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High-Fiber Orange Juice as a Nutrition Supplement in Women: A Randomized, Double-Blind, Placebo-Controlled Study of Tolerance and Effectiveness

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Abstract

Background: The daily consumption of dietary fiber is frequently below suggested recommendations. Using a double-blind, controlled, randomized study, we assessed the efficiency and tolerance of a fiber-enriched orange juice to supplement fiber intake in women. *Materials and Methods*: After 1 week of noninterventional observation, 192 healthy adult women ingested 400 mL of orange juice for 21 days, which either was not (placebo group) or was enriched with fiber (fiber group). Orange juice ingestion was registered daily and controlled for each week during the study period. Macronutrient, fiber, and energy intake were determined using a 3-day food record, validated food chemical composition databases, and the "Pro Diet" software. Gastrointestinal symptoms were self-evaluated daily by scoring 4 grades of symptom intensity and using a visual analog scale to grade pain severity. *Results*: No changes were observed for macronutrient and energy ingestion. For the placebo group (n = 97), the total fiber intake record was under the daily recommended value. In contrast, the fiber group (n = 95) displayed higher comparative values of total and soluble fiber consumption ($P \leq .001$), achieving the daily recommended values of fiber intake. Both groups reported an increased frequency of slight bloating and rumbles over time ($P \leq .05$). The fiber group also experienced a higher frequency of slight flatulence over time ($P = .002$). *Conclusion*: Consumption of fiber-enriched orange juice was efficient to achieve the daily fiber intake recommendation for women, was not accompanied by intense adverse events, and may represent a suitable method to supplement fiber intake in woman. (*JPEN J Parenter Enteral Nutr*. XXXX;xx:xx-xx)

Keywords

fiber; tolerance; orange juice

Clinical Relevancy Statement

Although reduced fiber ingestion has been related to several chronic diseases, its daily consumption is frequently below suggested recommendations due to low fruit, vegetable, legume, and cereal consumption. Alternatively, fiber supplements added to widespread intake food could have a better overall adherence. In our study, the consumption of a fiber-enriched orange juice was efficient to achieve the daily fiber intake recommendation for women, was not accompanied by adverse events, and may represent a suitable method to supplement fiber intake.

Introduction

The physical and chemical properties of dietary fiber are associated with benefits in health maintenance and disease prevention.[1] Reduced fiber ingestion has been related to several chronic diseases, such as metabolic disorders, obesity, type 2 diabetes mellitus, cancer, and cardiovascular diseases (CVDs).[1]

Despite the health benefits associated with dietary fiber, epidemiological studies have shown that fiber intake is below recommended requirements, due to low fruit, vegetable, legume, and cereal consumption.[2-5] Low fiber ingestion is mainly associated with the fact that fiber-rich foods may have an unpleasant taste for many people, and most are perishable and require appropriate preparation for consumption.[6] Therefore, it is important to not only recognize the health

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benefits of dietary fiber but also identify alternatives to enable fiber intake at sufficient levels to achieve these health benefits.

In Brazil, specific studies measuring fiber ingestion are scarce. However, the Brazilian population is estimated to consume less than half of the recommended amount of fruit and vegetables as recommended by the Food and Agriculture Organization (FAO) of the United Nations.[7] Oranges are the most produced fruit in Brazil, and its juice is the most consumed fruit juice locally and also around the world.[8]

The addition of industrialized fibers, such as fructooligosaccharide (FOS), inulin, and polydextrose, to food and beverages is emerging as a potential alternative for achieving the recommended fiber intake levels.[9] However, the introduction of industrialized fiber types into a routine diet can lead to digestive disturbances due to excessive fiber consumption.[10] This prospective, randomized, double-blind, parallel study in adult healthy Brazilian women was undertaken to evaluate the tolerance and effectiveness of a fiber-enriched orange juice designed to improve fiber consumption.

Table 1. Nutrition Composition per 100 g of Studied Orange Juices Enriched or Not Enriched With Fiber.

Nutrient	Orange Juice Without Fiber Addition (Placebo Group), %	Orange Juice Added With Fiber (Fiber Group), %[a]
Water	81.8	81.8
Concentrate orange juice	7.3	7.3
Sugar	7.7	7.7
Flavor	0.0025	0.0025
Citric acid	0.25	0.25
FOS P95	0	1.06[b]
Nutriose	0	1.25[c]
Polydextrose	0	0.29[d]

FOS, fructooligosaccharide.
[a]2.25% fiber in the finished product.
[b]Equivalent to 0.96% fiber from FOS.
[c]Equivalent to 1.03% fiber from Nutriose (Roquette, Lestrem, France).
[d]Equivalent to 0.26% fiber from polydextrose.

