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Effects of a soluble dietary fiber supplementation with NUTRIOSE® on weight management

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Introduction

- **Overweight and obesity** are a growing health concern all over the world. In China, the prevalence of overweight in adult population is estimated at 23% based on WHO (World Health Organization) classification of Body Mass Index (BMI)[1]. According to the cut-off points recommended by The Working Group on Obesity in China[2] (WGOC: 24 ≤ BMI for overweight ≤ 28; BMI for obesity > 28), this prevalence is of 34%. According to a recent study[1], these cut-off values are positively associated with increased prevalence of a cluster of risk factors related to the *Metabolic Syndrome (MetS)*, including type 2 diabetes and dyslipidemia in adults.
- In a preventive approach, dietary factors, including **fiber supplementation**, are to be considered as modifiable risk factors. NUTRIOSE® soluble fiber is a resistant food dextrin with high fiber content (85% on dry substance) that exhibits high digestive tolerance both in short[3] and long-term uses[4], induces prebiotic effects[5][6] and may help controlling calorie intake[7].
- In this study, we investigated the effects of a medium-term consumption of **NUTRIOSE®** on some characteristics specifically linked to an increased risk of developing **Metabolic Syndrom** in male volunteers.

Material and Methods

Subjects

- 120 **healthy** Chinese male volunteers (20-35 y)
- **Overweighed** at the start of the study (baseline) according to WGOC[2]

Design

- 12-week double-blind, placebo controlled trial, 2 groups of 60 randomized in parallel
- comparisons between both groups, at baseline and throughout the study.

Methodology

- Consumption at the same moment, twice daily (10:00 am and 4:00 pm) of 250 ml fruit juice (similar taste and color in both groups) containing:
  - **NUTRIOSE®** group : 17 g NUTRIOSE® (= 34 g/day), equivalent of 14 g (26.4 g/day) dietary fiber
  - **PLACEBO** group : 17 g (= 34 g/day) standard maltodextrin
- comparisons of parameters within and between groups at baseline and at weeks 4, 8 and 12:
  - **Anthropometric measurements :**
    - body weight (BW in kg)
    - body mass index (BMI in kg/m²)
    - percentages of body fat (% BF) (bio-electrical impedance analysis or impedancemetry)
    - waist circumference (WC) measured in cm (values taken twice).
  - **Hunger feeling and dietary intakes :**
    - Hunger feeling (HF) by questionnaires
    - Energy Intake in kcal/day by Food Frequency Questionnaire (24-hour recall) and/or food record of dietary intakes

Results

ANTHROPOMETRIC MEASUREMENTS

Body weight

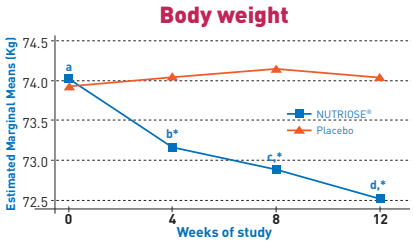


Figure 1: Estimated Marginal Means of Body Weight (kg) measurements for the NUTRIOSE® and placebo groups.

- The placebo group remained fairly stable throughout the study.
- In the NUTRIOSE® group, volunteers **had significant weight loss** from one month to the other starting from week 4 (p<0.0001).
- The difference between groups, not significant at baseline, was significant at weeks 4 (p=0.01), 8 (p<0.001) and 12 (p<0.001) when adjusted to disparities.
- *In the NUTRIOSE® group, 66.1% (n=37) of participants who completed the study **lost weight** (2.3 kg on average) for only 16.4% (n=9) in the PLACEBO group (0.4 kg on average).*

Body Mass Index

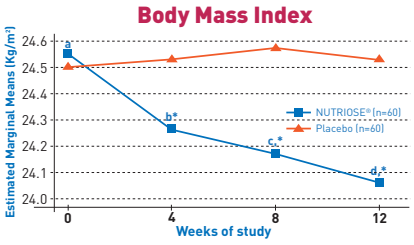


Figure 2: Estimated Marginal Means of Body Mass Index (kg/m²) in the NUTRIOSE® and placebo groups.

