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Research Article

Efficacy of Broccoli Sprout Powder in Management of Metabolic Health Risk Factors: a Randomized, Double Blind, Placebo Controlled Clinical Study

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Abstract

Objective: Broccoli is a rich source of antioxidants and other bioactives associated with various health benefits. Broccoli sprouts contain higher content of such bioactives than mature broccoli. The objective of this randomized, double blind, placebo controlled study with 288 subjects was to evaluate the efficacy of daily consumption of broccoli sprout powder on metabolic disorder risk factors. **Method:** Subjects were randomised into three groups comprising of (a) elevated fasting and post prandial blood glucose (b) body mass index and (c) triglycerides respectively, and further assigned to placebo and test arms. Blood glucose profile, glycosylated haemoglobin, lipid profile, anthropometric measurements and safety parameters were assessed at baseline and after 12 weeks of intervention. **Results:** A total of 265 subjects completed the study. Statistically significant reduction of lipid profile and blood glucose profile markers was observed in test group compared to placebo group. **Conclusion:** Daily consumption of broccoli sprout powder showed efficacy in managing cardiovascular and diabetes risk factors thus suggesting the potential health benefits of including the ingredient as part of daily diet.

Keywords: metabolic syndrome, broccoli sprout, diabetes, cardiovascular, obesity

Abbreviations: HDL: High Density Lipoproteins; T2DM:Type 2 Diabetes mellitus; BSP: Broccoli Sprout Powder; WHO: World Health Organisation; CDC: Centre for Disease Control and Prevention; FBG: Fasting Blood Glucose; PPBG: Post Prandial Blood Glucose; HbA1c: Glycosylated haemoglobin; TC: Total Cholesterol; LDL: Low Density Lipoprotein; VLDL: Very Low Density Lipoprotein; HDL: High Density Lipoprotein; PCS: Physical Component Summary; MCS: Mental Component Summary; BMI: Body Mass Index; SGOT: Serum Glutamic Oxaloacetic Transaminase; SGPT: Serum Glutamic Pyruvic Transaminase; ARE: Antioxidant Responsive Element; CVD: Cardiovascular Disease; SFN: Sulforaphane

Introduction

Lifestyle disorders such as metabolic syndrome refer to a cluster of conditions such as high blood pressure, high blood sugar, high triglyceride levels, excess body fat around the waist and low HDL, that increase the chances of Type 2 Diabetes Mellitus (T2DM), cardiovascular disease and stroke [1,2]. Risk of long term complications associated with T2DM increases with prevalence of hypertension and obesity which are common comorbidities in adults with T2DM [3]. Chronic hyperglycaemia is also associated with atherosclerosis, and cardiovascular diseases are the leading

cause of mortality worldwide [4,5]. The comorbidity burden is further impacted by poor nutritional status as observed in a cohort study with obese Asian population [6]. With an increase in diet and lifestyle related disorders, the concept of functional foods has emerged with inclusion of phytochemicals in the daily diet [7]. Functional foods provide additional physiological benefits in addition to their nutritional profile [8].Various in vitro, in vivo, and clinical studies have been conducted to understand the role and significance of functional foods with respect to micronutrient as well as bioactive composition. In addition to whole grains, legumes and nuts, vegetables and fruits rich in phytochemicals and antioxidants have also been explored [9].

Cruciferous vegetables, such as broccoli, cabbage, kale etc have been shown to be powerhouses of chemoprotective agents and other micronutrients [10]. Broccoli contains glucosinolates, the precursors of bioactive isothiocyanates. One of the well-studied isothiocyanates, sulforaphane is formed from a precursor glucosinolate molecule, glucoraphanin via enzymatic reaction in the presence of myrosinase. In broccoli plant cells glucoraphanin and myrosinase are in two different compartments and in presence of water or by chewing both come in contact leading to formation of sulforaphane [11,12]. Sprouts of broccoli contain 20-50 times higher glucosinolates than mature broccoli [13-15]. The beneficial antioxidant effect of broccoli sprout consumption is well elucidated. In a study involving administration of sulforaphane, up-regulation of glutathione system by phase 2 enzyme inducers in in aortic smooth muscle cells from spontaneously hypertensive rats was observed [16]. Similarly, administration of 200mg per day of dried broccoli sprouts to rats, showed significant improvement in oxidative stress markers in cardiovascular and kidney tissues [17].