Materials and Methods

Ethical Considerations

The current study was registered in the Clinical Trials Database (ID: NCT 01282983) and performed according to the ethical recommendations of the Declaration of Helsinki, the Ethical Committee of the Real e Benemérita Associação Portuguesa de Beneficência do Hospital São Joaquim, and the Ethical Committee of the University of São Paulo School of Medicine. All patients enrolled provided written informed consent.

Patients

Two hundred healthy adult, nonsmoking, and literate women, aged 18–45 years, from the city of São Paulo, Brazil, were screened between October 2010 and March 2011 for eligibility to participate in the study. Additional criteria included adequate intestinal function (excluding individuals with diarrhea or constipation, as evaluated by the Bristol scale[11]), body mass index (BMI) between 18.5 and 29.9 kg/m^2, stable body weight over the previous 2 months, use of a contraceptive method, and normal tolerance for routine ingestion of orange juice. Other exclusion criteria included diagnosis of a gastrointestinal (GI) disease in the past 12 months, such as gastritis; cancer history in the past 5 years; previous abdominal surgery; inflammatory bowel disease; renal, heart, or liver disease; diabetes or any metabolic disorder; changes in thyroid function; history of eating disorders; any treatment for body weight loss; adherence to any specific diet; any allergy or food intolerance; alcoholism; pregnancy or lactation; regular use of antibiotics (30 days before beginning the study) or medications affecting intestinal motility; and regular intake (≥3 times/wk) of industrialized fibers or products containing prebiotics or probiotics, including yogurts and dairy drinks.

Fiber Supplementation

All included volunteers were randomly selected to receive 21 days of orange juice that was enriched (fiber group) or not (placebo group) with 2.25 g per 100 mL with a fiber mixture composed of FOS, resistant dextrin (Nutriose; Roquette, Lestrem, France), and polydextrose. Juice drinking was performed in 2 daily doses (400 mL; total of 9.0 g of fiber) at different times, with a minimum interval of 6 hours. Fiber and placebo juices were prepared in 200-mL packages (Tetrapack®, São Paulo, Brazil) by their manufacturer. They were identical in appearance (consistency and texture), taste, and smell (compositions in Table 1).

The fiber content and shelf-life stability were verified by the Indirect Methods of Association of Official Agricultural Chemists: 997-08 (FOS) and 2001-03 (Nutriose and polydextrose). Juices were stored at room temperature in a dry and airy place until consumption. Juice consumption was monitored weekly when volunteers returned to the consultation with their empty Tetrapak packages to seek a new supply of orange juice packages and also by self-reported consumption in their individual diaries.

Data Collection

Data were collected 1 week before fiber supplementation (baseline data) and daily during the 21 days of fiber supplementation. Each patient kept a specific diary to self-report juice, food, and beverage consumption; GI symptoms; and evacuation data. Reported data were monitored weekly by a trained dietitian (L.M.H.), who also recorded any complication that may have occurred during the fiber supplementation period.

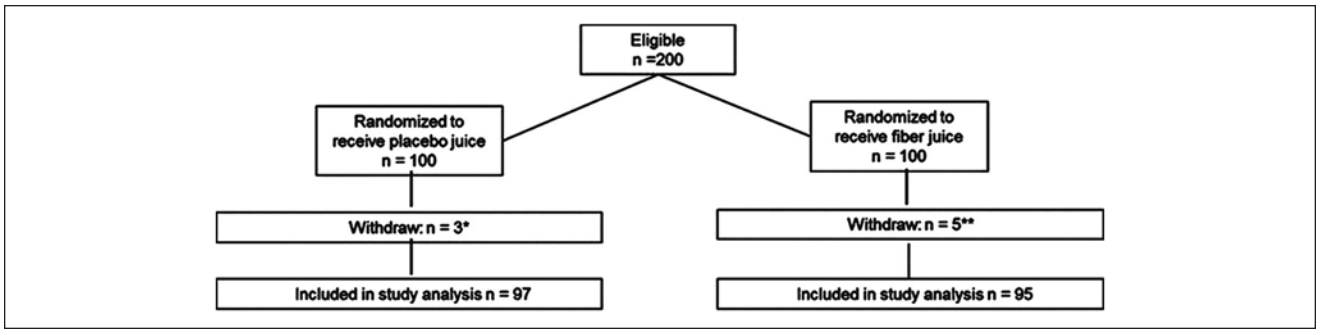

Figure 1. CONSORT flowchart of study participants. *Stomach pain and bloating (n = 1) and not attended medical appointments (n = 2). **Heartburn (n = 1), body mass index >29.9 kg/m^2 (n = 1), and loss of juice ingestion (n = 3).

Nutrition Intake Documentation

Data were collected at baseline by 24-hour food recall and during the 21 days of fiber supplementation, using the 3-day food record.[12] A representation of the participant's normal food intake pattern was determined through her diary records. For the 3-day food record, the participant was asked to self-record the type and amount of food and beverages consumed. This was done on 3 nonconsecutive days of each study week, one of which was on the weekend. In this way, 9 food records per participant were obtained from the beginning to the end of the study.