- The PLACEBO group had a relatively stable BMI throughout the study.
- Within the NUTRIOSE® group, volunteers had **a significant BMI's reduction** from one month to the other starting from week 4 (p<0.001), indicating a continued and additional effect of NUTRIOSE®.
- The difference between groups, even not significant at baseline, became significant at weeks 4 (p=0.02), 8 (p=0.01) and 12 (p=0.045).
- *Among the 66.1% of the NUTRIOSE® group who lost weight, all also lost an average of 0.75 BMI, attaining an average of 23.8 at the end of the trial.*

Waist circumference

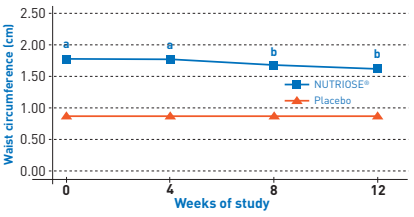


Figure 3: Estimated Marginal Means of Waist Circumference measurements for the NUTRIOSE® and placebo groups.

- The PLACEBO group had a relatively stable average WC throughout the study.
- In the NUTRIOSE® group, volunteers had a **noted decrease in WC** as compared to baseline mainly observed at weeks 8 and 12 (about 0.2 cm, p< 0.05).
- Nevertheless, the WC difference between groups was never significant.

➤ Different letters (a, b, c) indicate significant differences between weeks within the NUTRIOSE® group. Asterisks (*) show a significant reduction for the NUTRIOSE® group as compared to the placebo group for the same week.

Body Fat

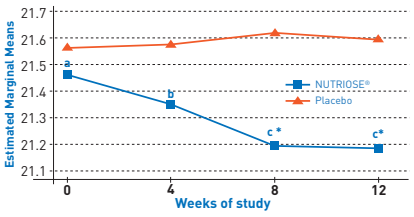


Figure 4: Estimated Marginal Means of Percent Body Fat measurements for the NUTRIOSE® and placebo groups.

- There was no change within the PLACEBO group.
- In the NUTRIOSE® group, the **%BF was significantly reduced** at weeks 4, 8 and 12 as compared to baseline (p<0.001) and at week 8 as compared to week 4 (p<0.0001). This decrease was leveled off at week 12, but sustained as compared to week 4 (p<0.05) and baseline (p< 0.005).
- % BF, not different between groups at baseline, differed significantly at weeks 8 (p=0.02) and 12 (p=0.045).
- *Only **5** participants in the PLACEBO group lost on average **0.5% BF** while **36** participants in the NUTRIOSE® group lost the same.*

QUESTIONNAIRES

Hunger feeling

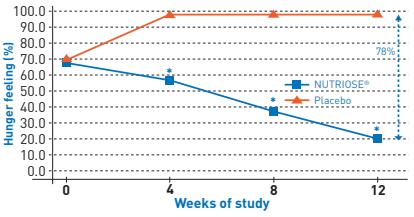
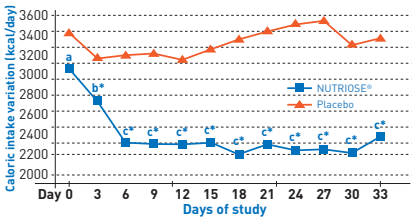


Figure 5 : % of volunteers who answer: "hungry", "very hungry" or "starving" in the NUTRIOSE® and placebo groups.

- In the PLACEBO group, 70% of the participants declared they were hungry at baseline versus 98 % at the end of the trial.
- In the NUTRIOSE® group, 68% of the participants reported they were hungry at baseline for only 20% at the end the study.
- The differences between groups, even not significant at baseline, were significant at weeks 4 (p < 0.01), 8 (p < 0.01) and 12 (p < 0.01),

Caloric intake



in kcal/day	NUTRIOSE	Placebo
Month 0	3063	3422
Month 1	2378	3368
Month 2	2295	3358
Month 3	2449	3538

Table 1: Caloric intake variation (in kcal/day) in the NUTRIOSE® and placebo groups.

Figure 6: Caloric intake variation (in kcal/day) over the first study period (weeks 0 to 4) in the NUTRIOSE® and placebo groups during the first study period.

