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Addition of oat bran reduces HDL-C and does not potentialize effect of a low-calorie diet on remission of metabolic syndrome: A pragmatic, randomized, controlled, open-label nutritional trial

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ABSTRACT

Objectives: It is unclear whether addition of soluble fiber to a low-calorie diet potentializes weight loss and amelioration of metabolic syndrome (MetS). The aim of this study was to analyze the effects of oat bran on prevalence of MetS and associated disorders.
Methods: A pragmatic, randomized controlled, 6-wk nutritional trial was carried out with 154 outpatients (mean age 47.6 ± 12.6 y of age). The intervention group (n = 83) received a low-calorie diet plus 40 g/d of oat bran; the control group (n = 71) received a low-calorie diet only. MetS parameters and prevalence were calculated and compared (using two-tailed statistical tests) before and after follow-up.
Results: After follow-up, a significant but similar reduction was observed in MetS prevalence (40% reduction, 63% and 64.8% prevalence in intervention and control groups, respectively; $P = 0.226$), body mass index, body weight, waist circumference, systolic and diastolic blood pressures, triacylglycerides, and blood glucose levels in both groups ($P < 0.05$). Mean high-density lipoprotein cholesterol (HDL-C) was reduced in the intervention group (43.6 ± 9.6 to 41.2 ± 9.5 mg/dL; $P = 0.025$), but not in the control group (44.6 ± 10.5 to 44.5 ± 12.1 mg/dL; $P = 0.890$). There was no significant difference in any of the variables between the groups, although the *P*-value for HDL-C was almost significant ($P = 0.078$). Calorie and dietetic fiber intake during the 6-wk period were similar in both groups.
Conclusions: Daily consumption of oat bran did not potentialize the beneficial effects of a traditional low-calorie diet on the prevalence of MetS and associated disorders. Additionally, it reduced HDL-C.

Introduction

Metabolic syndrome (MetS) is a complex disorder that encompasses a set of cardiovascular risk factors related to visceral fat and signifies an increased likelihood of death. MetS components include visceral fat, high blood pressure (BP), low levels of high-density lipoprotein cholesterol (HDL-C), and high levels of triacylglycerides (TGs) and glucose [1].

Two major definitions of MetS have been proposed. One focuses on the accumulation of risk factors, as per the American Heart Association (AHA) and the National Heart, Lung, and Blood Institute (NHLBI); the other focuses on abdominal obesity, as per the International Diabetes Federation (IDF) and the Japanese government. The latter definition takes waist circumference (WC) into consideration as an obligatory component, whereas the former does not use this parameter. In 2009, the IDF, NHLBI, AHA, and other organizations attempted to unify these criteria; as a result, WC is no longer an obligatory component of those systems [2].

Obesity and insulin resistance are two important conditions that put an individual at higher risk for developing MetS, type 2 diabetes, and cardiovascular disease [3]. Because of the association of MetS with excess body weight, the nutritional treatment suggested involves a low-calorie diet to reduce abdominal and total body weight and to ameliorate metabolic disorders. These recommendations have been derived from consensus, based on

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observational studies that have analyzed only the metabolic components [4,5]. It is important to emphasize that observational studies lack evidences for a causal relation when compared with clinical trials.

In a systematic review [6], 15 nutritional trials were found to have analyzed MetS remission as the main outcome. Nutritional strategies were based on hypocaloric or normocaloric proposals with or without physical exercises. Monounsaturated fatty acid sources [7], nonfat dairy products [8], whole cereals [9], soy-based meal replacements [10], or changed macronutrient percentages of the diet have been used for hypocaloric proposals [11,12].

Recently, an Italian study [13] demonstrated improved body composition and metabolic parameters in obese patients with MetS, in a 10-wk trial with probiotic and prebiotic yogurt (when compared with plain low-fat yogurt). However, owing to methodological heterogeneity of the nutritional trials and the recommendations of the First Brazilian Guideline on Diagnosis and Treatment of Metabolic Syndrome [4], further research is needed to elucidate the causal relation between food and MetS.