The obtained data were used to calculate the consumption of total dietary fiber, soluble fiber, and insoluble fiber, as well as energy, protein, carbohydrate, and fat intake via the software "Pro Diet version 2012" (Dietpro 5.5; Software de Nutrição, Viçosa, Brazil). The following data sources were used to determine food chemical composition: the food chemical composition table,[13] the Brazilian food chemical composition table TACO,[14] and the nutrition information provided on the food label.

Tolerance evaluation. On a daily basis, volunteers self-recorded their perception of abdominal manifestations (reflux, eructation, heartburn, stomach burning, burning pain, nausea, vomiting, colic, fullness, abdominal pain, bloating, rumbles, meteorism, flatulence, effort and pain to evacuate). These recordings were graded according to 4 scores (0, no symptoms; 1, tolerable symptoms; 2, bothersome symptoms; 3, symptoms impairing daily activities).

Participants also self-evaluated pain intensity daily by using a visual analog scale (VAS) with increasing grades of pain severity (0, no pain; 2, some pain; 4, mild pain; 6, moderate pain; 8, severe pain; 10, worst pain imaginable) and recorded stool frequency and stool consistency and shape (classified by the Bristol scale: 1, nut-like; 2, lumpy sausage; 3, sausage with cracks; 4, smooth snake; 5, soft blobs; 6, fluffy pieces; and 7, watery).

All these participants' personal registers were done after being carefully instructed by a trained dietitian (L.M.H.) using a specific manual, which was taken home to record the required information daily, as they had been instructed.

Sample Size and Statistical Analysis

The sample size for this study was calculated by assuming a ratio of GI symptoms of at least 2 and considering a 25% incidence in the placebo group. Fisher exact test was used to compare proportions with a significance level of 5% and 90% power. The calculation indicated that 71 cases in each group were needed to determine a difference.[15] Considering possible losses of individuals during the fiber supplementation stage, we included 40% more individuals per group.

Sample homogeneity was tested for all variables using the Kolmogorov-Smirnov test. Tolerance data were evaluated weekly according to the mean frequency of each symptom, independently of its graduation, and by considering the different grades from the VAS. To compare means, the Student *t* test was used when the variables were normally distributed, and a nonparametric Mann-Whitney test was used otherwise. Descriptive variables were compared by the χ^2 test or the Fisher exact test when the approach of the first was not adequate. Nutrient consumption and fiber tolerance were statistically analyzed during the period of juice intake, evaluating the effect of time and groups, as well as whether any interaction between them occurred. For this analysis, we used the nonparametric analysis of ordinal data for repeated measures with 2 factors, Wald and analysis of variance (ANOVA) type, as proposed by Brunner and Langer.[16] A significance level of 5% was considered for all tests, which were performed using the R program (version 2.14.3; R Foundation, Vienna, Austria).

Results

Patients

We randomized 200 patients to 2 groups (100 patients per group). Eight patients (placebo group: n = 3; fiber group: n = 5) provided incomplete data and were excluded from statistical analysis. Figure 1 shows a CONSORT diagram demonstrating the flow of participants. From the 192 women who completed the study, 58% consumed juice without any failure (2 daily complete doses) during the 3 fiber supplementation weeks. The

Table 2. Baseline Demographic and Descriptive Data of the Study Population.

Characteristic	Placebo Group	Fiber Group	*P* Value
Age, y	29.0	28.6	.748
Disease,[a] %	26.3	25.8	.940
Medical drugs use, %	4.5	5.2	1.000
Cardiac frequency, bpm	78.2	78.7	.730
Systolic pressure, mm Hg	114.3	114.5	.880
Diastolic pressure, mm Hg	73.2	74.8	.420
Body temperature, °C	35.9	35.8	.100
Body weight, kg	63.0	61.3	.210
Body mass index, kg/m^2	23.6	23.1	.190
Individuals performing physical activity, %	28.4	34.0	.439

[a]Presence of diseases not considered as exclusion criteria (eg, hypertension).

average rate of individual compliance of correct juice consumption was 97.5%. At baseline, the placebo and fiber groups were well matched for demographic and descriptive data (Table 2).

Nutrient Intake

Total fiber consumption ($P < .001$, Figure 2A) and soluble fiber consumption ($P < .001$, Figure 2B) were significantly higher in the fiber group compared with the placebo group. Insoluble fiber consumption was similar in the 2 groups (mean of 4 g/d; $P = .120$, Figure 2C). Only the fiber group achieved the daily fiber consumption values recommended by the U.S. National Cancer Institute (Figure 2A).

