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The soluble fiber NUTRIOSE induces a dose-dependent beneficial impact on satiety over time in humans

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Abstract

Strong evidence supports the ability of dietary fibers to improve satiety. However, large variations in the physical and chemical characteristics of dietary fiber modulate the physiologic responses. We hypothesized that a nonviscous soluble dietary fiber may influence satiety. This randomized, double-blind, placebo-controlled clinical study in 100 overweight healthy adults in China investigated the effect of different dosages of dietary supplementation with a dextrin, NUTRIOSE (ROQUETTE frères, Lestrem, France), on short-term satiety over time. Subjects were randomized by body mass index and energy intake and then assigned to receive either placebo or 8, 14, 18, or 24 g/d of NUTRIOSE mixed with orange juice (n = 20 volunteers per group). On days −2, 0, 2, 5, 7, 14, and 21, short-term satiety was evaluated with a visual analog scale, and hunger feeling status was assessed with Likert scale. NUTRIOSE exhibits a progressive and significant impact on short-term satiety, which is time and dosage correlated. Some statistical differences appear for the group 8 g/d from day 5, and from day 0 for the groups 14, 18, and 24 g/d. The hunger feeling status decreases significantly from day 5 to the end of the evaluation for the group 24 g and from day 7 for the groups 14 and 18 g. By day 5, the group 24 g showed significantly longer time to hunger between meals compared with placebo. These results suggest that dietary supplementation with a soluble fiber can decrease hunger feeling and increase short-term satiety over time when added to a beverage from 8 to 24 g/d with time- and dose-responses relationship.

Keywords: Dietary fiber; Dextrin; Satiety; Hunger; Clinical trial
Abbreviations: BMI, body mass index; VAS, visual analog scales.

1. Introduction

Obesity is a major contributor to the global burden of chronic disease and disability. Worldwide, at least 300 million adults are clinically obese [1]. By 2015, an estimated 2.3 billion adults will be overweight and more than 700 million will be obese [2]. Governments and other key stakeholders are making prevention and treatment of obesity a public health priority to prevent concomitant epidemics of diabetes, heart disease, and other chronic illnesses. Evidence shows that a high intake of dietary fiber supports the regulation of energy intake and satiety and could contribute favorably to the fight against obesity [3].

Dietary fiber is an essential constituent of a healthy diet and is well known for its satiety impact [4]. It had been recommended by the Scientific Panel on Dietetic Products, Nutrition and Allergies of the European Food Safety

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Authority that dietary fiber should include all nondigestible carbohydrates in accordance with the proposal for a CODEX definition of dietary fiber. According to the Annex II of the Commission Directive 2008/100/EC of 28 October 2008 (European Commission, 2008), dietary fiber is now defined in the European Union as follows: "carbohydrate polymers with three or more monomeric units, which are neither digested nor absorbed in the human small intestine and belong to the following categories:

-edible carbohydrate polymers naturally occurring in the food as consumed;
-edible carbohydrate polymers which have been obtained from food raw material by physical, enzymatic or chemical means and which have a beneficial physiological effect demonstrated by generally accepted scientific evidence;
-edible synthetic carbohydrate polymers which have a beneficial physiological effect demonstrated by generally accepted scientific evidence."

Large variations that exist in the physical and chemical characteristics of dietary fiber influence physiologic responses in humans [5,6]. Lyon and Reichert [7] have found that certain types of dietary fiber might promote satiety by reducing postprandial glycemia. Similarly, Bodinham et al [8] found that short-term consumption of resistant starch type 2 dietary fiber improves postprandial glucose metabolism in healthy individuals. Beneficial effects have been demonstrated with use of fiber from diverse sources, some traditional, others novel [5]. For example, data suggest that the viscosity-forming capacity of water-soluble fibers, such as guar gum and oat β-glucan, is crucial for their impact on satiety-related attributes [9]. Lyon and Reichert [7] recently tested a soluble, highly viscous polysaccharide manufactured by reacting glucomannan with other soluble polysaccharides using a proprietary process. They found that the fiber might help sedentary overweight and obese adults lose weight when combined with lifestyle modifications.