Human clinical studies demonstrate some of the health benefits of broccoli sprouts, sprout powders and extracts. In a study evaluating the effect of consumption of 100 grams of broccoli sprouts in 12 subjects for a duration of one week, an improvement in cholesterol biomarkers was observed [18]. A study with 63 diabetic subjects observed significant reduction of oxidative stress markers upon consumption of 5-10g of broccoli sprout powder for four weeks [19].Similarly, effect of 5-10g of broccoli sprout powder in 72 diabetic adults was evaluated and favourable changes in lipid profile markers within the study groups were observed [20]. Overall, from several short term studies, health benefits of broccoli sprout consumption are evident. These studies have largely been conducted in smaller study groups for shorter duration of time. Here, we aimed to evaluate efficacy of long term consumption (12 weeks) of broccoli sprout powder (BSP) on blood glucose and lipid biomarkers in target population at risk of metabolic disorder.

Materials and methods

Subjects and Study Design

The study was randomised, double blind and placebo controlled. The study was approved by independent ethics committees and registered with Clinical Trials Registry India (CTRI/2016/05/006977). Both males and females in the age group 18-60 years were included as subjects in the study. Subjects with history of thyroid diseases, HIV, cancer, smoking and alcohol consumption were excluded from the study. All subjects provided written informed consent to participate in the study prior to being screened. A total of 288 subjects from India, were enrolled in the study. Subjects were distributed across three groups to include metabolic syndrome risk factors of elevated glucose, obesity and elevated triglycerides, since most previous studies have focused on either healthy or diabetic subjects. Cut off levels as defined by WHO and CDC were used. Group A comprised of hyperglycaemic subjects with elevated fasting and post prandial blood glucose levels i.e. ≥ 130mg/dl and ≥200mg/dl respectively. Group B comprised of overweight and obese subjects with BMI in the range of 25 – 35 kg/m2 and Group C com-prised of dyslipidaemic subjects with elevated fasting triglyceride levels i.e. ≥ 150mg/dl. A total of 96 subjects were recruited into each study group and further sub grouped into test and placebo arms. The study duration was 12 weeks. All laboratory assessments were carried out at baseline and end of treatment.

Intervention

Each test capsule contained 200mg of commercially procured broccoli sprout powder and placebo capsule comprised of equivalent quantity of maltodextrin. Each arm received either test or placebo capsules to be consumed as two capsules at a time before meal.

Laboratory assessments

All laboratory assessments were carried out at baseline and end of treatment visits. Subjects were tested for fasting and post prandial blood glucose (FBG and PPBG respectively), glycosylated haemoglobin (HbA1c), lipid profile (triglycerides, total cholesterol TC, Low density lipoprotein LDL, Very low density lipoprotein VLDL, High density lipoprotein HDL) Physical and Mental Component Summary (PCS and MCS respectively as measured by Quality of life questionnaire SF-36), Anthropometry (Body Mass Index BMI, waist and hip circumference, body weight), Renal Function Test (Creatinine, urea, blood urea nitrogen, Sodium, Potassium and Chloride), Liver Function Test (Alkaline Phosphatase ALP, Bilirubin, Albumin, serum glutamic oxaloacetic transaminase SGOT, serum glutamic pyruvic transaminase

SGPT) and Vitals (pulse rate, respiratory rate, blood pressure, temperature).

Statistical analyses

SAS software version 9.1 was used for the statistical analysis. The sample size considered 5% significance level and 80 % power. The difference within the group was assessed using paired t-test. The difference between the groups was assessed using independent t-test.

Results

The details on study participation are shown in (Figure 1). Of the 96 subjects enrolled in each group, 84 subjects completed the study in Group A (42 each in test and placebo), 92 subjects completed the study in Group B (46 each in test and placebo) and 89 subjects completed the study in Group C (45 in test and 44 in placebo arms). (Table 1) shows the demographic details of study subjects. The average age of subjects across groups was similar, ranging from 47 - 48 years in Group A, 44 - 46 years in Group B and 47 - 48 years in Group C. The average weight of subjects in group B test arm was 75.7 kgs and in placebo arm was 73.9 kgs which was slightly higher than groups A and C where average weight of subjects in test arm was 72.6 and 70.1 kgs respectively and average weight of subjects in placebo arms was 72.9 and 71.1 kgs respectively. Similarly, the BMI of subjects across groups was in overweight range. The BMI of subjects in group B test arm was 29.8 kg/m2 and in placebo arm was 29.7 kg/m2 which was slightly higher than groups A and C where average BMI of subjects in test arm was 27.8 and 28.1 kg/m2 respectively and average weight of subjects in placebo arms was 28.6 and 28.2 kg/m2 respectively. Waist circumference and hip circumference were in similar range for subjects across all groups.