There were no differences in fat ($P = .611$, Figure 3A), carbohydrate ($P = .516$, Figure 3B), and protein ($P = .141$, Figure 3C) intake between placebo and fiber groups. Energy intake changed over time by increasing in placebo group and decreasing in fiber group ($P = .010$), but it was not statistically different between these groups ($P = .170$). Considering the Dietary Guidelines of the Department of Agriculture and Department of Health and Human Services, carbohydrate intake was lower, fat intake was higher, but energy intake was according to dietary recommendations. It should be noted that the placebo group had energy consumption near the maximum recommendation, while fiber group had near the minimum recommendation (Figure 3D).

Tolerance Findings

Patients from both groups presented similar baseline values for fullness, abdominal pain, bloating, rumbles, meteorism, flatulence, reflux, eructation, heartburn, stomach burning, burning pain, nausea, and vomit frequencies ($P \geq .05$). Different baseline values were observed for colic, which was more frequent in the placebo group ($P = .03$, Figure 4A).

Changes in abdominal symptoms were observed within the groups over time. For both the fiber supplementation and the placebo groups, the frequency of bloating increased during the supplementation period ($P \leq .05$, Figure 4C) and the frequency of rumbles increased in the first ($P = .004$, Figure 4D) and third ($P = .001$, Figure 4D) weeks of supplementation compared with the baseline values. Flatulence was less frequent in the placebo group at the second week of supplementation (baseline vs second week, $P = .038$; first vs second week, $P = .008$) and more frequent in the fiber group throughout the supplementation period compared with the baseline week ($P \leq .020$, Figure 4B). Differences between groups occurred only for flatulence, which was higher in the fiber than in the placebo group after the second week of fiber supplementation ($P = .003$, Figure 4B).

VAS scores of pain showed increases in the intensity of bloating ($P = .002$), rumbles ($P = .005$), flatulence ($P = .003$), and meteorism ($P = .012$) in both groups at the first and second weeks of supplementation. These changes ranged from grade 0 to grade 2 of the VAS.

No changes in evacuation frequency were observed during the study period ($P = .968$, Figure 5). The fiber group showed a higher frequency of Bristol scale scores 1 and 2 at baseline compared with the placebo group (10% vs 5.9%, $P = .006$); however, no differences in Bristol scale scores were observed between placebo and fiber groups during the supplementation period ($P > .050$, data not shown). Similar baseline values were observed for difficulty to evacuate (13.7% vs 18.6%, $P = .690$) and pain while evacuating (6.3% vs 4.1%, $P = .790$); however, no changes were observed in evacuation symptoms during the supplementation period ($P > .050$, data not shown).

Discussion

Adequate dietary fiber intake is recommended by governmental public health agencies to help maintain or improve health.[1,18,19] In the present study, women from the placebo group displayed fiber consumption values that were below these recommendations, while women who received orange juice supplemented with fiber (30% of the recommended daily intake) achieved a minimum of 20 g, as previously recommended by the National Cancer Institute.[18]

Reports have shown a deficiency in fruit, vegetable, and cereal ingestion among Brazilians.[6,20] Cited reasons for these dietary fiber deficits include unpleasant taste, lack of habit, no time available to purchase and prepare, and high perishable risk.[6] These reasons may account for the low ingestion of fiber that was presently observed in both groups of women at baseline and in the placebo group throughout the study period. Highly processed and "fast" foods are commonly ingested in urban centers, such as São Paulo, which may also contribute to the low ingestion of fiber observed.[21]

In the Women's Health Initiative trial, the development of educational guidelines to increase fiber intake achieved only a modest increase in fruit and vegetable intake over a 6-year period and a decrease in whole-grain intake.[22] This finding suggests that fiber supplements may show a better overall adherence than making substantial improvements in dietary practices.[13,22] However, fiber supplementation can be accompanied by GI discomfort,

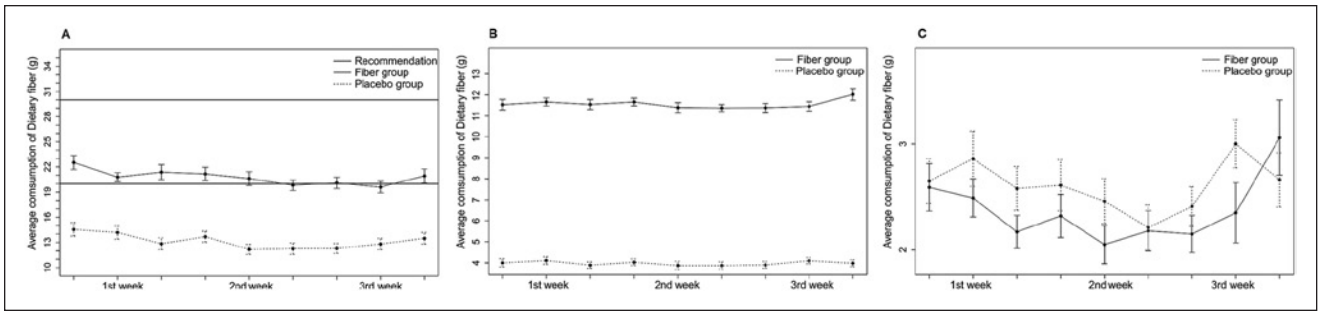

Figure 2. Three-day food record of average weekly consumption of total (A), soluble (B), and insoluble (C) fiber in women after 21 days of ingesting orange juice supplemented or not with fiber (fiber group, n = 95 and placebo group, n = 97). *National Cancer Institute.[2]