In addition, the addition of dietary fiber to foods as well as beverages has been associated with greater satiety [10-13] and reduced energy intake in the short term [14]. Although fibers tend to show good correlation to satiety [14-17], results are variable most likely because of the diverse physicochemical and gastrointestinal transit behavior of these materials. For example, nonviscous insoluble fibers, such as soy fiber and oat hull fiber, did not show efficacy in promoting satiety [18-22].

Although many dietary fibers are known to affect satiety, not all are equally effective, and comparative assessments require careful attention. Few studies have been performed on the effect of a nonviscous soluble fiber formulation on short-term satiety over time with chronic supplementation of fibers. We hypothesized that a nonviscous soluble dietary fiber, NUTRIOSE (ROQUETTE frères, Lestrem, France), may improve short-term satiety and hunger feeling when chronically administered to overweight adults. The objective of the present study was to investigate the impact of different dosages of NUTRIOSE on short-term satiety and on hunger feeling status.

2. Methods and materials

2.1. Subjects

One hundred healthy overweight male and female factory workers between the ages of 35 and 55 years were recruited from a single-center manufacturing plant in the region of Jinhua China. Inclusion criteria included body mass index (BMI) of 24 to 28 kg/m^2 with no acute/terminal or chronic diseases and working 7 days a week at the manufacturing plant. Exclusion criteria included current or past use (during the past 3 months) of any dietary fiber or probiotic supplementation, except from food sources; known allergic reaction to wheat products (eg, gluten intolerance, celiac disease); use of an antibiotic either currently or within the past 3 months; enrollment in another clinical trial within the past 3 months; or contraindications to dietary fiber supplementation, that is, chronic diarrhea, irritable bowel syndrome, chronic use of laxatives, cirrhosis of the liver, inflammatory bowel disease, ulcerative colitis, or Crohn disease. The study protocol was reviewed by a local institutional review board and carried out in accordance with the Declaration of Helsinki. All study subjects gave written informed consent.

2.2. Study design

This 3-week evaluation was a substudy of a larger 9-week study and was performed according to a randomized, double-blind, placebo-controlled, dose-response design. The satiety parameters were evaluated on a 3-week period, whereas the anthropometric parameters that are long-term parameters were measured on a 9-week period. The aim of the present study was to present the satiety evaluation. Weight, BMI, body fat, and energy intake will be the subject of a second article.

The primary objective of the study was to investigate whether dietary supplementation with NUTRIOSE at different dosages was associated with an increase of short-term satiety over time and a decrease in energy intake (data not shown). The secondary objective was to investigate whether dietary supplementation with NUTRIOSE at different dosages was associated with a decrease in body-weight, BMI, and body fat (data not shown) and a modulation of the hunger feeling status. The study included a 2-day run-in period in which all subjects received placebo (250 mL of orange juice) twice daily. They were then randomized by baseline energy intake and BMI and assigned to 1 of 5 groups of 20 Chinese male and female (1:1) volunteers. Each subject received 250 mL of orange juice twice daily either alone (placebo) or supplemented with NUTRIOSE at different dosages (8 g/d [4 g × 2], 14 g/d

Table 1
Indicative values of glycosidic bonds distributions (%) in NUTRIOSE, standard maltodextrin GLUCIDEX (ROQUETTE, Lestrem, France), and starch

Type of osidic linkages	NUTRIOSE	GLUCIDEX	Starch
(1,4)	41	95	95
(1,6)	32	5	5
(1,2)	13	0	0
(1,3)	14	0	0

[7 g × 2], 18 g/d [9 g × 2], or 24 g/d [12 g × 2]). All beverages had the same appearance, taste, smell, and consistency. At baseline (day 0) until week 9, subjects received NUTRIOSE or placebo orally 3 hours after breakfast (at 10 AM) and 4 hours after lunch (at 4 PM) in the presence of research staff who verified and recorded product consumption. Subjects ate their usual meals with a free access to food in the canteen at the same time (breakfast at 7 AM, lunch at noon, and dinner at 6:30 PM) every day throughout the study period. Subjects worked from 7 AM to 6:30 PM each day and had no access to additional food during this period. A computer-generated urn randomization allocation was used in this trial.

