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(54) Title: OLIGOSACCHARIDES COMPOSITION FOR PREVENTING OR REDUCING THE RISK OF METABOLIC SYNDROME

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The present invention relates to the use of a galactooligosaccharide composition for preventing or reducing the risk of developing metabolic syndrome.

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(54) **Title**: OLIGOSACCHARIDES COMPOSITION FOR PREVENTING OR REDUCING THE RISK OF METABOLIC SYNDROME

(57) **Abstract**: The present invention relates to the use of a galactooligosaccharide composition for preventing or reducing the risk of developing metabolic syndrome.

OLIGOSACCHARIDES COMPOSITION FOR PREVENTING OR REDUCING THE RISK OF METABOLIC SYNDROME

The present invention relates to a composition comprising a mixture of galactooligosaccharides for use in a method for the prevention or reduction of the risk of developing metabolic syndrome. It also relates to a method of preventing or reducing the risk of developing metabolic syndrome by orally administering a composition comprising a mixture of galactooligosaccharides. Galactooligosaccharides are non-digestible carbohydrates which are resistant to mammalian gastrointestinal digestive enzymes but are fermented by specific colonic bacteria.

Metabolic syndrome is the name given to a group of risk factors that occur together and that result in an increase in the risk of cardiovascular disorders such as coronary artery disease, heart disease, heart attack and heart damage, as well as increased risk of stroke.

There have been several definitions of metabolic syndrome but the most commonly used one at present is the World Health Organisation (WHO) definition.

According to WHO the criteria or risk factors for metabolic syndrome are 1) central obesity with a waist:hip ratio above 0.9 for men and 0.85 for women; 2) body mass index (BMI) above 30 kg/m^2; 3) blood pressure above 140/90; 4) triglycerides above 1.7 mmol/l; 5) high density lipoprotein (HDL) cholesterol < 0.9 mmol/l in men and <1 mmol/l in women; 6) glucose fasting or 2 hours after a glucose load above 7.8 mmol/l and 7) glucose uptake during hyperinsulinaemic euglycaemic clamp in lowest quartile for population.

In general, an individual's risk of heart disease, diabetes and stroke increases with the number of metabolic risk factors they have. A person who has metabolic syndrome is twice as likely to develop heart disease and five times as likely to develop diabetes as someone who does not have metabolic syndrome.

To date, the goal of managing metabolic syndrome is to reduce the risk of heart disease and diabetes. Doctors usually recommend lifestyle changes and/or prescribe medicines, such as a combination of beta-blockers, diuretics and/or a daily low-dose of aspirin to reduce blood pressure, low density lipoprotein (LDL) cholesterol and blood sugar. Recommendations for lifestyle changes will include weight loss, probably by eating 500-1,000 fewer calories per day, and 30 minutes of moderate intensity exercise, such as walking, 5-7 days per week.

It has now been found in a double-blind randomised, placebo controlled, cross-over human trial that oral administration of a composition comprising a mixture of galactooligosaccharides can lower cholesterol and triglyceride levels in the blood and thus be used in a method for the prevention or reduction of the risk of developing metabolic syndrome.

The mixture of galactooligosaccharides comprised disaccharides Gal (ß1-3)-Glc; Gal (ß1-3)-Gal; Gale (ß1-6)-Gal; Gal (α1-6)-Gal; trisaccharides Gal (ß1-6)-Gal (ß1-4)-Glc; Gal (ß1-3)-Gal (ß1-4)-Glc; tetrasaccharide Gal (ß1-6)-Gal (ß1-6)-Gal (ß1-4)-Glc and pentasachar ide Gal (ß1-6)-Gal (ß1-6)-Gal (ß1-6)-Gal (ß1-4)-Glc.

This mixture of galactooligosaccharides is disclosed in EP 1 644 482, which describes a novel strain of *Bifidobacterium bifidum* that produces a galactosidase enzyme activity that converts lactose to this novel mixture of galactooligosaccharides. This novel mixture has been shown to have prebiotic and anti-inflammatory properties in the gut.