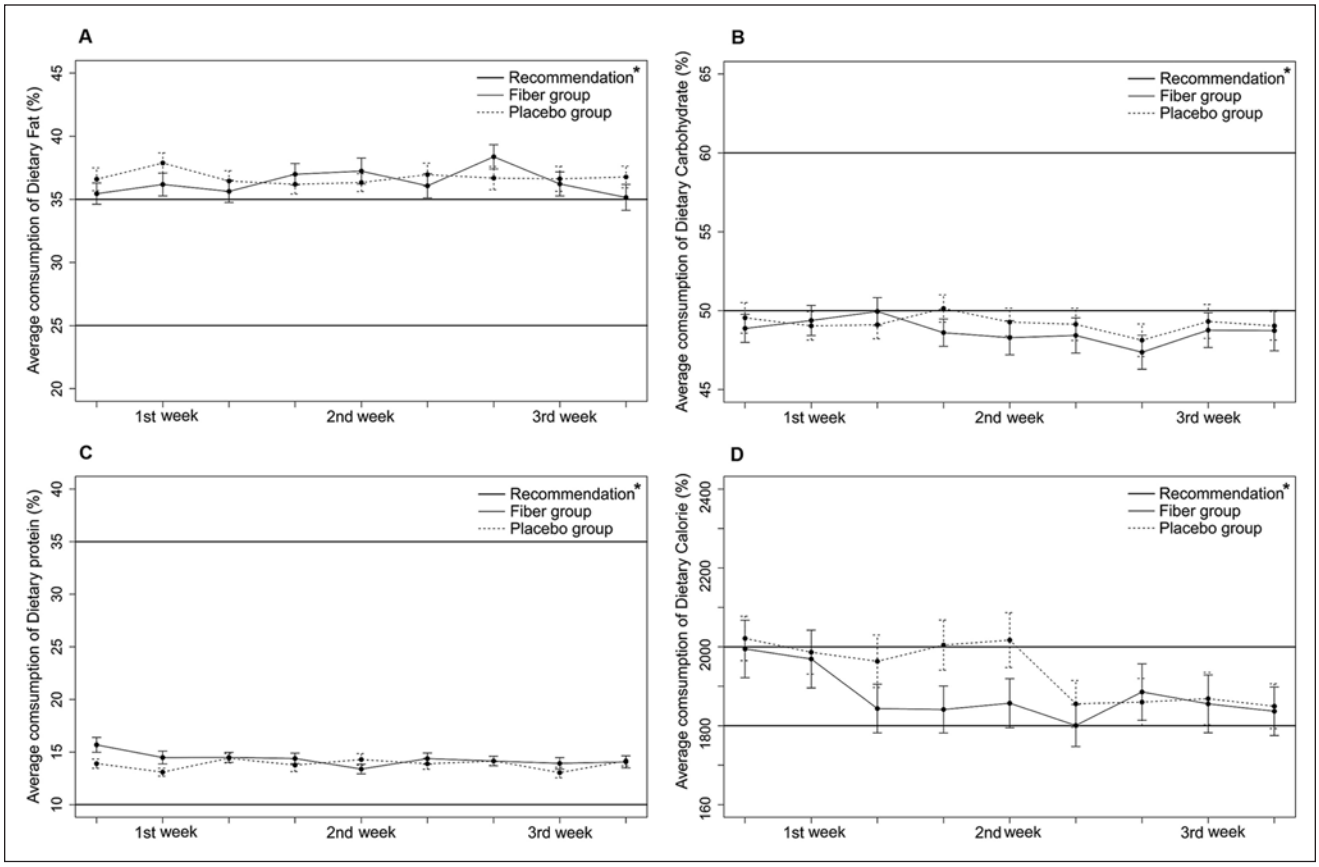

Figure 3. Weekly consumption of total fat (A), carbohydrate (B), protein (C), and energy (D) in women after 3 weeks of ingesting orange juice supplemented or not with fiber (fiber group, n = 95 and placebo group, n = 97), based on 3-day food record average. Energy and fiber content of the ingested orange juice are included in the figures. *Dietary Guidelines of the Department of Agriculture and Department of Health and Human Services.[17]

such as flatulence, bloating, abdominal cramps, and eventually diarrhea.[10] Orange juice consumption can lead to gastric adverse events associated with the acidity of orange, including heartburn, stomach burning, and burning pain.