2.3. Study substance

NUTRIOSE is a glucose polysaccharide produced from maize, wheat, or other edible starch heated at high temperature. The final product, NUTRIOSE, is a mixture of glucose polymers with a fairly narrow range of molecular weight (number average molecular weight, Mn = 2600 g/mol; weight average molecular weight, Mw = 5000 g/mol) [27]. The degree of polymerization is approximately 18. In comparison, starch may contain up to 1 million glucose units. During the heating step, hydrolysis and repolymerization occur. In addition to the typical starch α-1,4 and α-1,6 glucosidic linkages, the recombination can result in other specific linkages that are not found in starch, including both linear and branched linkages: (α-1,6 and/or β-1,6), (α-1,2 and/or β-1,2), (α-1,3 and/or β-1,3), and β-1,4 (Table 1). This confers to the product a resistance against the action of endogenous glucidolytic enzymes and permits classification of the product among the soluble dietary fibers with a total fiber content of nearly 85%. Approximately 15% of NUTRIOSE is digested, and 75% is fermented in the gastrointestinal tract [23,24], and the dosage of NUTRIOSE that does not induce digestive disorders has been estimated at 45 g/d either on the long and the short term [24-26].

2.4. Measurements

Short-term satiety (delay of return of hunger after consumption of the tested product) was measured on days −2, 0, 2, 5, 7, 14, and 21 by using standardized 100-mm visual analog scales (VAS) anchored with "not at all" and "extremely." Volunteers completed scores in the morning and in the afternoon just before product intake (−2 minutes) and at 10, 30, 60, 90, and 120 minutes after consumption by answering the following questions: "How satisfied do you feel?" and "How hungry do you feel?" Nurses assigned to the 100 subjects each oversaw the completion of the VAS for 10 subjects during the 2 sessions of the day. Hunger feeling status was evaluated on days −2, 0, 2, 5, 7, 14, and 21, immediately before consumption of the study product (10 AM and 4 PM). Subjects were asked to describe their current hunger on a 6-point Likert scale with the following possible answers: full (0), satisfied (1), somewhat hungry (2), hungry (3), very hungry (4), and starving (5). Subjects were also asked "How long after their last meal did they become hungry?" (number of hours after breakfast or after lunch).

Each administration of placebo or NUTRIOSE was documented on a daily attendance form, one for each day of the supplementation period. All adverse events or reactions to the study product were recorded daily on an adverse event form.