- In the PLACEBO group, during the first study period (weeks 0 to 4), caloric intake slightly decreased (max reduction 7.5%) before going up again.
- In the NUTRIOSE® group, a sharp decrease in caloric intake was observed during the first week (24.4%) and this reduction was maintained over the weeks (max at day 18, p<0.001 on average) until the end of the study.
- There was no difference between groups at baseline, but the maximum difference during this first period between groups reached its maximum at week 4 (p = 0.001) and was still significant at weeks 8 (p = 0.001) and 12 (p = 0.002).
- *A growing difference (decrease) in **caloric intake** was only seen for the **NUTRIOSE®** group that exhibited a **reduction of about 22%** vs. **1.6%** for the **PLACEBO** group at the end of the study.*

Discussion

- **Significant decreases in BW (p<0.001), BMI (p<0.001), BF (p<0.001) and HF (p<0.001), associated with a decreased caloric intake (p<0. 001) were observed throughout the study in the NUTRIOSE® group, as well as a final significant reduction in WC (p<0.001), while no changes were observed in the placebo group.**
- NUTRIOSE® supplementation greatly **decreased HF** over the trial.
- The reduction in caloric intake in the NUTRIOSE® group might be partly explained by a decreased hunger feeling and further make understandable the noted decreases observed in BW, BMI and BF. Be that as it may, this study has shown that the metabolic syndrome status of the volunteers is largely improved with NUTRIOSE®.

Conclusion

- People who lost body fat also lost weight and Body Mass Index.
- Dietary intervention through NUTRIOSE® supplementation (17 g, twice daily) significantly modified hunger feeling and biological markers of Metabolic Syndrom, including body weight.
- This makes of NUTRIOSE® a promising tool for **fortification of diets in fibers**, but also for **weight management** and **chronic metabolic disorders** associated with **overweight**.

Bibliographic references

1. Tao T, Helga B, Roza A. Prevalence of overweight or obesity and obesity-related diseases in Qingdao region, China. *Journal of Chinese Clinical Medicine*, 2006; **1**(2) : 76-86.
2. Chen Y-M, Ho SC, Lam SSH, Chan SSG. Validity of body mass index and waist circumference in the classification of obesity as compared to percent body fat in Chinese middle-aged women. *Intenational Journal of Obesity*, 2006, **30** : 918-925.
3. van Den Heuvel EGHM, Wils D, Pasman WJ, Bakker M, Saniez MH, Kardinaal AFM. Short-term digestive tolerance of different doses of NUTRIOSE® FB, a food dextrin, in adult men. *European Journal of Clinical Nutrition*, 2004, **58** : 1046-1055.
4. Pasman W, Wils D, Saniez MH, Kardinaal A. Long-term gastrointestinal tolerance of NUTRIOSE® FB in healthy men. *European Journal of Clinical Nutrition*, 2006, **60** (8) : 1024-34 Epub 2006 Feb 15
5. Lefranc-Millot C, Wils D, Neut C, Saniez MH. Effects of a soluble fiber with excellent tolerance, NUTRIOSE® 06, on the gut ecosystem: a review. Dietary Fibre 2006, Helsinki, Finland, 12-14 June.
6. van den Heuvel EGHM, Wils D, Pasman WJ, Saniez MH and Kardinaal AF. Dietary supplementation of different doses of NUTRIOSE® FB, a fermentable dextrin, alters the activity of faecal enzymes in healthy men. *European Journal of Nutrition*, 2005, **44**: 445-451.
7. Vermorel M, Coudray YC, Wils D, Sinaud S, Tressol JC, Montaurier C, Vernet J, Brandolini M, Bouteloup-Demange C and Rayssiguier Y. Energy value of a low-digestible carbohydrate, NUTRIOSE® FB, and its impact on magnesium, calcium and zinc apparent absorption and retention in healthy young men. *European Journal of Nutrition*, 2004, **43**: 344-352.

SPRIM

Effects of a soluble dietary fiber supplementation with NUTRIOSE® on weight management.

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Introduction: Abdominal obesity is one key underlying risk factor of the Metabolic Syndrom (MS). The MS, and in particular overweight and hypertension, is widely influenced by dietary factors; and among them, supplementation with fiber. The impact of NUTRIOSE® a soluble dietary fiber, on some MS characteristics, was investigated in a clinical placebo controlled trial.

Methods: 120 overweight Chinese male volunteers were enrolled in two groups receiving in beverage either 17 g NUTRIOSE® or 17 g standard maltodextrin at the same time, twice daily, for 12 weeks. Comparisons of body weight (BW), body mass index (BMI), body fat (BF), waist circumference (WC), caloric intake (CI), hunger feeling (HF) and systolic blood pressure (SBP) between the two groups at baseline and throughout the study were analyzed.