This mixture of galactooligosaccharides is marketed commercially under the name Bimuno (registered trade m ark) and is available from Clasado Ltd (Milton Keynes, UK).

According to one aspect of the invention there is provided a composition comprising a mixture of galactooligosaccharides as defined above for use in a method for preventing or reducing the risk of developing metabolic syndrome.

This mixture of galactooligosaccharides may also be used in a method for the prevention of cardiovascular disorders such as coronary artery disease, coronary heart disease, heart attack and stroke. An effective amount of galactooligosaccharide is preferably administered daily as a single dose or alternatively as two separate doses several hours apart.

According to a second aspect of the invention there is provided a method of preventing or reducing the risk of developing metabolic syndrome comprising administering to a mammal such as a human an effective amount of a galactooligosaccharide composition comprising a mixture of galactooligosaccharides as defined above.

The product known as Bimuno comprises at least 49% of the dry matter as the mixture of galactooligosaccharides. The remainder of the composition may comprise non-active components such as glucose, galactose, lactose, acacia gum and citric acid.

The composition may be presented in freeze-dried powder form, in syrup form or in pastille form. It is preferably taken orally on a daily basis. The powder composition preferably comprises from 1.35g to 9.6g of galactooligosaccharide in 2.75g to 20g of the powdered composition, preferably from 1.96g to 4.9g of galactooligosaccharide in 4g to 10g of the powder, most preferably 2.7g galactooligosaccharide in 5.5g of composition. The composition may be added to a drink, preferably a hot drink, or sprinkled on food, for example, on breakfast cereal.

Alternatively, the galactooligosaccharide may be presented as a syrup or pastilles (dehydrated syrup) in which the non-active components may comprise glucose, galactose, lactose and citric acid. A daily dose of the syrup may comprise from 1.35g to 9.6g of the galactooligosaccharide mixture in 3.55g to 25.29g of the syrup composition, preferably from 1.96g to 4.9g of galactooligosaccharide in 5.16g to 12.9g of the syrup, most preferably 2.7g galactooligosacchride in 7.25g of the syrup.

The invention will be further described by way of reference to the following examples:-

Example 1

Freeze-dried powdered composition packaged in a 'stick-pack' and containing per 5.5g final product:-

Galactooligosaccharide (GOS) mixture	2.75g
Lactose	1.40g
Monosaccharides (glucose, galactose)	0.64g
Drying aid	0.24g
Ash	0.23g
Moisture	0.19g
Protein	0.05g

Example 2

Syrup composition per 7.25g finished product:-

Galactooligosaccharide (GOS) mixture	2.75g
Lactose	0.58g
Monosaccharides (glucose, galactose)	1.69g
Ash	0.23g
Moisture	1.95g
Protein	0.05g

Example 3

Effectiveness of galactooligosaccharides on metabolic syndrome risk factors in overweight adults

Study

A total of 45-50 human subjects with three or more risk factors associated with metabolic syndrome and its increased risk of cardiovascular disease were recruited. Equal numbers of men and women were included in the study cohort.

Metabolic syndrome factors used to select subjects included: insulin resistance (measured as increased ratio of fasting glucose (6-7 mmol/l) and insulin), high blood pressure, dyslipidaemia [low high density lipoprotein (HDL) cholesterol (<1 mmol/l), high triglyceride (> 1.3 mmol/l)], waist circumference (> 40 in men; >35 in women).

