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A Preliminary in Vestigation into the Effects of a Soluble Dietary Fibre and Mineral Formulation on Post-Prandial Glucose Regulation and Satiation in Healthy Adults

Michael Haynes*

Department of Chicago Transit Authority, Chicago.

Corresponding Author: Michael Haynes, Department of Chicago Transit Authority, Chicago.

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Abstract

Prevalence of obesity and overweight has steadily increased over the past decade, urging the development, and refining of various methods of intervention to combat the epidemic. Glucomannan is a dietary fibre with gelling properties, contributing to satiety. Chromium picolinate is an artificial additive, initially suggested to be an essential trace element, contributing to lipid and carbohydrate metabolism. Fructo-oligosaccharides are among a group of calorie free prebiotics, contributing to mineral absorption. Here, we are presenting an open label, preliminary investigation, to explore the effect of a formulation containing glucomannan, chromium picolinate and fructo-oligosaccharides on post-prandial blood glucose modulation and hunger and satiation in 17 adults (Mean ± SD: age 26.35 ± 5.18 years; height 171 ± 11.22 cm; body weight 73.24 ± 13.23 kg; BMI 24.89 ± 2.72 kg/m^2). Data have shown significant reductions in feelings of hunger (P = > .001), and desire to eat (P= > .001), with no significant effect on blood glucose control. These findings have suggested use of this formulation in dietary intervention, through controlling obesity related parameters.

Keywords: Vestigation, Fibre, formulation, Glucose, Healthy Adults

1. Introduction

In recent years, levels of obesity and overweight in individuals has steadily increased, along with it, health diseases such as atherosclerosis and type 2 diabetes (T2DM), triggering an increasing interest in weight loss and management [1,2,3]. Obesity has been recognised as a disease for decades, since the inception of the World Health Organisation (WHO) in 1948, where it has retained its specification throughout the updating process until this day. It can be argued however, that obesity was not purposefully confronted on a global scale until the 1970's where research centres were established in response to major reports from the United States and the United Kingdom, which shed more light on the many health implications of the disease [4,5]. With the unprecedented outbreak of coronavirus in 2019, recent studies have argued that society now faces one of the most profound public health challenges in modern times, with the pandemic potentially having long term, negative effects on the already threatening obesity epidemic [6]. It is evident that intervention has been well overdue. Surgical interventions such as sleeve gastronomy, gastric bypass and gastric banding have been developed, which are commendable in their ability to significantly contribute to weight loss and be treatment for obese individuals. These procedures help to improve related conditions such as high blood pressure and T2DM. However, being major surgical operations, they come with associated medical risks including blood clots, wound infection, and malnutrition [7,8]. Dietary intervention on the other hand, comes with no such serious risk.

A healthy diet, as a part of a wholesome lifestyle is widely accepted as one of the most efficient ways to combat the ever-looming concern of obesity, being the advised initial tactic not only for individuals who suffer from metabolic syndrome, but also those who are seeking to optimise their nutrition [9]. However, with the plethora of studies supporting dietary intervention as a method of weight and disease management, comes a pool of information which makes the specifics of a universally 'healthy diet' difficult to define for scholars, let alone the average individual. Food intake should be varied according to personal needs, with research supporting various dietary practices such as high fat-low carbohydrate, very-low fat, and high-fibre among others for assistance in weight management. Stimulation of body fat loss, body water fluctuation and changes in hunger and compliance levels, result from the application of either of these practices, through mechanisms such as ketosis and neurochemical modification [10,11]. Despite dietary interventions' success, positives tend to be over the short term, often associated with weight gain in the longer term. With the invasive nature and risks associated with surgeries, considerable levels of commitment to lifestyle changes through traditional diets,

pharmacotherapy is at times a key alternative for individuals [12]. Despite this seemingly last hope, several drugs have been withdrawn from distribution following some adverse effects, highlighting that there are actually very limited options for treatment via pharmacotherapy [12]. Therefore, it is crucial for chemical compounds to be further advanced, to safely tackle and efficiently treat obesity. Well-known and studied dietary supplements include, but are not limited to, *Irvingia Gabonensis*, fibre complexes, Chromium picolinate (CrPic) and green tea [13].