2.5. Statistical analyses

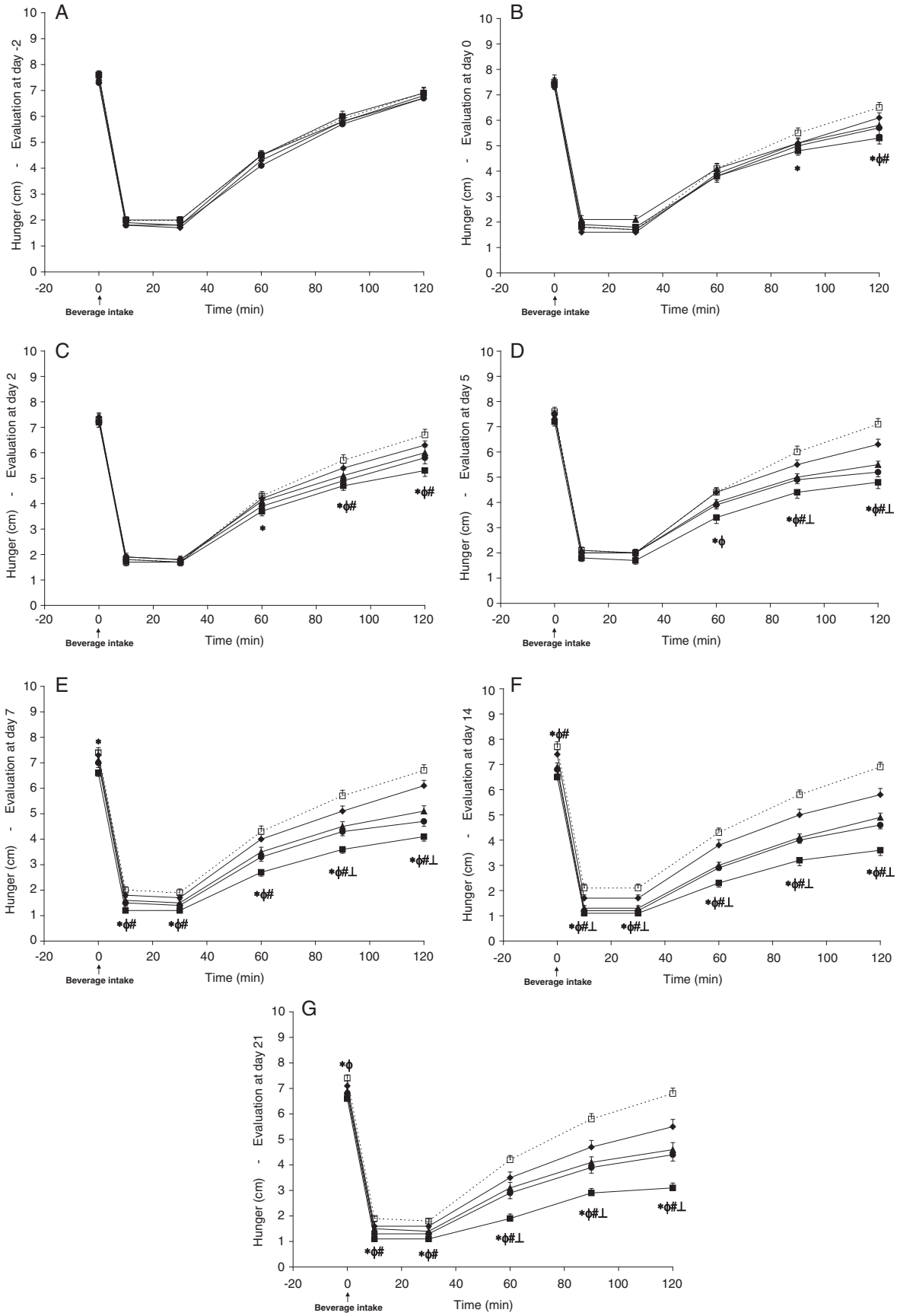
The sample size of 100 total subjects (20 per group) was calculated based on an anticipated effect size of 1.0 with each product dose vs placebo, assuming a 2-sided α level of .05, statistical power of 80%, and a 10% attrition rate.

All data were recorded on case report forms, double-entered, verified, and independently monitored for accuracy by Sprim China Ltd (Shanghai, China). Statistical analyses were performed using SAS/STAT software (Release 9.2; SAS Institute, Cary, NC). Continuous variables are reported as means ± SD or SEM. Categorical variables are presented