Further inclusion criteria were:-

18-65 years

BMI >25 kg/m^2

not having suffered a myocardial infarction/stroke or cancer in the past 12 months

not diabetic (diagnosed or fasting glucose > 7mmol/l) or suffering from other endocrine disorders

not suffering from chronic coronary, renal, bowel disease/gastrointestinal disorder or having a history of choleostatic liver or pancreatitis

not on drug treatment for hyperlipidaemia, hypertension, inflammation, hypercoagulation or using drugs that affect intestinal motility or absorption

no history of alcohol/drug abuse

not planning or on a weight reducing regime

not taking any dietary antioxidant or other phytochemical, prebiotics or probiotic supplements

not pregnant, lactating, planning a pregnancy in the next 6 month or of child bearing potential and not using effective contraceptive precautions

not taking antibiotics for the previous 1 month

not anaemic (haemoglobin men >14g/dl; women >11.5g/dl)

non smokers

Volunteers who met the inclusion criteria were asked to attend a screening session during which a fasting (12 hours) blood sample was taken and their BMI, waist circumference and blood pressure measured. The screening blood sample (~10ml) was analysed at the Royal Berkshire Hospital for total cholesterol (TC), HDL cholesterol, triacylglycerol, glucose and insulin. Individuals who were anaemic (Hb < 14g/dl male, 11.5g/dl female) or who had 'abnormal' blood biochemistry based on the above analysis, were automatically excluded. The measurements were used to identify individuals at higher metabolic risk, who were then invited to participate in the study.

Treatment A or B was randomly assigned to each participant using an allocation ratio of 1:1 for the 2 study groups (including stratification for gender). Volunteers were required to attend the University for a total of 6 visits. The study was a randomised, controlled, double-blind crossover trial with Maltodextrin as the placebo. Volunteers were instructed to ingest the test product (GOS) and/or placebo daily for 12 weeks, with a 6 week washout period between. Both GOS and placebo were supplied in powder sachets (5.5g) and volunteers were instructed to either sprinkle these over a bowl of cereal or add them to any drink, and ingest them daily. Habitual diet was assessed by pre-validated 4-day food diaries (2 weekend and 2 week days). At 0, 6 and 12 wk of intervention, volunteers visited the nutrition unit and samples and measurements were taken.

On each visit a fasting blood sample (~20ml) as taken and this was used to analyse a number of risk markers (all using commercially available kits). The markers studied were:

Lipid profile (total, low density lipoprotein (LDL) and HDL cholesterol, triglycerides and non-esterified fatty acids)

Insulin resistance derived from fasted measures of glucose and insulin ratio

Inflammatory/thrombotic biomarkers (including C-reactive protein, and IL6)

At 0, 12, 18 and 30 weeks a series of anthroprometric measurements (including weight, blood pressure and waist circumference) were taken in order to determine any

changes.

Results

Baseline characteristics of subjects

The demographic characteristics of the study population are presented in Table 1.

Table 1. Baseline characteristics of subjects participating in the study.

Characteristics	Male (n=16)	Female (n=29)
Age (yr)	42.8±12.1	46.4±11.8
BMI (kg/m^2)	30.7±5.3	32.1±6.3
Waist circumference (cm)	103.7±11.0	99.2±14.5
Fasting insulin (pmol/L)	66.3±28.3	70.3±30.6
Fasting glucose (mmol/L)	5.5±0.8	5.2±0.6
Systolic Blood Pressure (mmHg)	127.9±10.1	125.9±15.8
Diastolic Blood Pressure (mmHg)	80.9±8.6	80.5±10.0
Total Cholesterol (mmol/L)	6.3±1.5	6.2±1.2
HDL cholesterol (mmol/L)	1.3±0.4	1.4±0.3
TAG (mmol/L)	1.9±0.9	1.4±0.5

Effect on colonic microbiota

Daily consumption of 5.5g of Bimuno (2.75g active GOS) showed after 6 wk to result in a significant increase in the bifidobacterial population compared to both the Placebo (1wk) ($p<0.05$) and baseline ($p<0.05$) levels (Table 2). After 12 wk of consumption, Bimuno intake resulted in significant increase in the populations of *Bifidobacterium* and *Lactobacillus* spp compared to Placebo (12wk) ($p<0.0001$) and baseline ($p<0.05$). At the same time the levels of species of the *Clostridium* hystoliticum group and *Desulfovibrio* spp were significantly reduced compared to Placebo (12wk) ($p<0.0001$) and baseline ($p<0.05$) (Table 2).