In literature, several types of foods have been attributed with specific health benefits including potentializing the effect of a low-calorie diet in MetS treatment [7,8]. Among the types of foods offered in Brazilian markets and worldwide, oats (*Avena sativa L.*) have received considerable attention for their high dietary fiber content, phytochemicals, and nutritional value. It is believed that oats possess hypocholesterolemic and anticancer properties [14]. Oats also have recently been considered suitable for celiac patients. This cereal is considered to be a nutraceutical owing to a high content of soluble fiber (oat bran) [15]. The FDA has accepted a health claim stating that a daily intake of 3 g of soluble oat β-glucan can lower the risk for coronary heart disease [16].

Clinical trials using oat bran have revealed positive results for MetS components such as reduction of blood glucose [17], TG levels [18], and high BP [19]. However, oat bran has not been studied in individuals diagnosed with MetS. In addition, a trend of using high quantities of specific foods to improve health instead of consuming fruits and vegetables *in natura* (as sources of fiber), has been observed in the general population. This behavior may lead to some undesirable effects such as mineral malabsorption and HDL reduction.

So, the aim of the present study was to analyze the effectiveness of addition of oat bran to a low-calorie diet on MetS remission and its components.

Materials and methods

Design and participants

A pragmatic, randomized, controlled, open-label, 6-wk nutritional trial was carried out with 154 outpatients at a public hospital in Rio de Janeiro, Brazil. Individuals ≥18 y of age, fulfilling MetS criteria in accordance with the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III 2001) [20], who consented formally to join the study, were invited to participate. Those who had thyroid abnormalities, hepatic or renal failure, were being treated with corticoid or hypolipemiant drugs, or were on a low-calorie diet for the previous 3 mo were excluded from the study.

Sample size

The primary outcome (MetS) was dichotomous, and participants were included in the two independent groups in a randomized way considering a reliability of 95%, study power of 80%, and pilot study MetS prevalences found in control group (50%) and intervention group (30%). By substituting this information according to the equation suggested by Friedman [21], we calculated that 190 individuals were needed. However, after 4 y of patient recruitment, 223 individuals were obtained, 154 met the study criteria, and after 12 losses, the trial was performed with 142 patients. Eighty-three patients received a low-calorie diet plus 40 g/d of oat bran. The remaining 71 were assigned to the control group and received the low-calorie diet alone.

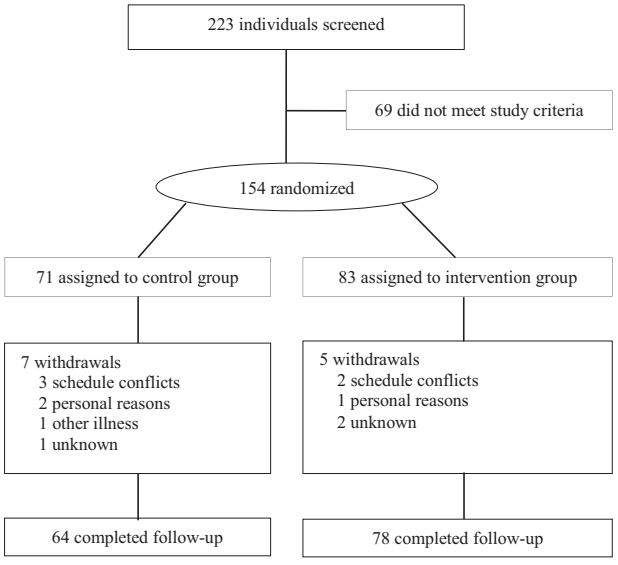

Fig. 1. Participant flowchart.

Screening and enrollment

The study enrollment was completed in 4 y (2007–2011). As seen in Figure 1, a total of 223 individuals responded to the recruitment effort and 154 eligible individuals were randomly assigned to a 6-wk protocol. Twelve participants discontinued the study. The patients' allocation in both groups was done weekly by the hospital dietitian, according to the scheduled outpatient agenda.

Dietary interventions

The participants were randomly assigned to either a low-calorie diet (control) group or to a low-calorie diet plus oat bran (intervention) group. The low-calorie diet was formulated as per The First Brazilian Guideline on Diagnosis and Treatment of Metabolic Syndrome [4]. Participants in the intervention group also received 40 g/d of oat bran (3 g β-glucan). All participants were responsible for purchasing and preparing their own food.