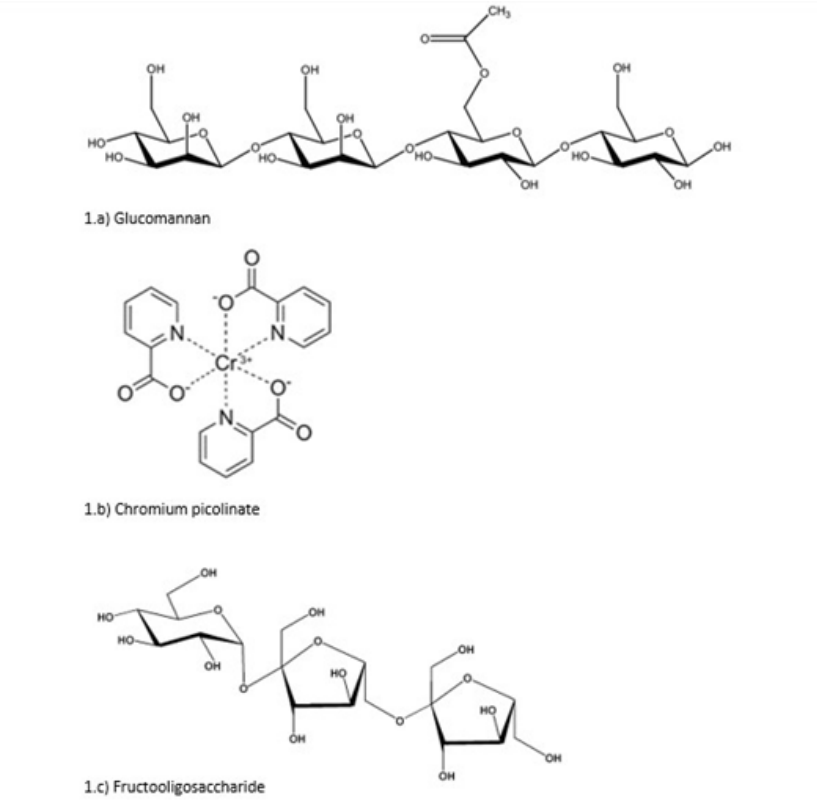


Figure 1: Molecular Structures of a) Konjac Complex of D-glucose and D-mannose Links, with Acetyl Group Attached b) Chromium Picolinate Complex, Consisting of Chromium(iii) and Picolinic Acid c) A Fructooligasaccharide Complex with D-fructose, D-galactose and D-glucose Links (RFO: Raffinose). Based on National Center for Biotechnology Information (2022).

Intaking dietary fibre is shown to be beneficial in its ability to minimise the risk of developing obesity, diabetes, stroke, and coronary heart disease [14-19]. Additionally, links have been found between fibre consumption and improvements in blood glucose control in T2DM patients, blood pressure reduction, and improvement in serum lipid concentrations [20-22]. Glucomannan is a fermentable, soluble fibre obtained from the roots of the herbaceous perennial plant *Amorphophallus rivieri / Amorphophallus konjac* [23]. This fibre is comprised of a polysaccharide chain with β (1 –4) links, having a backbone of D-mannosyl and D-glucosyl units with acetyl groups attached (**Figure 1a**) [23]. The weight management applications of glucomannan are considered to arise from its ability to increase levels of satiation, displacing other nutrient's energy through its water absorptive properties. The molecule is also able to interact synergistically with other polymers, making it efficient in drug delivery applications such as a component of food additives and fibre supplements [23,24]. Recent meta-analysis and reviews have yielded contrasting results for glucomannans ability to contribute to weight loss. In six randomised clinical trials, one of which included children, it was determined that in otherwise healthy, overweight adults, there is evidence supporting glucomannan's ability to reduce body weight over the short term, but not BMI [25]. Onakpoya however, concluded that glucomannan intake did not have a statistically significant impact on weight loss, emphasising the need for more rigorous and better reported clinical trials [26].