Table 2
Baseline characteristics of subjects by study group

Characteristic	Groups				
	Placebo	NUTRIOSE 8 g/d	NUTRIOSE 14 g/d	NUTRIOSE 18 g/d	NUTRIOSE 24 g/d
Age (y)	45.0 ± 5.2	44.9 ± 5.4	44.1 ± 5.1	45.5 ± 5.2	44.1 ± 5.2
Sex: female, n (%)	10 (50)	10 (50)	10 (50)	10 (50)	10 (50)
Sex: male, n (%)	10 (50)	10 (50)	10 (50)	10 (50)	10 (50)
Weight (kg)	73.06 ± 6.18	73.06 ± 6.74	73.04 ± 7.53	73.03 ± 7.30	73.09 ± 7.36
Height (cm)	167.4 ± 6.0	167.4 ± 7.4	167.3 ± 8.2	167.2 ± 7.6	167.4 ± 7.5
BMI (kg/m^2)	26.03 ± 1.13	26.03 ± 1.28	26.04 ± 1.05	26.04 ± 0.82	26.02 ± 1.07
Body fat (kg)	20.76 ± 2.97	20.74 ± 2.83	20.69 ± 2.38	20.66 ± 2.35	20.74 ± 2.90

Data are presented as means ± SD, n = 20.


A
B
C
D
E
F
G
Hunger (cm) - Evaluation at day -2
Hunger (cm) - Evaluation at day 0
Hunger (cm) - Evaluation at day 2
Hunger (cm) - Evaluation at day 5
Hunger (cm) - Evaluation at day 7
Hunger (cm) - Evaluation at day 14
Hunger (cm) - Evaluation at day 21
Beverage intake
Time (min)

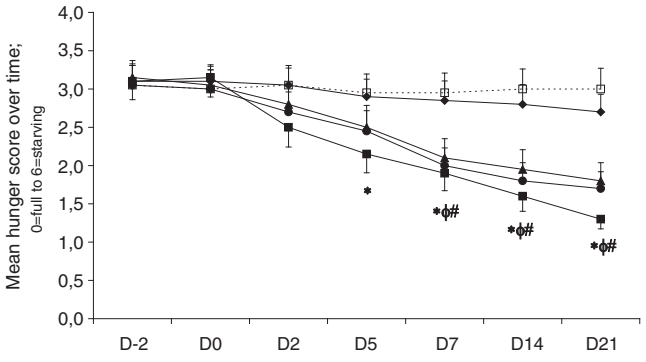


Fig. 2. Mean hunger score by study group over time (morning). Values are presented as mean hunger scores ± SEM (n = 20) for placebo (□), 8 g of NUTRIOSE (♦), 14 g of NUTRIOSE (▲), 18 g of NUTRIOSE (●), and 24 g of NUTRIOSE (■). The symbols represent the statistical differences compared with the placebo group ($P < .05$): NUTRIOSE 8 g (⊥), NUTRIOSE 14 g (ϕ), NUTRIOSE 18 g (#), and NUTRIOSE 24 g (*).

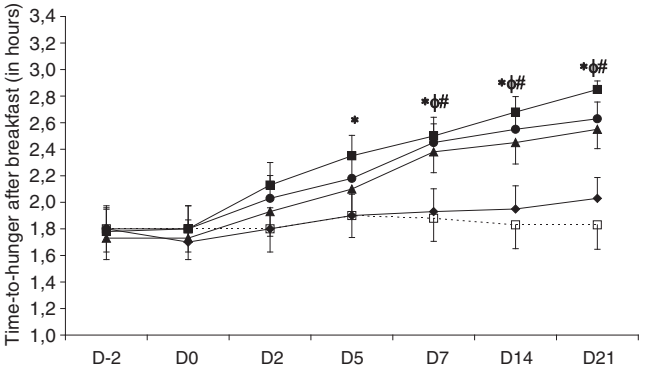


Fig. 3. Mean time to hunger after the breakfast by study group over time. Values are presented as time to hunger in hours ± SEM (n = 20) for placebo (□), 8 g of NUTRIOSE (♦), 14 g of NUTRIOSE (▲), 18 g of NUTRIOSE (●), and 24 g of NUTRIOSE (■). The symbols represent the statistical differences compared with the placebo group ($P < .05$): NUTRIOSE 8 g (⊥), NUTRIOSE 14 g (ϕ), NUTRIOSE 18 g (#), and NUTRIOSE 24 g (*).

as n (%). Repeated-measures analysis of variance was used to assess between-group differences in hunger scores and in time to return to hunger after the last meal. A Duncan post hoc test was applied to adjust for multiple comparisons. $P < .05$ was considered statistically significant. Hunger VAS scores were stratified by time of day (ie, morning or afternoon) to control for intraday hunger variations.