Nutrition counseling

At randomization, all participants received 45 min of individual dietary instruction from a registered dietitian and were given an individually calculated diet plan to achieve a 1-pound weight loss each week, and a booklet with a food diary; structured menus that provided meal choices and recipes were also distributed. During the 6-wk study, participants were scheduled for six 30-min visits with the dietitian for additional dietary counseling.

Intervention adherence

Participants were instructed to keep a daily food diary, which was reviewed weekly during the study visits. Dietary data were obtained for 7 d of the 42 food diary d during the 6 wk of the study. Nutrient data were analyzed using the Brazilian Table of Food Composition (TACO) [22].

Outcomes

The primary outcome was MetS remission at the end of the study. In addition, we collected data on BP (measured with a manual sphygmomanometer after a 5-min rest period) and lipids (measured from serum samples collected after an overnight fast). Body weight was measured with participants in light clothing and bare feet, using a digital scale accurate to the nearest 0.1 kg. Height was measured without shoes to the nearest 0.5 cm. Body mass index (BMI) was calculated as the weight (kg) divided by the square of the height (m) [23]. WC was measured with a non-stretchable tape measure in the standing position after a normal expiration at the level midway between the caudal part of the lateral costal arch and the iliac crest [4,24]. Plasma glucose and TGs were measured by enzymatic immunoassay. HDL-C was isolated by centrifugation and precipitation with a sodium

Table 1
Baseline characteristics of participants

	Control group	Intervention group	*P*-value*
n	71	83	
Age (y)	47.6 ± 12.4	47.6 ± 12.6	0.993
Body weight (kg)	89.1 ± 17.6	90.5 ± 19.2	0.653
BMI (kg/m^2)	33.9 ± 5.2	35 ± 5.9	0.255
Waist circumference (cm)	106.4 ± 12.1	107.1 ± 11.7	0.718
Systolic blood pressure (mm Hg)	135.1 ± 17.6	135.7 ± 16.4	0.832
Diastolic blood pressure (mm Hg)	87.3 ± 13.5	88.8 ± 12.6	0.472
Triacylglycerides (mg/dL)	225.3 ± 159.9	209.9 ± 126.1	0.480
HDL-C (mg/dL)	44.4 ± 10.3	43.5 ± 9.7	0.571
Plasma glucose (mg/dL)	124.7 ± 52.1	118.6 ± 49.1	0.401

BMI, body mass index; HDL-C, high-density lipoprotein cholesterol.
Data are means ± SD.
*t test.

Table 2
Prevalences of metabolic syndrome and isolated metabolic alterations between groups before and after follow-up

	Control group (n = 71) Before	After	Intervention group (n = 83) Before	After	*P*-value* Before	After
Metabolic syndrome (%)	64	100	78	100	0.815	
Central obesity (%)	93	79.7	89.2	82.9	0.413	0.627
Hyperglycemia (%)	42.3	23.4	38.6	23.4	0.641	0.993
Hypertension (%)	87.3	54.7	84.3	51.9	0.598	0.746
Hypertriglyceridemia (%)	74.6	46.9	71.1	48.1	0.621	0.889
Low HDL cholesterol (%)	74.6	69.4	66.3	64.9	0.257	0.582

HDL, high-density lipoprotein.
*t test.

phosphotungstate and magnesium chloride solution. All laboratory analyses were made in the pathology laboratory at the hospital.

Statistical analysis

All statistical analyses were performed using SPSS version 21 (SPSS, Chicago, IL, USA). The unpaired Student's t test was used to compare baseline and 6-wk variables among the two groups. Data not normally distributed, as determined using the Kolmogorov–Smirnov test, were logarithmically transformed to obtain near normality before analysis. Values were reported as means and SD. The χ^2 test was used to compare the incidences of MetS and its components before and after follow-up. MetS prevalence was estimated after the trial. The paired Student's t test was used to analyze variables within groups. All statistical tests were two-tailed with a significance level of 0.05.

Ethics statement

The study was approved by the Ethics Committee of the University Hospital of Rio de Janeiro. The clinical trial was registered on the Registro Brasileiro de Ensaios Clínicos. All participants gave written informed consent.

Results

At baseline, participants (women: 71.8% and 74.7% in intervention and control groups, respectively) were similar in demographic and anthropometric characteristics, BP, serum glucose, and lipids (Table 1). Data collection was complete for 95.2% and 90.1% of intervention and control groups respectively ($P = 0.226$).