Results: Significant decreases in BW ($p<0.001$), BMI ($p<0.001$), BF ($p<0.001$) and HF ($p<0.001$), associated with a decreased caloric intake ($p<0. 001$) were observed throughout the study in the NUTRIOSE® group, as well as a fi nal significant reduction in WC as measured by abdominal scans ($p<0.001$), while no changes were observed in the placebo group. There was no difference between groups for SBP.

Conclusion: Dietary intervention through NUTRIOSE® supplementation signifi cantly modified hunger feeling and biological markers of MS, including body weight. This makes of NUTRIOSE® a promising tool for diet fortifi cation with fibers, particularly in the context of weight management and chronic metabolic disorders associated with overweight.

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[1] Conflict of interest: None
[2] Funding: Research relating to this abstract was funded by Roquette (Lestrem, France)

Dose-response impact of a soluble prebiotic fiber, on satiety and weight management

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Introduction

The role of the diet in the prevention of obesity is widely acknowledged. Dietary carbohydrates may impact body fatness and affect the likelihood of passive over-consumption and long-term weight change[1]. In this context, fibre supplements seem to favour adherence to a low energy diet and hence weight loss. Some fibres may potentially play a role in hunger feeling, caloric intake, satiety and therefore food intake management. NUTRIOSE® has demonstrated strong effects on hunger feeling and weight management at a daily oral intake of 34g/day in a first clinical study. The aim of this second clinical trial was to investigate whether oral dietary supplementation with this resistant dextrin at **different dosages** was associated with a **positive impact on satiety-related and some anthropometric parameters**.

Material and Methods

Outcomes

- Primary: Impact on short-term satiety, food/caloric intakes, bodyweight
- Secondary: Impact on hunger feeling and other anthropometric parameters

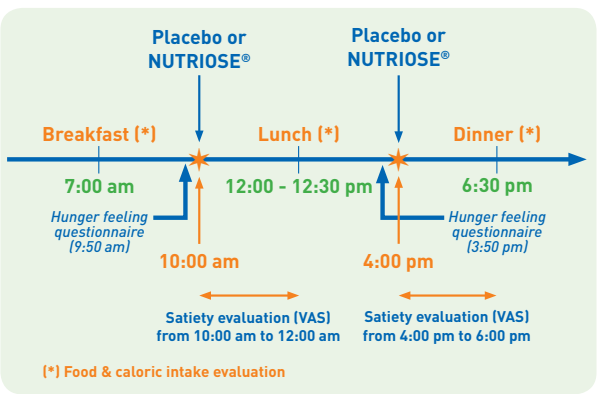
Design

- 9-week randomized, placebo-controlled, double blind, parallel, single center
- 5 groups of 20 overweight Chinese male and female (50/50) volunteers ($24 \leq BMI \leq 28$ kg/m²), factory workers eating each meal in the canteen (7d/7).
- Clinical measures:
  - **Satiety related parameters :**
    - → **satiety** *(from D-2 to D21)*: measured over 2 hours after product intakes through a standardized referenced visual analog scale (VAS-09)
    - → **hunger feeling** *(from D-2 to D21)*: 2 daily evaluations before NUTRIOSE® intakes ("How hungry do you feel?")
    - → **food/caloric intake** *(daily)*: individually assessed through a pre-calculated menu and a Daily Food Record at every meal from day -2 to day 63.
  - **Anthropometric parameters:** bodyweight, BMI, body fat, waist circumference *(weekly from D-2 to D63)*

Products

- Placebo group : orange juice → 2 daily intakes of 250 ml (a)
- Treatment groups : NUTRIOSE® in orange juice → **2** daily intakes of 250 ml containing either **4g** (b), **7g** (c), **9g** (d), **12g** (e) of NUTRIOSE®, namely **8**, **14**, **18** or **24** g of NUTRIOSE®/day