In terms of changes in the populations of *Atopobium spp, C. coccoides / E. rectale, E. cylindroides, E. hallii, Clostridium cluster IX , F. prausnitzii cluster, beta-*

Proteobacteria, Bacteroides spp no significant effect was recorded either after the intake of Bimuno or Placebo during the 12 wks treatment period.

Effect on biomarkers of inflammation

Results on the levels of faecal sIgA (secretory immunoglobulin A), faecal calprotectin and blood inflammatory biomarkers (IL-6, CRP) during the study periods (Placebo, Bimuno) are shown in Table 3.

Daily intake of Bimuno for 12 weeks resulted in a significant reduction of both secretory IgA ($p<0.05$ vs Placebo; $p<0.01$ vs baseline) and calprotectin ($p<0.01$ vs placebo; $p<0.05$ vs baseline) (Table 3). At the same time a significant reaction in the blood levels of the pro-inflammatory cytokine IL-6 ($p<0.05$ vs Placebo; $p<0.05$ vs baseline) and in the inflammatory biomarker C-reactive protein ($p<0.05$ vs Placebo; $p<0.05$ vs baseline) was determined after daily intake of Bimuno for 12 weeks.

Effect on Metabolic Syndrome risk factors

Daily intake of Bimuno for 12 weeks resulted in a significant reduction in blood insulin levels ($p<0.05$ vs Placebo; $p<0.01$ vs baseline), blood triglycerides ($p<0.05$ vs placebo; $p<0.05$ vs baseline), total cholesterol ($p<0.05$ vs Placebo; $p<0.05$ vs baseline) and the ratio of total cholesterol over HDL cholesterol ($p<0.05$ vs Placebo; $p<0.05$ vs baseline) indicating an overall reduction of the risk of Metabolic syndrome (Table 4).

Conclusion

Supplementation with 5.5g Bimuno (delivering 2.75g of active GOS) in a population at risk of developing metabolic syndrome resulted in a significant change in the composition of their colonic microbiota by increasing the resident beneficial bacteria of *Bifidobacterium* genus and *Lactobacillus* genus, while decreasing the levels of detrimental bacteria such as those belonging to the *C.* hystoliticum subgroup and the sulphate reducing

bacteria. This microbiota change resulted in an increase in the colonisation resistance in the gut reducing the colonic inflammation as seen through the reduction of the calprotectin levels. At the same time increased levels of sIgA would suggest a better barrier function of the epithelium which in combination with the reduced colonic inflammation could result in the reduction of the levels of inflammatory biomarkers in the host (IL-6, CRP).

This overall protection through the improvements in the composition of the colonic microbiota and the intestinal barrier function appears to have a beneficial effect in the levels of insulin, cholesterol and triglycerides that are known risk factors of metabolic syndrome.

Table 2. Changes in the numbers (Log_{10}) of the various bacterial groups monitored during the study periods (Placebo, Bimuno), as determined by fluorescent in situ hybridisation (FISH)

	Placebo		5.5g Bimuno	
	Wk6	Wk12	Wk6	Wk12
Bifidobacterium spp	0.17±0.13	0.3±0.19	0.78±0.23*	1.13±0.29*
Lactobacillus – *Enterococcus* spp	-0.04±0.09	-0.12±0.18	0.24±0.15	0.43±0.22*
C. hystoliticum group	0.15±0.11	0.23±0.07	0.12±0.21	-0.61±0.24*
Desulfovibrio spp	0.02±0.09	-0.03±0.11	-0.04±0.07	-0.63±0.17*

*significantly different from Baseline ($p<0.05$)

Table 3. Changes in the levels of the faecal and blood biomarkers of inflammation during the study periods (Placebo, Bimuno)

