mucosal dendritic cell function and production of butyrate with its anti-inflammatory properties could all be involved in this effect[42,43]. Further justification for such studies lies in the fact that no efficient treatment is yet available despite a prevalence of 25–150 per 100 000 worldwide.

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