Daily schedule

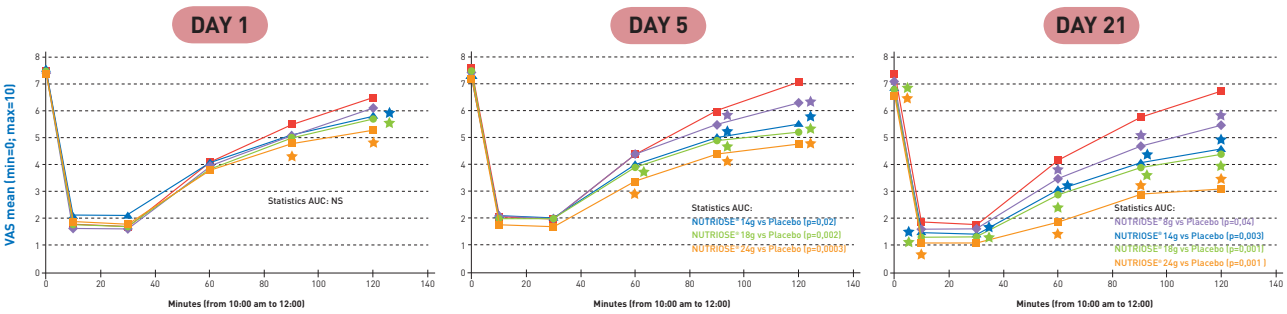


Results

Satiety evaluation

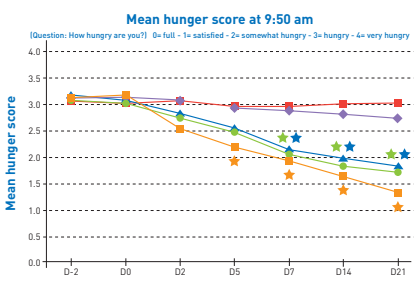
"How hungry do you feel?"
VAS evaluation in the morning

DAY 1 DAY 5 DAY 21

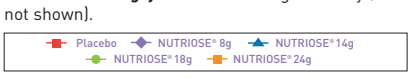


During the study, NUTRIOSE® exhibits a progressive and significant impact on short-term **satiety** (see figures 1, 2 and 3). This effect is **time correlated**, the impact on satiety becoming visible earlier while progressing in the trial and increasing in value from day 0 to day 21. Be that as it may, some statistical differences appear for the 8g/d group from Day 5. Moreover, this effect is also **correlated to the ingested dose**, the significance increasing with the dosage.

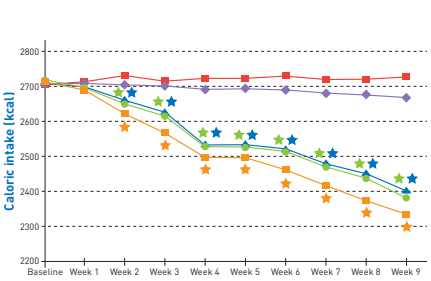
Hunger evaluation



The **hunger feeling status decreases** over the study; this decrease is significant from Day 5 to the end of the evaluation for the group 24g and from Day 7 for the groups 14g and 18g. The **number of volunteers who are not hungry** increases during the study (data not shown).

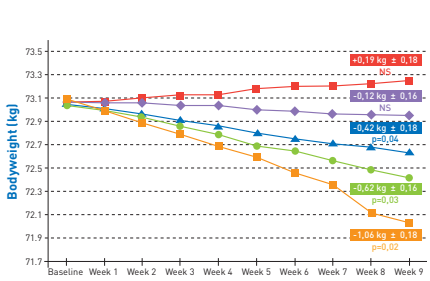


Total caloric intake per day



There is a **significant decrease** in **caloric intake** (and in food intake - data not shown) correlated with the decrease in hunger, from week 2 to the end of the study for the groups 14g, 18g and 24g of NUTRIOSE® and at week 9 for the group 8g of NUTRIOSE® .

Body weight



As a consequence, NUTRIOSE® intake induces a strong and prolonged **impact on weight management**. The **decrease** observed from baseline to the end is significant for the groups 14g, 18g and 24g/day. In the meantime **BMI, body fat and waist circumference** display significant decreases (not shown) for these 3 groups. For each of the tested parameters, the results are also **dose-correlated**.