	Placebo		5.5g Bimuno	
	Wk6	Wk12	Wk6	Wk12
sIgA (ug/g faeces)	NA	-230±243	NA	902±214*
Calprotectin (ug/g faeces)	2.57±4.03	2.58±3.28	-2.91±3.97	-9.61±3.27*
IL-6 (ng/ml)	NA	7.97±13.01	NA	-33.34±12.9*
C-Reactive protein (ng/ml)	0.46±0.42	0.75±0.40	0.66±0.39	-1.56±0.41*

*significantly different from Baseline ($p<0.05$)

Table 4. Changes in the levels of insulin, TAG and cholesterol after 12 wk supplementation of Placebo or Bimuno

	Placebo		5.5g Bimuno	
	Wk6	Wk12	Wk6	Wk12
Insulin (pmol/L)	5.15±3.14	7.42±2.89	-0.02±0.07	**-10.37±3.04***
Triglycerides (mmol/L)	0.09±0.08	-0.03±0.09	-0.08±0.09	**-0.79±0.11***
Total Cholesterol (mmol/L)	0.14±0.11	0.05±0.06	-0.10±0.08	-0.39±0.12*
Total Cholesterol:HDL	0.01±0.04	-0.06±0.09	-0.19±0.08	**-0.44±0.1***

*significantly different from Baseline ($p<0.05$)

What is claimed:

1. A composition comprising a mixture of galactooligosaccharides which comprises disaccharides Gal (β1-3)-Glc; Gal (β1-3)-Gal; Gal (β1-6)-Gal; Gal (α1-6)-Gal; trisaccharides Gal (β1-6)-Gal (β1-4)-Glc; Gal (β1-3)-Gal (β1-4)-Glc; tetrasaccharide Gal (β1-6)-Gal (β1-6)-Gal (β1-4)-Glc and pentasaccharide Gal (β1-6)-Gal (β1-6)-Gal (β1-6)-Gal (β1-4)-Glc for preventing or reducing the risk of developing metabolic syndrome.

2. A composition comprising a mixture of galactooligosaccharides which comprises disaccharides Gal (β1-3)-Glc; Gal (β1-3)-Gal; Gal (β1-6)-Gal; Gal (α1-6)-Gal; trisaccharides Gal (β1-6)-Gal (β1-4)-Glc; Gal (β1-3)-Gal (β1-4)-Glc; tetrasaccharide Gal (β1-6)-Gal (β1-6)-Gal (β1-4)-Glc and pentasaccharide Gal (β1-6)-Gal (β1-6)-Gal (β1-6)-Gal (β1-4)-Glc for preventing or reducing the risk of a cardiovascular disorder.

3. The composition according to claim 2, wherein the cardiovascular disorder is coronary artery disease, coronary heart disease, heart attack or stroke.

4. The composition according to any one of claims 1-3, which is presented in freeze-dried powder form, syrup form or pastille form.

5. The composition according to claim 4 which is in freeze-dried powder form and comprises from 1.35g to 9.6g of galactooligosaccharides in 2.75g to 20g of the powder composition.

6. The composition according to claim 4 which is in syrup form and comprises from 1.35g to 9.6g of galactooligosaccharides in 3.55g to 25.29g of the syrup.

7. A use of a composition comprising a mixture of galactooligosaccharides which comprises disaccharides Gal β1-3)-Glc; Gal (β1-3)-Gal; Gal (β1-6)-Gal; Gal (α1-6)-Gal; trisaccharides Gal (β1-6)-Gal (β1-4)-Glc; Gal (β1-3)-Gal (β1-4)-Glc; tetrasaccharide Gal (β1-6)-Gal (β1-6)-Gal (β1-4)-

Glc and pentasaccharide Gal (βl-6)-Gal (βl-6)-Gal (βl-6)-Gal (βl-4)-Glc for preventing or reducing the risk of developing metabolic syndrome.