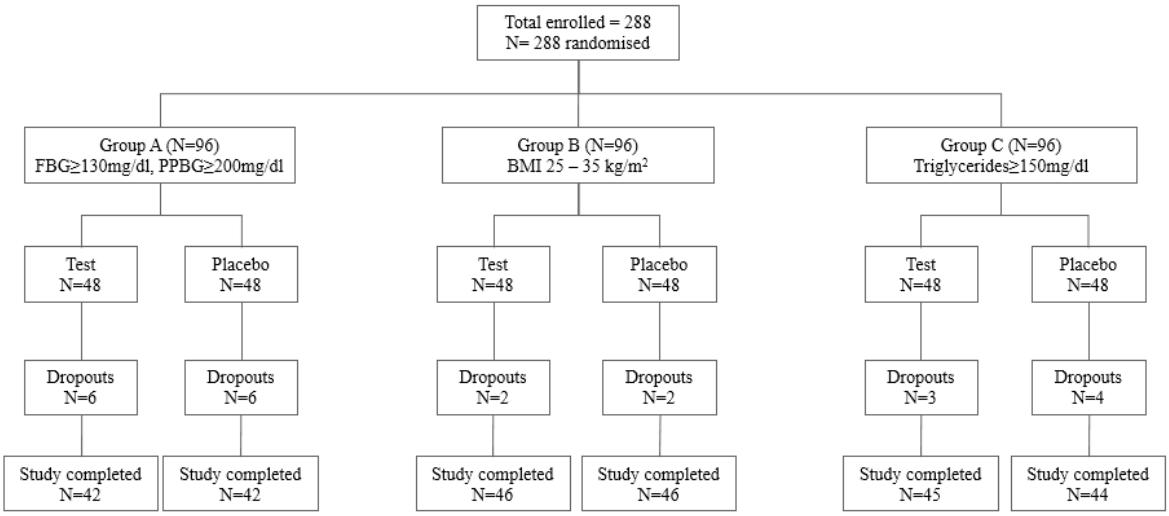

Figure 1: shows the flow chart of study participation

Parameter	Group A				Group B				Group C			
	Test		Placebo		Test		Placebo		Test		Placebo	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Age (Years)	47.4	8.6	47.8	8.3	46.2	10.5	44.3	10.7	46.9	8.3	47.5	7.8
Weight (kg)	72.6	10.8	72.9	9.8	75.7	11.1	73.9	10.4	70.1	10.7	71.1	9.9
Height (cm)	158.2	18.5	156.9	17.1	148.4	32.5	153.4	22.7	153.6	22.1	158.9	7.0
BMI (Kg/m^2)	27.8	3.6	28.6	3.2	29.8	3.8	29.7	2.9	28.1	3.6	28.2	3.4
Waist circumference (cm)	91.7	17.7	92.6	12.7	95.7	14.4	93.4	14.3	93.2	12.0	94.7	13.5
Hip circumference (cm)	99.1	20.7	103.1	14.8	104.5	14.3	103.3	15.1	96.5	13.4	98.6	21.3

Table 1: Demographic details of subjects in Groups A, B and C

Table 2 shows the values of assessment parameters at the baseline and end of treatment in test and placebo arms of Group A comprising of hyperglycaemic subjects. A significant reduction in PPBG was observed between test and placebo arms (p=0.0327). Additionally, LDL and PCS also showed a significant improvement in test arm compared to placebo arm (p=0.0232, 0.0051 respectively). Other parameters such as HbA1c, TG, TC, HDL and VLDL showed improvement in the test arm when compared to placebo arm, however, these changes were not statistically significant. Table 2 shows the change in outcome measures from baseline to end of treatment (EoT) in Group A study subjects.