According to our data, the consumption of orange juice was associated with increased bloating and rumbles over time, independent of fiber supplementation. Among the various factors that might contribute to the generation of these symptoms, we could include changes in gut microbiota[23] by the change in diet.[24] There were high amounts of sucrose in both the placebo and high-fiber orange juices (7.7 g/100 mL of juice), with each volunteer having a daily intake of 400 mL of 30.8 g total sugar. This amount of sugar usually is not taken by women with an average age of 28 years in Brazil; moreover, many of the women included in our study were dietitians. It could be possible that the increase of sucrose intake had propitiated changes in gut

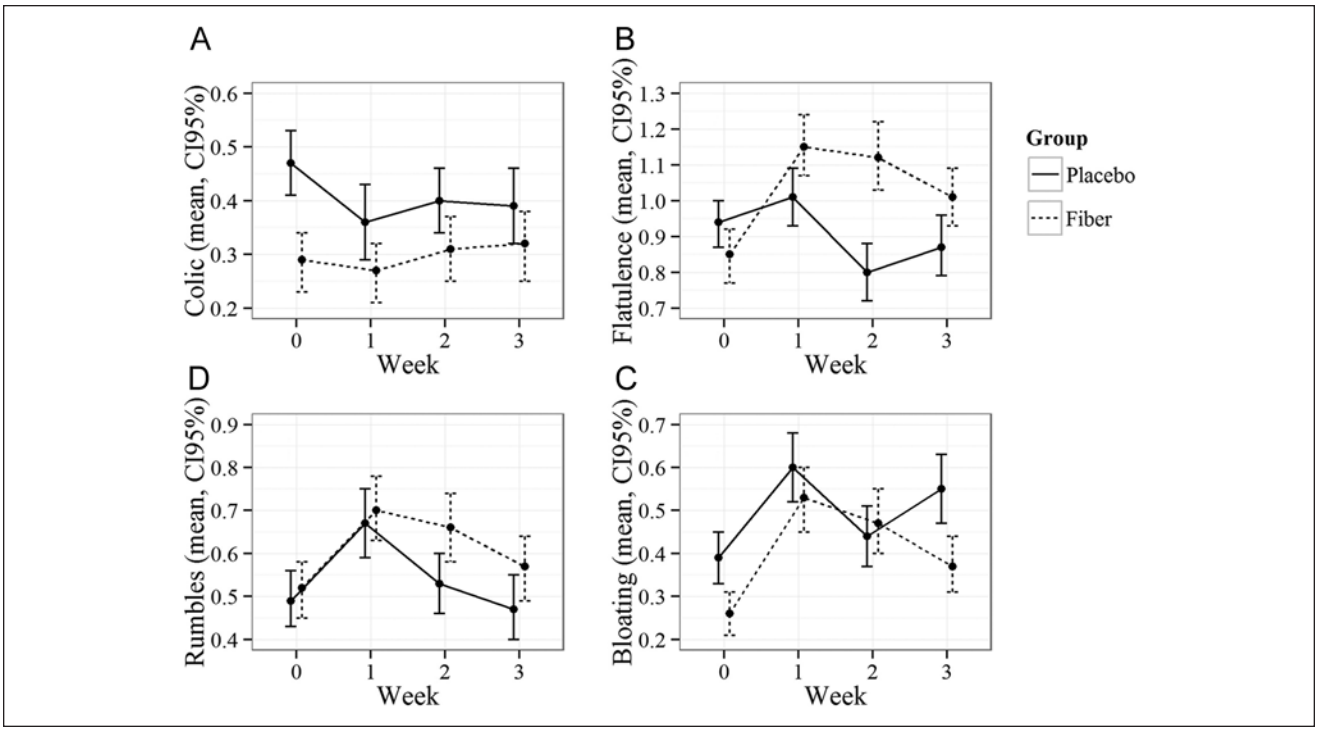

Figure 4. Significant differences in abdominal symptoms in women at baseline and after 3 weeks of ingesting orange juice supplemented or not with fiber (fiber group, n = 95 and placebo group, n = 97).