8. A use of a composition comprising a mixture of galactooligosaccharides which comprises disaccharides Gal βl-3)-Glc; Gal (βl-3)-Gal; Gal (βl-6)-Gal; Gal (αl-6)-Gal; trisaccharides Gal (βl-6)-Gal (βl-4)-Glc; Gal (βl-3)-Gal (βl-4)-Glc; tetrasaccharide Gal (βl-6)-Gal (βl-6)-Gal (βl-4)-Glc and pentasaccharide Gal (βl-6)-Gal (βl-6)-Gal (βl-6)-Gal (βl-4)-Glc for preparing a medicament for preventing or reducing the risk of developing metabolic syndrome.

9. A use of a composition comprising a mixture of galactooligosaccharides which comprises disaccharides Gal (βl-3)-Glc; Gal (βl-3)-Gal; Gal (βl-6)-Gal; Gal (αl-6)-Gal; trisaccharides Gal (βl-6)-Gal (βl-4)-Glc; Gal (βl-3)-Gal (βl-4)-Glc; tetrasaccharide Gal (βl-6)-Gal (βl-6)-Gal (βl-4)-Glc and pentasaccharide Gal (βl-6)-Gal (βl-6)-Gal (βl-6)-Gal (βl-4)-Glc for preventing or reducing the risk of a cardiovascular disorder.

10. A use of a composition comprising a mixture of galactooligosaccharides which comprises disaccharides Gal (βl-3)-Glc; Gal (βl-3)-Gal; Gal (βl-6)-Gal; Gal (αl-6)-Gal; trisaccharides Gal (βl-6)-Gal (βl-4)-Glc; Gal (βl-3)-Gal (βl-4)-Glc; tetrasaccharide Gal (βl-6)-Gal (βl-6)-Gal (βl-4)-Glc and pentasaccharide Gal (βl-6)-Gal (βl-6)-Gal (βl-6)-Gal (βl-4)-Glc for preparing a medicament for preventing or reducing the risk of a cardiovascular disorder.

11. The use according to claim 9 or 10, wherein the cardiovascular disorder is coronary artery disease, coronary heart disease, heart attack or stroke.

12. A use of a composition comprising a mixture of galactooligosaccharides which comprises disaccharides Gal (βl-3)-Glc; Gal (βl-3)-Gal; Gal (βl-6)-Gal; Gal (αl-6)-Gal; trisaccharides Gal (βl-6)-Gal (βl-4)-Glc; Gal (βl-3)-Gal (βl-4)-Glc; tetrasaccharide Gal (βl-6)-Gal (βl-6)-Gal (βl-4)-Glc and pentasaccharide Gal (βl-6)-Gal (βl-6)-Gal (βl-6)-Gal (βl-4)-Glc in the preparation of a medicament for lowering cholesterol and triglyceride levels in the blood.

13. A use of a composition comprising a mixture of galactooligosaccharides which comprises disaccharides Gal (βl-3)-Glc; Gal (βl-3)-Gal; Gal (βl-6)-Gal; Gal (αl-6)-Gal; trisaccharides Gal

(βl-6)-Gal (βl-4)-Glc; Gal (βl-3)-Gal (βl-4)-Glc; tetrasaccharide Gal (βl-6)-Gal (βl-6)-Gal (βl-4)-Glc and pentasaccharide Gal (βl-6)-Gal (βl-6)-Gal (βl-6)-Gal (βl-4)-Glc for lowering cholesterol and triglyceride levels in the blood.

14. The composition according to claim 4 which is in freeze-dried powder form and comprises from 1.96g to 4.9g of galactooligosaccharides in 4g to l0g of the powder.

15. The composition according to claim 4 which is in freeze-dried powder form and comprises 2.7g of galactooligosaccharides in 5.5g of the powder.

16. The composition according to claim 4 which is in syrup form and comprises from 1.96 g to 4.9g of galactooligosaccharides in 5.16g to 12.9g of the syrup.

17. The composition according to claim 4 which is in syrup form and comprises 2.7g of galactooligosaccharides in 7.25g of the syrup.