3. Results

3.1. Group characteristics

Table 2 shows baseline characteristics of study participants. One hundred subjects (50 males and 50 females) with a mean age range of 44.1 ± 5.1 to 45.5 ± 5.2 years took part in the study. No significant differences were observed in weight (in kilograms), height (in centimeters), BMI (in kilograms per squared meter), or body fat (in percent and kilograms).

3.2. Short-term satiety over time

Within each observation day, the values obtained in the morning were similar and highly positively correlated with the values obtained in the afternoon (data not shown). Across all study days as well as within each day, VAS hunger scores in all groups followed the same pattern—a significant decline at 10 minutes, with a steady increase from 30 to 120 minutes. At −2 minutes, mean VAS scores ranged from 6.5 to 7.7. An impact of the consumption of the orange juice was demonstrated by a drop in VAS scores by 5.4 to 5.7 points within 10 minutes of taking the study product. Fig. 1 (A-G) shows the mean VAS hunger scores for all groups at −2, 10, 30, 60, 90, and 120 minutes. During the study, NUTRIOSE exhibited a progressive and significant impact on short-term satiety. This effect was time correlated, that is, the impact on satiety became visible earlier while progressing in the trial and increased in value from day 0 to 21. This effect was also correlated to the ingested dose with the significance increasing with the dosages. No significant differences were observed among the study groups at day −2 before the consumption of the tested product. At day 0, in the morning after the first administration of the beverage, 12 g of NUTRIOSE (group "24 g") produced significantly less perceived hunger at 90 and 120 minutes compared with the beverage without fiber ($P < .05$). A difference can be observed at 120 minutes for the beverage containing 7 g (group "14 g") and 9 g (group "18 g"). At day 2, NUTRIOSE shows a significant modulation of hunger with 14 and 18 g (at 90 and 120 minutes) and with 24 g (at 60, 90, and 120 minutes; $P = .0172$). On day 5, the fiber groups with 8, 14, 18, and 24 g of NUTRIOSE per day had significantly less perceived hunger compared with those in placebo (respectively from 90, 90, 60, and 60 minutes). From day 7 to 21, the statistically demonstrated differences were stronger over

Fig. 1. A–G Values are presented as mean ratings in centimeters ± SEM (n = 20) for placebo (□), 8 g of NUTRIOSE (♦), 14 g of NUTRIOSE (▲), 18 g of NUTRIOSE (●), and 24 g of NUTRIOSE (■). The symbols represent the statistical differences compared with the placebo group ($P < .05$): NUTRIOSE 8 g (⊥), NUTRIOSE 14 g (ϕ), NUTRIOSE 18 g (#), and NUTRIOSE 24 g (*). A, Perception dimension of hunger ratings on the VAS from the beverage intake to the lunch at baseline (day -2). There is no statistical differences between the NUTRIOSE groups and the placebo group. B, Perception dimension of hunger ratings on the VAS from the beverage intake to the lunch at day 0. C, Perception dimension of hunger ratings on the VAS from the beverage intake to the lunch at day 2. D, Perception dimension of hunger ratings on the VAS from the beverage intake to the lunch at day 5. E, Perception dimension of hunger ratings on the VAS from the beverage intake to the lunch at day 7. F, Perception dimension of hunger ratings on the VAS from the beverage intake to the lunch at day 14. G, Perception dimension of hunger ratings on the VAS from the beverage intake to the lunch at day 21.

time showing an increase in short-term satiety over time. Moreover, the VAS evaluation at days 7, 14, and 21 shows a specific pattern because some statistical differences appear before the consumption of NUTRIOSE and within 10 minutes after NUTRIOSE consumption suggesting a modulation of the global hunger feeling over the period.