Most studies, however, show positive effects, with additional benefits when used in conjunction with other chemicals. MaiaLandim reported that a 500g dose of glucomannan with 500g of Garcinia *cambogia* produced weight loss, reducing fat mass, visceral fat, lipid, and blood glucose profiles while increasing basal metabolic rate. Chromium picolinate is an artificial additive, initially suggested to be an essential trace element for mammals by increasing insulin sensitivity (**Figure 1b**), contributing to lipid and carbohydrate metabolism [27,28,29]. The compound's effects have since been revaluated, with its current significance debatable [27,30]. CrPic supplementation has been linked with some improvements in body composition, specifically body fat percentage and body weight in participants who were overweight and obese [31]. A recent study revealed that a 400µg dose of CrPic daily, significantly reduced insulin

secretion, triglycerides and fetuin-A, while increasing the quantitative insulin sensitivity check index (QUICKI) in patients with non-alcoholic fatty liver disease (NAFLD) [32]. These results corroborated earlier conclusions that both a 400µg and 600µg dose of CrPic has beneficial effects on glycaemic control, with the ability to maintain lean body mass and improve body composition, without affecting the lipid profile [33,34].

Contrarily, it was determined that in controlled energy intake conditions, CrPic supplementation at a dose of 200µg had no independent influence on body composition in a sample of women [35]. It was assumed that a daily dosage of 400µg CrPic has no effect on levels of HDLs, LDLs or HbA1C, and it was determined that further study is required to verify the effect of varying the dosage of chromium on these factors, Prebiotics are another dietary supplement that has brought about speculation surrounding their involvement in weight management [32,33]. Fructo-oligosaccharides (FOS) are among the main group of prebiotics, occurring naturally in a few plant species, having a composition of straight chain fructose units linked with β (2-1) bonds (**Figure 1c**). Oligosaccharides are produced via hydrolysis of polymers through enzymatic action, such as transglycosylation reactions and inulin hydrolysis (**Figure 2**) [36,37]. To establish claims of a substance having prebiotic properties, human trials must ultimately be performed. In early comparative studies exploring the fermentation sensitivity of various FOSs, lactulose and inulin, it was reported that FOS had the highest selectivity at pH 6.8 and at 1% (w/v) substrate [38]. FOS have been found to be calorie free, possess a low sweetness intensity, and are considered a soluble dietary fibre, with benefits of improving mineral absorption and having a stimulatory impact of the prebiotic effect, whilst being non-carcinogenic and non-digestible [39]. In an investigation exploring the effects of oligosaccharides on natural ingredients in the presence of inulin, it was determined that independent of lifestyle change, supplementation of FOS may be able to offer beneficial mpacts on body weight and composition, validating its function as a food supplement, specifically in cases of chronic disease [40].

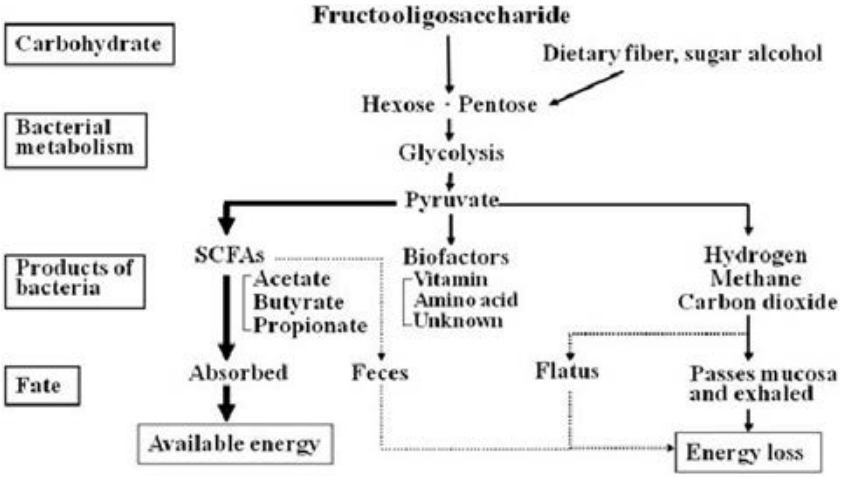


Figure 2: The metabolic pathway of fructooligosaccharide through gut microbiota (Oku 2017)