Parameter	Unit	Baseline (Test)	SD	EoT (Test)	SD	Baseline (Placebo)	SD	EoT (Placebo)	SD	p value (test vs placebo)
FBG	mg/dL	205.1	74.5	162.5***	59.0	187	56.4	174.5	45.8	0.0663
PPBG	mg/dL	305.3	76.6	237.7***	70.8	282.9	68.3	270	65.4	0.0327
HbA1c	%	9.6	2.2	8.1***	2.0	9	1.9	8.8	1.7	0.1041
TG	mg/dL	181.1	78.6	149.4**	76.6	176.4	96.8	173	98.7	0.2249
TC	mg/dL	188	38.6	177.1*	34.4	186.4	37.7	180.5	42.1	0.6836
LDL	mg/dL	113.9	33.3	100.3**	25.6	115.2	28.8	115.7	34.9	0.0232
HDL	mg/dL	38.5	12.7	40.7	20.8	40.1	9.6	37.9	13.6	0.4688
VLDL	mg/dL	35.6	13.7	31.2*	11.6	41.5	57.4	45.7	14.9	0.1209
BMI	kg/m2	28.7	3.8	28.4	3.7	27.9	3.1	27.8	2.9	0.4037
Body weight	kg	74.7	11.3	73.8**	11.4	70.8	8.8	70.4	8.9	0.14
Waist circumference	cm	93.5	12.5	92.7**	12.2	91.6	14.4	91.1	14.0	0.5882
Hip circumference	cm	102.5	16.3	101.7*	15.7	102	16.0	100.9**	15.8	0.8118
PCS	NA	41.9	7.4	48.1***	7.9	41.9	6.4	43.4	6.0	0.0051
MCS	NA	47.3	8.8	50.8**	5.0	47.2	7.0	47.7	6.8	0.4152

Fasting Blood Glucose (FBG), Post Prandial Blood Glucose (PPBG), Glycosylated Haemoglobin (HbA1c), Triglycerides (TG), Total Cholesterol (TC), Low Density Lipoproteins (LDL), High Density Lipoproteins (HDL), Very Low Density Lipoproteins (VLDL), Body Mass Index (BMI), Body Weight (BW), Waist Circumference (WC), Hip circumference (HC), Physical Component Summary (PCS), Mental Component Summary (MCS). Statistical significance between baseline and EoT indicated by * p≤ 0.05 ** p≤ 0.01 *** p≤ 0.001

Table 2: Efficacy outcome measures of subjects in group A

Table 3 shows the values of assessment parameters at the baseline and end of treatment in test and placebo arms of Group B comprising of overweight subjects. While placebo arm showed an increase in BMI between baseline and end of treatment, test arm showed a significant reduction within test arm between baseline and end of treatment (p=0.0029). However, this reduction was not significant when compared to placebo arm. A significant reduction in FBG, TG and LDL was observed in test arm compared to placebo arm. Significant improvement in HDL was also observed in test arm compared to placebo arm. Other parameters such as PPBG, HbA1c, TC, VLDL also showed reduction in test arm compared to placebo arm, however, these changes were not statistically significant. Table 3 shows the change in outcome measures from baseline to end of treatment (EoT) in Group B study subjects.

Parameter	Unit	Baseline (Test)	SD	EoT (Test)	SD	Baseline (Placebo)	SD	EoT (Placebo)	SD	p value (test vs placebo)
FBG	mg/dL	100.4	70.0	93.8*	23.3	97.1	29.6	118.7***	45.8	0.0009
PPBG	mg/dL	164.9	1.7	150.8	55.5	152.6	65.6	161.2	79.4	0.4068
HbA1c	%	7	56.8	6.8	1.4	7.9	10.2	6.6	1.8	0.5293
TG	mg/dL	125.6	39.2	106.9	32.5	129	55.2	133.7	52.6	0.0042
TC	mg/dL	178.2	32.5	171.9	42.5	179.1	38.9	175	40.1	0.6715

LDL	mg/dL	108.8	12.5	102.6	36.8	112.1	35.2	118.6	38.8	0.0464
HDL	mg/dL	43.8	12.9	44.2	14.2	40.8	8.2	36.5*	11.7	0.0066
VLDL	mg/dL	31.7	4.0	26.0*	11.0	24.6	13.1	25.7	10.8	0.8981
BMI	kg/m2	30	11.9	29.0**	3.4	29.7	2.8	31.8	15.7	0.2762
Body weight	kg	76.5	15.4	76.2	12.2	74.6	9.7	75.1	10.0	0.6733
Waist circumference	cm	97.3	15.3	96.0***	14.4	95.6	18.0	93.4	12.3	0.3736
Hip circumference	cm	106.5	6.6	105.6*	14.8	103	14.0	103.4	13.1	0.4667
PCS	NA	43.3	6.3	46.9*	7.1	45.6	7.4	45.6	7.5	0.8281
MCS	NA	47.2		52.1**	6.7	48.9	6.5	49.2	5.7	0.8519