Discussion - Conclusion

- NUTRIOSE®, a non viscous soluble fibre, has previously demonstrated a positive impact on weight management in a 12-week dietary intervention in 120 healthy overweight Chinese men at a daily dosage of 34 g. In this second study, NUTRIOSE® displays significant time- and dose-related effects on **short-term satiety** (from day 5 at 8 g/day), **hunger feeling** (from day 5 at 24 g and day 7 at 14g/day), **food and caloric intakes** (from day 21 at 14 g/day).
- Several hypotheses may be formulated. The modulation of the microbial ratios in the gut flora composition may firstly enlighten these results (2;3). Moreover, the slow and prolonged production of short chain fatty acids (SCFAs) along the colon may provide long lasting energy and delay or reduce hunger feeling. Finally, due to its fermentation pattern described *in vitro* as long-lasting and producing high propionate concentrations from 8 to 24 hours (4), it is also in line with some described role of SCFAs, such as:
  - butyrate may promote satiety (5) and have a direct effect on afferent terminals in rats (6);
  - the pattern of fermentation, mostly the ratio of acetate to propionate reaching the liver, is a putative intermediate marker possibly predicting the potential lipid lowering properties of non digestible carbohydrates;
  - the classical deleterious role attributed to acetate as a precursor of lipogenesis might be modulated (7).
- Finally, the results of this second study bring additional evidence to the fact that **NUTRIOSE® may be a useful tool in the modulation of satiety** from 8-14g/day, and in **weight management** from 14g/day.

Bibliography

1. van Dam RM & Seidell JC (2007) Carbohydrate intake and obesity. *Eur J Clin Nutr* **61 Suppl 1**, S75-S99.
2. Ley RE, Backhed F, Turnbaugh P, Lozupone CA, Knight RD & Gordon JI (2005) Obesity alters gut microbial ecology. *Proc Natl Acad Sci U S A* **102**, 11070-11075.
3. Ley RE, Turnbaugh PJ, Klein S & Gordon JI (2006) Microbial ecology: human gut microbes associated with obesity. *Nature* **444**, 1022-1023.
4. Stewart ML, Rushton A, Paredes-Diaz A, Savarino V and Slavin JL (2007) Wheat Dextrin (WD), Inulin, and Partially Hydrolyzed Guar Gum (PHGG) Produce Unique Short-Chain Fatty Acid Concentration in Model Colonic Fermentation. *Gastroenterology*, **132** (4 Suppl. 2): A-585.
5. Hamer HM, Jonkers D, Venema K, Vanhoutvin S, Troost FJ & Brummer RJ (2008) Review article: the role of butyrate on colonic function. *Aliment Pharmacol Ther* **27**, 104-119.
6. Lal S, Kirkup AJ, Brunsden AM, Thompson DG & Grundy D (2001) Vagal afferent responses to fatty acids of different chain length in the rat. *Am J Physiol Gastrointest Liver Physiol* **281**, G907-G915.
7. Delzenne NM, Cani PD & Neyrinck A (2008) Prebiotics and Lipid Metabolism. *In Therapeutic Microbiology: Probiotics and Related Strategies,* pp. 183-192 [Versalovic J. and Wilson M, editors]. Washington, DC: ASM Press.

Dose response evaluation of the effects of NUTRIOSE® on satiety and weight management

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Introduction: resistant dextrin, NUTRIOSE® (Roquette, France), has previously shown positive impacts on hunger feeling and weight management at a daily dosage of 34g/day orally. In this second study, we investigated whether NUTRIOSE® could have a dose-related positive impact on some satiety-related and anthropometric parameters.

Methods: In a randomized, placebo-controlled, double blind, parallel, single-center trial, 5 groups of 20 Chinese adult volunteers (24BMI28 kg/m^2) ingested orange juice twice daily for 9 weeks either alone (Placebo) or supplemented with NUTRIOSE® at different dosages (8g/d,14g/d, 18g/d, 24g/d). Satiety (satiety and hunger feeling, food and caloric intakes) and anthropometric parameters (bodyweight, BMI, body fat, waist circumference) were followed.

Results: A significant impact of NUTRIOSE® on satiety was observed over the study, appearing from day 5 for the group 8g/d. The hunger feeling status decreased over the study, becoming significantly different from the Placebo group from day 5 for the group 24g/d and from day 7 for the groups 14 and 18g/d. Correlated with this, a significant decrease of the food and caloric intakes was observed as soon as from week 2 to the end of the study for many groups. Consecutive significant, dose-correlated decreases in body weight, BMI, body fat and waist circumference were observed from baseline until the end, significant for the groups 14g, 18g and 24g/d.

Conclusion: NUTRIOSE® is therefore effective in the modulation of satiety from 8-14g/d, and in weight management from 14g/d. As a soluble fiber, it may be a useful tool in the context of epidemic obesity.

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