3.3. Hunger feeling evaluation

Fig. 2 shows the mean hunger score on the 6-point Likert scale obtained for the morning evaluation. NUTRIOSE consumption had a positive impact on the hunger feeling score over the study period with a statistical difference from day 5. Time to hunger after breakfast followed a similar pattern, with the fiber group showing longer time to hunger from days 5 to 21 (Fig. 3). When the results were expressed in mean difference vs placebo in hours after breakfast, on day 5, the fiber group with 24 g (0.34 [−0.01, 0.69]) had significantly more time to hunger after the meal compared with placebo ($P < .001$), whereas a tendency was observed at day 2 ($P = .062$). A tendency was also observed in the 18 g group ($P = .057$). On days 7 and 14, the fiber groups 14 g, 18 g, and 24 g had significantly more time to hunger after the last meal compared with placebo. The same was true on day 21: 0.89 (0.58, 1.20), $P < .001$; 1.01 (0.70, 1.32), $P < .001$; and 1.28 (0.96, 1.58), $P < .001$ for the 14 g, 18 g, and 21 g groups, respectively. There were no adverse events associated with intake of NUTRIOSE throughout the study period.

4. Discussion

This analysis of short-term satiety and hunger feeling demonstrated that NUTRIOSE added to orange juice increased short-term satiety over the study period and lengthened time to hunger between meals in overweight factory workers who took the product after morning and afternoon meals. Short-term satiety, as measured by the delay of return of hunger after the beverage consumption, was significantly greater in the NUTRIOSE group compared with placebo. Hunger feeling, as measured by time to hunger after the last meal and mean hunger score, was significantly modulated in the NUTRIOSE groups compared with placebo. The effects are also correlated to the ingested dose; the significance increasing with the dosage. Compared with placebo, the NUTRIOSE groups ate significantly fewer energy at subsequent meals with intergroup differences noted as early as 2 weeks for the 14 g, 18 g, and 24 g groups up to a reduction of 1588 kJ. As a consequence, mean values for body weight, BMI, and body fat declined steadily for all fiber groups from baseline throughout the study. For example, declines in body weight between baseline and week 9 were 0.12 ± 0.16 kg for the 8 g group, 0.42 ± 0.18 kg for the 14 g group, 0.62 ± 0.16 kg for the 18 g group, and 1.06 ± 0.18 kg for the 24 g group.

Dietary fiber is an essential constituent of a healthy diet and is well known for its high satiety impact [4]. NUTRIOSE is a nonviscous soluble fiber made from starch using a highly controlled process of dextrinization. It is mostly resistant to digestion in the small intestine and largely fermented in the colon [27]. A process of dextrinization includes a degree of hydrolysis followed by repolymerization that converts the starch into fiber by forming nondigestible glycosidic bonds. NUTRIOSE is totally soluble in cold water without inducing viscosity [27].

Recently, a report by Bodinhan et al [8] found that a nonviscous resistant starch significantly lowered energy intake after intake of the supplement compared with placebo during both an ad libitum test meal ($P = .033$) and over 24 hours ($P = .044$). Cani et al [28] found that treatment with the fermentable dietary fiber oligofructose increased satiety after breakfast and dinner and reduced hunger and prospective food consumption after dinner, suggesting a role for the use oligofructose supplements in the management of food intake in overweight and obese patients.

Pereira and Ludwig [14] summarized physiologic mechanisms by which dietary fiber affects satiety and body weight regulation. Three main factors—intrinsic, hormonal, and colonic effects of dietary fiber—decrease food intake by promoting satiation and/or satiety. Although many dietary fibers promote satiety and decrease food intake, not all are equivalent in their effect because of extreme variance in viscosity, solubility in the gut, fermentation profiles, and hormonal responses [3].