Fasting Blood Glucose (FBG), Post Prandial Blood Glucose (PPBG), Glycosylated Haemoglobin (HbA1c), Triglycerides (TG), Total Cholesterol (TC), Low Density Lipoproteins (LDL), High Density Lipoproteins (HDL), Very Low Density Lipoproteins (VLDL), Body Mass Index (BMI), Body Weight (BW), Waist Circumference (WC), Hip circumference (HC), Physical Component Summary (PCS), Mental Component Summary (MCS). Statistical significance between baseline and EoT indicated by * p≤ 0.05 ** p≤ 0.01 *** p≤ 0.001

Table 3: Efficacy outcome measures of subjects in group B

Table 4 shows the values of assessment parameters at the baseline and end of treatment in test and placebo arms of Group C comprising of dyslipidaemic subjects. A significant reduction in TC between test and placebo arms was observed (p=0.0206). Additionally, FBG, PPBG and HbA1c also showed significant reduction in test arm compared to placebo arm. Significant improvement in PCS was also observed in test arm compared to placebo arm. Other parameters such as TG, LDL, and VLDL also showed reduction in test arm compared to placebo arm, however, these changes were not statistically significant. Table 4 shows the change in outcome measures from baseline to end of treatment (EoT) in Group C study subjects.

Parameter	**Unit**	**Baseline (Test)**	**SD**	**EoT (Test)**	**SD**	**Baseline (Placebo)**	**SD**	**EoT (Placebo)**	**SD**	**p value (test vs placebo)**
FBG	mg/dL	127.3	61.6	111.0*	38.3	132.7	43.2	133.7	48.8	0.0184
PPBG	mg/dL	181.9	72.0	160.5	64.7	207.4	75.8	207.5	66.2	0.0013
HbA1c	%	7.1	1.6	6.7*	1.6	7.7	1.6	7.7	1.6	0.0038
TG	mg/dL	260.1	124.3	217.2**	127.0	262.8	104.5	250.5	103.1	0.1858
TC	mg/dL	190.4	40.4	173.6*	39.7	188.5	35.2	183.3	30.7	0.0206
LDL	mg/dL	107	30.7	102.6	33.1	108.9	30.9	105.1	22.6	0.6867
HDL	mg/dL	40.3	7.1	40.1	24.9	37.6	7.0	36.5	8.4	0.3777
VLDL	mg/dL	48.3	25.4	40.6*	14.8	45.5	25.9	41.4	12.4	0.7833
BMI	kg/m2	27.9	4.1	27.9	3.8	28	3.4	28.1	3.5	0.7435
Body weight	kg	70.7	11.3	70.3	11.3	70.9	9.9	71.2	9.7	0.7115
Waist circumference	cm	92.9	12.4	91.7*	11.7	92.4	13.4	92.6	13.2	0.7359
Hip circumference	cm	97.8	13.1	96.5*	11.7	99.7	15.8	98.1	18.6	0.6234
PCS	NA	44.3	6.6	49.1***	8.8	43.7	7.4	44	6.7	0.0061
MCS	NA	49.3	7.2	52.6**	7.3	48.6	6.9	48.6	6.8	0.014

Fasting Blood Glucose (FBG), Post Prandial Blood Glucose (PPBG), Glycosylated Haemoglobin (HbA1c), Triglycerides (TG), Total Cholesterol (TC), Low Density Lipoproteins (LDL), High Density Lipoproteins (HDL), Very Low Density Lipoproteins (VLDL), Body Mass Index (BMI), Body Weight (BW), Waist Circumference (WC), Hip circumference (HC), Physical Component Summary (PCS), Mental Component Summary (MCS). Statistical significance between baseline and EoT indicated by * p≤ 0.05 ** p≤ 0.01 *** p≤ 0.001

Table 4: Efficacy outcome measures of subjects in group C

BSP showed no significant change in safety parameters between test and placebo arms across groups, as shown in (Table 5).