At the end of the study, a 40% remission on MetS prevalence was observed in both groups (prevalence of 63% for intervention and 64.8% for control group). Prevalence of the metabolic components was also similar between dietary groups at baseline, and changes in these parameters were comparable between groups over the 6-wk period. High BP was reduced by 39.4% and 44.3% in the intervention and control groups, respectively; prevalence of low levels of HDL-C reduced by 2.1% and 6.9% in the intervention and control groups, respectively, over the study period (Table 2).

Intragroup analysis revealed a significant reduction in BMI, body weight, WC, systolic and diastolic blood pressures, TGs, and glucose means after follow-up in both groups ($P < 0.05$). Mean HDL-C was reduced in the intervention group (43.6 [9.6] to 41.2 [9.5] mg/dL; $P = 0.025$), but not in the control group (44.6 ± 10.5 to 44.5 ± 12.1 mg/dL; $P = 0.890$). Intergroup analysis showed that there were no significant differences in any of the variables between the two groups (Table 3).

Based on food diary analysis, nutrients consumed over the 6-wk period were compared between groups. Calorie and lipid consumption was significantly reduced, and carbohydrate and protein consumption was improved over the 6-wk period in both the groups. An increased intake of vitamins A and C, as well as magnesium, calcium, and potassium was observed in both the groups (Table 4).

Discussion

The results of this study show that in 154 middle-aged men and women with MetS, the addition of 40 g/d of oat bran (3 g β-glucan) did not significantly affect the prevalence of MetS. However, significant HDL reduction occurred in the intervention group.

Table 3
Intra- and inter-group analyses of anthropometric, clinical, and biochemical outcomes

	Control Before (n = 71)	Control After (n = 64)	*P*-value*	Intervention Before (n = 83)	Intervention After (n = 78)	*P*-value*	Control Δ (n = 64)	Intervention Δ (n = 78)	*P*-value†
WC (cm)	106.7 ± 12.4	102.4 ± 1.9	<0.001	108.1 ± 11.4	103.1 ± 10.9	<0.001	−4.25	−4.8	0.507
SBP (mm Hg)	136.2 ± 18.1	124.1 ± 13.7	<0.001	135.4 ± 16.9	124.6 ± 17.1	<0.001	−12.1	−10.8	0.675
DBP (mm Hg)	87.6 ± 14	80.7 ± 10.5	0.002	89.1 ± 12.6	80.8 ± 11.4	<0.001	−6.9	−8.2	0.606
TG‡ (mg/dL)	208.9 ± 105.6	172.5 ± 92.9	<0.001	208.1 ± 126.6	170.9 ± 107.1	<0.001	−36.4	−37.1	0.948
HDL	44.6 ± 10.5	44.5 ± 12.1	0.890	43.6 ± 9.6	41.2 ± 9.5	0.025	−0.1	−2.3	0.122
GLU‡ (mg/dL)	123.2 ± 52.3	105 ± 30.6	<0.001	115.7 ± 44.5	103.1 ± 34.3	<0.001	−18.1	−12.4	0.231
BW (kg)	89.7 ± 17.9	86.3 ± 17.2	<0.001	91.5 ± 19.1	88.1 ± 18.5	<0.001	−3.4	−3.3	0.862
BMI (kg/m^2)	34.2 ± 5.4	32.9 ± 5.4	<0.001	35.2 ± 5.9	33.9 ± 5.8	<0.001	−1.3	−1.3	0.922

BMI, body mass index; BW, body weight; DBP, diastolic blood pressure; GLU, plasma glucose; HDL, high-density lipoprotein; SBP, systolic blood pressure; TG, triacylglycerides; WC, waist circumference.
*Paired t test.
†Unpaired t test.
‡Logarithmically transformed.