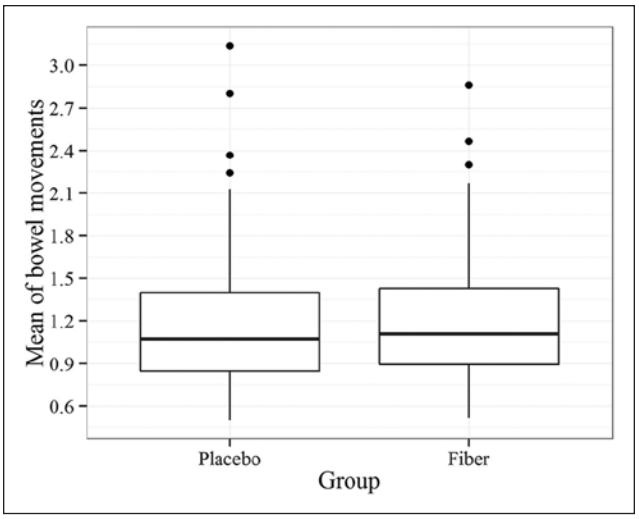

Figure 5. Mean number of bowel movements for women after 3 weeks of ingesting orange juice supplemented or not with fiber (fiber group, n = 95 and placebo group, n = 97).

microbiota, therefore contributing to the occurrence of these symptoms. Our present data suggest a potential relevance to decreasing the addition of sucrose in industrialized orange juices supplemented or not with fiber.

In the present study, fiber supplementation was associated only with increased flatulence, which has been previously reported.[25,26] Women from the placebo group experienced a low flatulence frequency, but only at the second week of fiber supplementation, suggestive of a placebo effect. This effect was frequently observed in our other fiber supplementation studies, suggesting that studies evaluating the issue would require more than 2 weeks of intervention.[27,28]

Dietary fiber can increase fecal bulking and viscosity, due to the bifidogenic effect and accumulation of bacteria mass for fiber degradation (soluble fibers) and water retention (insoluble fibers).[29] These properties may stimulate intestinal peristalsis, decrease intestinal transit time, and enhance evacuation frequency,[29] but no changes were observed in terms of evacuation frequency, stool consistency and shape, or GI symptoms related to evacuation in the fiber or placebo group.

Importantly, although our women experienced more bloating, rumbles, and flatulence when consuming the high-fiber orange juice, data from the VAS of pain revealed that the intensity of these symptoms was slight. In addition, we observed a high average rate of individual compliance of correct juice consumption (97.5%). Therefore, when consuming fiber-supplemented orange juice, these adverse events seemed to be sufficiently minor so as not to impair juice ingestion.

Women from the fiber group also experienced a higher frequency of colic, with scores of 1 or 2 on the Bristol scale at baseline. There is no specific explanation as to why this occurred. Notwithstanding, these baseline differences most likely did not influence our findings, as both groups displayed similar colic complaints and Bristol scores throughout the supplementation period.

Some limitations of our study should be highlighted. It included only healthy young adult women, and similar results may not be achieved in other age groups or in men. We did not perform an intent-to-treat analysis; however, our patient compliance failure was less than 10% of the total sample. Although current guidelines suggest a minimum intake of 25 g of fiber per day for young women,[18,30] this study was designed aiming to achieve a minimum 20 g of fiber/d intake as previously suggested by the National Cancer Institute and still adopted in some countries.[31] The new U.S. fiber intake recommendations could be achieved by increasing the daily doses of orange juice, but we do not know the repercussions of digestive symptoms. The increase of fiber consumption after ingestion of supplemented orange juice was accompanied by a higher intake of soluble fiber but not of insoluble fiber. These observations reinforce the efficiency of the studied fiber-enriched orange juice, which was supplemented with FOS and Nutriose polydextrose, components characteristic of soluble fiber. Soluble fiber is associated with metabolic and intestinal benefits, but the impact of the consumption of supplemented orange juice on health benefits was not evaluated.[1]

In conclusion, our data demonstrate a deficiency in fiber ingestion by Brazilian women that was corrected by supplementing fiber in an orange juice form. This finding was not accompanied by intense adverse events.