Parameter	Group A				Group B				Group C			
	Test		Placebo		Test		Placebo		Test		Placebo	
	Baseline	EoT	Baseline	EoT	Baseline	EoT	Baseline	EoT	Baseline	EoT	Baseline	EoT
Creatinine	0.73±0.2	0.68±0.2	0.75±0.2	0.73±0.2	0.79±0.2	0.89±0.6	0.8±0.2	0.88±0.8	0.78±0.2	0.76±0.2	0.79±0.2	0.94±1.3
Urea	22.07±6.7	20.42±6.0	21.88±6.8	20.31±6.7	20.89±7.1	21.75±6.2	23.09±8.3	21.78±8.1	22.28±7.8	22.68±5.3	22.63±7.0	22.32±5.9
Blood Urea Nitrogen	10.18±3.1	9.81±2.5	10.51±3.4	10.54±3.2	10.13±4.1	10.4±3.1	10.73±3.7	10.64±3.4	10.62±3.8	10.6±3.0	10.58±3.6	10.63±2.8
Sodium	137.48±2.5	137.64±3.2	138.19±3.0	137.76±3.6	139.15±2.7	137.78±2.4	136.72±18.7	131.84±26.1	138.33±4.3	137.74±2.6	139.33±2.9	138.14±3.3
Potassium	4.85±0.6	4.71±0.5	4.71±0.5	4.66±0.5	4.63±0.4	4.58±0.4	4.74±0.6	4.63±0.5	4.66±0.6	4.68±0.4	6.46±7.9	4.71±0.5
Chloride	98.67±11.2	97.57±14.2	98.55±5.7	98.93±4.0	101.37±3.5	101.46±2.8	101.74±3.5	100.47±3.4	100.91±3.7	100.7±2.4	100.65±3.1	100.4±2.7
Alkaline phosphatase	99.02±26.1	86.73±26.1	93.76±24.7	91.77±26.2	89.96±23.2	83.22±19.4	80.17±20.0	80.53±20.2	0.65±0.3	0.57±0.3	0.76±0.6	0.64±0.3
Bilirubin	0.67±0.3	0.7±0.6	0.64±0.3	0.72±0.6	0.63±0.2	0.63±0.2	0.62±0.2	0.57±0.2	27.23±8.9	26.84±10.4	34.88±28.7	30.72±14.0
Albumin	4.16±0.4	4.36±1.9	4.15±0.3	4.53±2.6	4.12±0.3	4.07±0.3	4.1±0.3	3.92±0.6	34.4±13.7	29.81±9.2	41.21±21.8	33.65±15.8
SGOT	25.02±11.1	24.6±9.7	25±9.7	27.64±9.6	24.17±7.8	25.35±7.6	25.7±11.0	26.76±11.5	4.18±0.3	4.07±0.3	4.22±0.4	5.03±5.5
SGPT	32.93±13.1	31.77±17.2	30.64±12.2	29.9±15.5	31.37±14.2	30.85±15.0	33.46±32.1	35.87±32.8	83.84±24.0	83.16±20.9	85.4±21.3	86.98±22.1

Renal function and liver function parameters of subjects in Groups A, B and C at baseline and end of study. Unit of measurement for creatinine, urea, blood urea nitrogen, bilirubin and albumin is mg/dL. Unit of measurement for sodium, potassium and chloride is meq/L. Unit of measurement for alkaline phosphatase, SGOT and SGPT is U/L.

Table 5: Renal function and liver parameters of groups A, B and C

Discussion

Metabolic disorders such as dyslipidemia, diabetes mellitus, obesity and hypertension tend to co-exist and are most often associated with one another thus implying that one condition may act as a potential risk factor for emergence of another condition [21-24]. This was also observed in a prospective observational study which showed that long term exposure to glycaemia impacted cardiovascular complications in T2DM patients. For every 1% reduction in HbA1c, a 14% reduction in risk of myocardial infarction and 37% reduction in risk of microvascular complications was observed [25]. Similarly, diabetes and hypertension were found to be associated with a significant increase in risk of cardiovascular diseases [26]. Additionally, effect of obesity on cardiovascular disease was also elaborated in a Mendelian randomisation analysis study which indicates the significance of obesity reduction in reducing risk of CVD through management of downstream metabolic disorders such as diabetes and hypertension [27]. A prospective cohort study showed that obesity is the central feature of metabolic syndrome wherein, BMI was identified as a common risk factor in both men and women [28]. These studies elucidate the co-existential nature of health conditions associated with metabolic disorders. Similar observations were made in our study wherein subjects with elevated triglycerides or fasting blood glucose also had higher BMI.