Table 4
Intra- and intergroup analyses for macro- and micronutrients consumed before the trial by 24-h recall (baseline) and during the 6-wk intervention by food diary (post-trial)

	Intragroup analyses						Intergroup analyses					
	Control baseline (n = 71)	Control post (n = 64)	*P*-value*	Intervention baseline (n = 83)	Intervention post (n = 78)	*P*-value*	Control baseline (n = 71)	Intervention baseline (n = 83)	*P*-value*	Control post (n = 64)	Intervention post (n = 78)	*P*-value*
Cal (kcal)	2183.1 ± 946.2	1426.2 ± 478.4	<0.001	1769.7 ± 1029.7	1509.3 ± 429.1	0.003	2183.1 ± 946.2	1769.7 ± 1029.7	0.092	1426.2 ± 478.4	1509.3 ± 429.1	0.037
Fib (g)	16.1 ± 11.3	16.8 ± 9	0.722	10.3 ± 5.1	20.2 ± 7.6	<0.001	16.1 ± 11.3	10.3 ± 5.1	0.004	16.8 ± 9	20.2 ± 7.6	<0.001
Ptn (%)	18.8 ± 5.3	24.4 ± 6.6	<0.001	21 ± 10.2	24.8 ± 7.1	0.002	18.8 ± 5.3	21 ± 10.2	0.293	24.4 ± 6.6	24.8 ± 7.1	0.488
Ch (%)	49.2 ± 8.9	51.7 ± 9.5	0.178	49.7 ± 13.5	51.4 ± 8.5	0.255	49.2 ± 8.9	49.7 ± 13.5	0.855	51.7 ± 9.5	51.4 ± 8.5	0.741
Lip (%)	32 ± 8.7	23.8 ± 7.4	<0.001	29.3 ± 9.3	23.7 ± 6.8	<0.001	32 ± 8.7	29.3 ± 9.3	0.219	23.8 ± 7.4	23.7 ± 6.8	0.794
Vit A (RE)	439.9 ± 353.2	1141.3 ± 2339.1	<0.001	596.7 ± 662.2	1255.6 ± 1789.2	0.002	439.9 ± 353.2	596.7 ± 662.2	0.249	1141.3 ± 2339.1	1255.6 ± 1789.2	0.523
Vit C (mg)	68.6 ± 116.8	126.7 ± 128.5	0.022	76.8 ± 130.0	120.1 ± 140.6	0.052	68.6 ± 116.8	76.8 ± 130	0.786	126.7 ± 128.5	120.1 ± 140.6	0.581
Vit E (mg)	11.6 ± 10.9	6.4 ± 4.4	<0.001	11.2 ± 9.9	7.6 ± 4.9	0.031	11.6 ± 10.9	11.2 ± 9.9	0.876	6.4 ± 4.4	7.6 ± 4.9	0.005
Vit B_{12} (mcg)	4.2 ± 5.7	4.5 ± 16.3	0.923	4.4 ± 9.6	4.6 ± 12.9	0.909	4.2 ± 5.7	4.4 ± 9.6	0.954	4.5 ± 16.3	4.6 ± 12.9	0.962
Iron (mg)	15.2 ± 8.9	10.8 ± 6.4	<0.001	11.8 ± 8.2	12.4 ± 5.7	0.564	15.2 ± 8.9	11.8 ± 8.2	0.107	10.8 ± 6.4	12.4 ± 5.7	0.003
Mg (mg)	162.9 ± 85.4	202.4 ± 83.4	0.018	145.3 ± 65.7	205.3 ± 75.8	<0.001	162.9 ± 85.4	145.3 ± 65.7	0.331	202.4 ± 83.4	205.3 ± 75.8	0.684
Ca (mg)	527.9 ± 376.5	633.5 ± 262.8	0.058	483.3 ± 409.7	660.5 ± 362.7	0.004	527.9 ± 376.5	483.3 ± 409.7	0.642	633.5 ± 262.8	660.5 ± 362.7	0.353
Na (mg)	2167.2 ± 1255.5	1599.7 ± 857.1	0.002	1956.3 ± 1399.3	1399.2 ± 855.7	0.079	2167.2 ± 1255.5	1956.3 ± 1399.3	0.519	1599.7 ± 857.1	1399.2 ± 855.7	0.260
K (mg)	1579 ± 781.1	2347 ± 974.4	<0.001	1488.9 ± 648.4	2522.5 ± 860.5	<0.001	1579 ± 781.1	1488.9 ± 648.4	0.601	2347 ± 974.4	2522.5 ± 860.5	0.030

Ca, calcium; Cal, calories; Ch, carbohydrate; Fib, fiber; K, potassium; Lip, lipids; Mg, magnesium; Na, sodium; Ptn, protein; RE, retinol equivalente; Vit, vitamin.
Data are means ± SD.
*Independent samples *t* test.