Acknowledgments

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References

1. Tungland BC, Meyer D. Nondigestible oligo- and polysaccharides (dietary fiber): their physiology and role in human health and food. *Compr Rev Food Sci Food Saf*. 2002;3:90-109.
2. Holmboe-Ottesen G, Wandel M. Changes in dietary habits after migration and consequences for health: a focus on South Asians in Europe. *Food Nutr Res*. 2012;56:1-13.
3. Shay CM, Van Horn L, Stamler J, et al; INTERMAP Research Group. Food and nutrient intakes and their associations with lower BMI in middle-aged US adults: the International Study of Macro-/Micronutrients and Blood Pressure (INTERMAP). *Am J Clin Nutr*. 2012;96:483-491.
4. O'Neil CE, Nicklas TA, Zanovec M, Cho S. Whole-grain consumption is associated with diet quality and nutrient intake in adults: the National Health and Nutrition Examination Survey, 1999-2004. *J Am Diet Assoc*. 2010;110:1461-1468.
5. Lanza E, Jones DY, Block G, Kessler L. Dietary fiber intake in the US population. *Am J Clin Nutr*. 1987;46:790-797.
6. Silva CL. *Consumo de frutas e hortaliças e conceito de alimentação saudável em adultos de Brasília* [dissertation]. Brasília: Universidade de Brasília; 2011.
7. Jaime PC, Machado FMS, Westphal MF, Monteiro CA. Educação Nutricional e Consumo de frutas e hortaliças: ensaio comunitário controlado. *Rev Saúde Pública*. 2007;41:154-157.
8. Silva PT, Fialho E, Lopes MLM, Valente-Mesquita VL. Sucos de laranja industrializados e preparados sólidos para refrescos: estabilidade química e físico-química. *Ciên Tecnol Aliment*. 2005;25:597-602.
9. Anderson JW, Baird P, Davis RH Jr, et al. Health benefits of dietary fiber. *Nutr Rev*. 2009;67:188-205.
10. Heading RC. Prevalence of upper gastrointestinal symptoms in the general population: a systematic review. *Scand J Gastroenterol Suppl*. 1999;231:3-8.
11. Lewis SJ, Heaton KW. Stool form scale as a useful guide to intestinal transit time. *Scand J Gastroenterol*. 1997;32:920-924.
12. Fisberg RM, Slater B, Martini LA. Métodos de Inquéritos Alimentares. In: Fisberg RM, Slater B, Marchioni DM, Martini LA, eds. *Inquéritos Alimentares: Métodos e Bases Científicas*. Barueri, Brazil: Manole; 2005:1-31.
13. Philip ST. *Tabela de Composição de Alimentos: Suporte para Decisão Nutricional*. São Paulo, Brazil: Manole; 2002.
14. Núcleo de Estudos e Pesquisas em Alimentação (NEPA). *TACO—Tabela Brasileira de Composição de Alimentos*. 4th ed. Campinas, Brazil: UNICAMP; 2011.
15. Chow S-C, Shao J, Wang H. *Sample Size Calculations in Clinical Research*. 2nd ed. New York, NY: Chapman & Hall/CRC; 2008.
16. Brunner E, Langer F. Nonparametric analysis of ordered categorical data in designs with longitudinal observations and small sample sizes. *Biometrical J*. 2000;42:663-675.
17. U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2010*. 7th ed. Washington, DC: U.S. Government Printing Office; 2010.
18. Butrum RR, Clifford CK, Lanza E. NCI dietary guidelines: rationale. *Am J Clin Nutr*. 1988;48(3)(suppl):888-895.
19. Nishida C, Uauy R, Kumanyika S, Shetty P. The joint WHO/FAO expert consultation on diet, nutrition and the prevention of chronic diseases: process, product and policy implications. *Public Health Nutr*. 2004;7:245-250.
20. Graciola C, Fortuna FV. Descrição do perfil nutricional e alimentar dos funcionários de um serviço público. *ConScientiae Saúde*. 2010;9:39-46.
21. Isganaitis E, Lustig RH. Fast food, central nervous system insulin resistance, and obesity. *Thromb Vasc Biol*. 2005;25:2451-2462.
22. Howard BV, Van Horn L, Hsia J, et al. Low-fat dietary pattern and risk of cardiovascular disease: the Women's Health Initiative Randomized Controlled Dietary Modification Trial. *J Am Med Assoc*. 2006;295:655-666.
23. Seo AY, Kim N, Oh DH. Abdominal bloating: pathophysiology and treatment. *J Neurogastroenterol Motil*. 2013;19:433-453.
24. Power SE, O'Toole PW, Stanton C, Ross RP, Fitzgerald GF. Intestinal microbiota, diet and health. *Br J Nutr*. 2014;111(3):387-402.
25. Bolin TD, Stanton RA. Flatus emission patterns and fibre intake. *Eur J Surg*. 1998;582:115-118.
26. Tomlin J, Lowis C, Read NW. Investigation of normal flatus production in healthy volunteers. *Gut*. 1991;32:665-669.
27. Waitzberg DL, Logullo LC, Bittencourt AF, et al. Effect of synbiotic in constipated adult women - a randomized, double-blind, placebo-controlled study of clinical response. *Clin Nutr*. 2013;32:27-33.
28. Waitzberg DL, Pereira CCA, Logullo L, et al. Microbiota benefits after inulin and partially hydrolized guar gum supplementation: a randomized clinical trial in constipated women. *Nutr Hosp*. 2012;27:123-129.
29. Lattimer JM, Haub MD. Effects of dietary fiber and its components on metabolic health. *Nutrients*. 2010;2:1266-1289.
30. Institute of Medicine, Panel on Macronutrients Staff, Subcommittees on Upper Reference Levels of Nutrients, Interpretation, Uses of Dietary Reference Intakes Staff, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes Staff. Summary tables. In: *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)*. Washington, DC: National Academies Press; 2005:1319-1332.
31. Ng TK, Chow SS, Chan LP, Lee CY, Lim SQ. Recommended nutrient intake for dietary fibre: bar set too high for malaysians? *Malays J Nutr*. 2010;16:271-280.