Soluble and fermentable fiber (eg, psyllium, pectin, alginate, guar gum, and barley fibers) represents a diverse class of hydrocolloids that appear to enhance satiety through gastric thickening that subsequently delays emptying [29,30]. Conversely, insoluble fibers with low viscosities (eg, soy and oat hull) show no effect on satiety [18,20,21]. Some soluble fibers with low viscosity, such as oligofructose and NUTRIOSE, may induce satiety effects through hormonal and colonic effects [28]. The modulation of the microbial ratios in the gut flora composition may partly explain this result [31]. Moreover, the prolonged production of short-chain fatty acids all along the colon may provide long lasting energy and delay the return of hunger. It is also in line with more recent results showing that the butyrate might be involved in inducing the production of some gut peptides such as peptide tyrosine tyrosine and glucagonlike peptide 1, which play an important role in the control of energy homeostasis and are secreted in response to ingested nutrients [32]. Butyrate, in particular, but also other short-chain fatty acids, may therefore promote satiety, even if more human studies are needed to clearly understand the underlying mechanisms. For example, a postabsorptive satiety has been related to the fermentation and fermentation site of nonviscous fibers, such as inulin and oligofructose [28,33].

Evidence from 1-shot studies shows that low-glycemic foods or meals produce higher satiety than high-glycemic foods or meals and that glycemic responses of foods modulate satiety [34,35]. Babio et al [36] found that the intake of viscous fiber induces short-term satiety and

decreases postprandial glucose levels. In a recent study, Bodinham et al [8] found significantly lower postprandial insulin response ($P = .029$) and a higher ratio of C-peptide to insulin compared with placebo ($P = .059$) after intake of a nonviscous resistant starch. They also observed a lower postprandial insulin response that could be explained by an increase in hepatic insulin clearance. Similarly, Livesey and Tagami [37] found that a nonviscous soluble polysaccharide attenuated the glycemic response to carbohydrate foods.

NUTRIOSE induces slow glycemic and insulinemic responses. Donazzolo et al [38] found that NUTRIOSE intake led to a low glucose response of 25 and an insulin response of 13. Lefranc-Millot [27] found that when used in a fruit drink and consumed after dilution with water, syrups made with NUTRIOSE elicited a glucose response of only 10% of the equivalent product made with sugar. A clinical study dealing with the effects of NUTRIOSE on energy intake, body weight, hunger feeling, and biomarkers of the metabolic syndrome has shown that NUTRIOSE improves insulin resistance [39,40]. Such data suggest that the glycemic responses of NUTRIOSE may explain its satiety-enhancing effect. However, it is not clear whether it is glucose per se or other factors that are responsible for promoting satiety because insulin and satiety hormones covary with glucose [41].

The strengths of this study include its randomized, double-blind, placebo-controlled design, stratification by BMI and energy intake to reduce intragroup variance in baseline characteristics, and conduct in a highly controlled environment to supervise and manage supplement and food intake. A limitation of the clinical trial is implementation in a single-center manufacturing plant in China, which may limit the ability to generalize outcomes to the population at large. The population selected in this study lived in highly standardized environment. Second, it could be interesting to observe the effects of NUTRIOSE on satiety from baseline to the end of the anthropometric evaluation at week 9 to make a strong correlation between body weight decrease and satiety modulation. In addition, the dosage of glucose, insulin, and gut peptides would have been of a great interest to go deeper in the mechanism of action of NUTRIOSE. Yet this study can be considered as an exploratory study allowing the choice of an effective dosage. Larger prospective studies are needed to confirm our findings in other ethnic populations.

Our results indicate that supplementing a beverage with a nonviscous soluble dietary fiber in doses ranging from 8 to 24 g/d produces significant improvements in short-term satiety and hunger over time with time- and dose-responses relationship.

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