Management of health conditions such as diabetes has been addressed through multiple routes including nutrition and dietary interventions, lifestyle modifications and medication among others. Nutraceuticals as described by DeFelice refer to a food or part of a food, which can be of vegetal or animal origin that has a beneficial pharmaceutical activity beyond its nutritional value [29]. In addition to efficacy, safety of nutraceutical compositions is of utmost importance and most regulations ensure that rigorous safety and toxicity studies are met before a product reaches the consumer. For instance, nutraceuticals

such as berberine, cocoa flavonoids, coenzyme Q etc are commonly used as co-adjuvants in management of diabetes and hypertension conditions and have well established safety data [30]. Similarly, ingredient such as cinnamon at recommended dosages is implicated in beneficial effects of weight management and diabetes and only at higher levels, presence of coumarin in spices such as cassia and cinnamon can be a safety concern [31-34]. In previous short term studies involving consumption for 1 – 4 weeks, BSP has been shown to be safe and efficacious. In a study with 12 healthy volunteers, the authors studied safety and metabolism of an equivalent of 12.6 – 50.4 grams of broccoli sprouts for a duration of 7 days and found no significant subjective or objective toxicities associated with its consumption [35]. Our study extends this finding wherein long term consumption of BSP for 12 weeks did not have any significant effects of safety parameters.

In vitro studies elucidate the mechanism of action of BSP bioactives leading to its physiological benefits. Chemoprotective effect of BSP is well established and the health benefits are largely attributed to antioxidant and anti-inflammatory properties involving upregulation of phase 2 detoxifying enzymes and Nrf2 pathway [36]. Nrf2-ARE loss of function in mice has been shown to be an important factor in determining susceptibility to toxicity. SFN owing to sulphur chemistry acts as an inducer of cytoprotective mechanism [37]. Our in vitro studies reveal additional efficacy of BSP in reducing absorption of lipids and glucose through inhibitory effects on lipase and glucosidase (data not shown).

Human clinical studies conducted with BSP as an intervention are few in number. Most human clinical studies have aimed to understand the metabolism of glucosinolates and isothiocyanates in the body, improvement of oxidative stress markers. Bahadoran et al published a series of interventional studies wherein BSP was administered to Type 2 Diabetic adult subjects showed improvement in inflammatory markers, oxidative stress markers and lipid profile [19,20]. Mirmiran et al (2012) also showed beneficial effects of BSP consumption on inflammatory markers in T2DM subjects [38].These studies demonstrate the efficacy of BSP in managing cardiovascular complications and inflammation which co-exist with hyperglycaemia. We further evaluated the efficacy of BSP consumption for an extended duration of 12 weeks as compared to most commonly evaluated duration of 1-4 weeks, in subjects with common risk factors of metabolic health, including hyperglycaemia, BMI and dyslipidaemia. Our study showed that consumption of broccoli sprout powder improves fasting and postprandial blood glucose, glycosylated haemoglobin and lipid profile markers in subjects with elevated fasting blood glucose and triglycerides.

Improvement of quality of life is one of the key goals in management of metabolic health conditions such as T2DM [39]. In a study that investigated relationship between psychological parameters and metabolic health, showed that psychological wellbeing was an important correlate (both in physical and mental domains) of metabolic syndrome [40]. In our study, all three groups showed an overall improvement of physical and mental component summary either within the test arm (between baseline and end of treatment) or between test and placebo arms.

Conclusion

The results from all three groups suggest that consumption of BSP is beneficial for management of risk factors of Type 2 diabetes as well as dyslipidemia. These findings together with established health benefits indicate the potential of incorporating BSP as a nutraceutical adjuvant in management of lifestyle disorders and can be explored further. To the best of our knowledge this is one of the first studies to be conducted with a large sample size of over 200 subjects for an extended duration of 12 weeks, which has shown significant improvement in diabetes and cardiovascular disease risk factors. Since there were no other significant recorded lifestyle changes in the study population and the study was placebo controlled, the effects may be attributed to the consumption of broccoli sprout powder.

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Ethical Approval: The study was approved by ethics committees at the respective study sites (Mediciti Ethics Committee, Medisys Clinisearch Ethical Review Board and Sri Venkateshwara Hospital Ethics Committee) and is listed on Clinical Trials Registry India (CTRI number CTRI/2016/05/006977)

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