Several nutritional trials have reported the advantages of oat bran addition for the treatment of MetS-associated conditions such as hypertension [17–19] and hyperglycemia [25,26]. However, in this study, dietary addition of this soluble fiber for individuals with MetS did not significantly affect the main outcome. The MetS remission of 40% and reduction of visceral fat, hypertension, TGs, and glucose was similar for both groups.

A possible explanation could be that the efficacy of caloric reduction was high for both groups, which resulted in BMI reduction (3.8% and 3.7% for control and intervention groups, respectively), so that the addition of oat bran may not have increased the benefits.

Similar results were observed by Case et al. [27] who described moderate weight reduction (7%) and substantial reductions in BP, plasma glucose, and TGs in patients with MetS on a low-calorie diet only, after a 4-wk period. It is known that dietary fiber influences satiation and satiety [28], but our results reinforce the idea that caloric reduction should be efficient for the treatment of patients with MetS.

A systematic review [6] of nutritional trials in patients with MetS suggested that the best results were observed in studies that offered low-calorie diets associated or not with physical activity. Katcher et al. [9] compared a whole-cereal diet with a refined-cereal diet and observed no significant differences in outcomes associated with the two diets. The authors attributed these results to weight reduction, derived from an equivalent low-caloric consumption after a 3-mo follow-up. Melanson et al. [29] reported similar weight reduction (5.6 and 6.2 kg for intervention and control groups respectively, with no statistical differences) in overweight adults after a 6-mo program offering a low-calorie diet with and without whole cereals. These studies [9,29] corroborate the results of the present study. Taken together, these evidences highlight the global significance of a healthy diet as a component of a healthy lifestyle; healthy diet and lifestyle have been recommended by organizations such as the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI), and the North American Association for the Study of Obesity (NAASO) for the prevention of cardiovascular diseases [24].

The present study has shown that adding 40 g oat bran may have resulted in undesirable HDL reduction. In contrast, Whitehead et al. [30], in a meta-analysis of randomized controlled trials with 2 to 12 wk of duration of treatment, found that adding ≥3 g β-glucan to the diet reduced low-density lipoprotein and total cholesterol, without changing HDL-C or TGs.

The decrease in HDL levels in the present study was unexpected, but it was similar to the effect on HDL reported from a 3-mo randomized controlled dietary intervention trial [31]. In this trial, the effects of β-glucan from oat bran incorporated in an energy-restricted meal plan were analyzed; the results show that for all the participants, HDL levels decreased significantly over time ($P < 0.001$). These evidences suggest the existence of a synergy between fiber and a low-calorie diet on HDL reduction. However, there are a number of confounding variables in the present study that warrant consideration.

First, this study was designed as a randomized trial but was not blinded because of the nature of the nutritional approach. This fact is likely to have led to spurious causality and bias. Second, the current trial was only of a 6-wk duration, and a 6-wk intervention may not be long enough to overcome the effects of variations in compliance on outcomes.

And finally, several participants withdrew at the end of the study so that the study sample size was smaller than the calculated; this may have limited the power of the study and affected the ability to detect the differences between groups.

Nevertheless, we can highlight the strengths of the study. To our knowledge, this is the only nutritional trial to analyze the effect of oat bran on MetS parameters as the main outcome, in outpatients with MetS. Both groups received the same guidelines for the low-calorie diet, and the only difference was the consumption of oat bran in the intervention group. Therefore, we were able to more accurately analyze the effect of addition of oat bran on MetS. Finally, this 6-wk study showed results that were consistent with the results of longer nutritional trials [9,11,12] that did not find differences between groups with a similar basic diet.

Conclusions

The present study showed that both the control and the intervention group experienced a similar improvement in measures such as MetS criteria, WC, systolic and diastolic blood pressure, TGs, plasma glucose, and overall weight loss; a reduction of HDL-C was observed only in the intervention group. The results of this study have shown evidence that the addition of 40 g of oat bran did not potentiate the benefits of a low-calorie diet only, and additionally reduced HDL-C levels. Despite the presence of confounding variables, we can conclude that individualized low-calorie diet promoting a modest weight reduction was enough to attenuate MetS-associated disorders and reduce cardiovascular risk in MetS outpatients. Further longitudinal studies are needed to confirm the efficacy of oat bran in MetS outpatients.

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