Each of the molecules' ability to influence body composition has been explored to some capacity, with each study yielding an assortment of conclusions, whether in favour or disproval of their use. However, to date, only two studies exist to have explored the impact of a combination of glucomannan, CrPic and FOS for their combined ability to affect anthropometric parameters. It was found that within a calorie restricted diet, a combination of agglomerated glucomannan, FOS and CrPic, may be beneficial in managing obesity related parameters, reducing subjective feelings of hunger and improving mood [41]. Neither of these studies, however, explored the combination's impact on blood glucose levels or the insulinemic response. Slimbiome® is a microbiome formulation with a combination of natural ingredients with claims to help reduce body weight while accelerating and aiding the sustainability of weight loss. Containing active ingredients such as glucomannan, FOS and CriPic, the product has the capacity to assist blood glucose modulation and stimulate positive gut flora, making it a vital to examine the extent of its proficiency as a nutritional aid. With the increase in pharmacological products that claim to have weight management advantages, it is evident that the benefit of appropriate supplementation is not fully understood. Consequently, improper dietary practices are employed, that are non-essential and at times even counterproductive. The aim of this pilot, open label, human intervention study is to investigate the effect of a combination of agglomerated glucomannan, CrPic and FOS, on the insulinemic response, blood glucose concentration, satiety, and satiation in healthy adults.

2. Methodology

2.1 Study Design and Setting

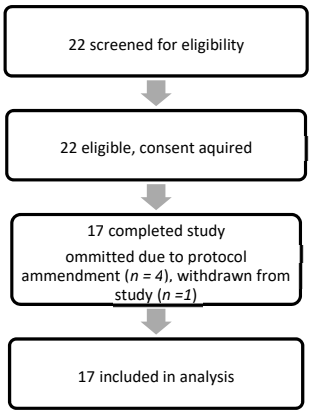
This study was a single group, prospective, open label pilot study, completed in the Sport and Exercise Science Research Laboratory, at Whitelands College of the University of Roehampton. The response variables measured in the study were blood glucose concentration pattern and subjective perceptions of various aspects of satiety, following the oral administration of a test solution containing a combination of dextrose, agglomerated glucomannan, fructo-oligosaccharides and chromium picolinate. The study was

subject to approval by the University of Roehampton ethics committee (**ID: LSC 18-238**).

2.2. Inclusion/ Exclusion Criteria

The study was comprised of a total of 17, healthy, adult volunteers, both men and women (Mean ± SD: age 26.35 ± 5.18 years; height 171 ± 11.22 cm; body weight 73.24 ± 13.23 kg; BMI 24.89 ± 2.72 kg/m^2). The full sample characteristics of volunteers who completed the entire study are laid out in **Table 2**. Individuals were eligible for inclusion in the study if they were within the 18 – 65-year age range and had a BMI >18.5 and <35 at the point of study entry. Individuals were not suitable for participation if they were: using fibre supplements at the time, had a known intolerance to foods and/ or glucose and fibre supplements, intending to modify current levels of physical activity, had any disorders that may have an impact on motility and satiety (difficulty swallowing, intestinal obstruction, inflammatory bowel disease, diverticulitis etc), had unstable metabolic conditions associated with body weight fluctuations (T2DM, hypothyroidism), or on medication that may potentially influence food absorption or body weight (anorexigenic agents, diuretics, anabolic aids). If there were to be a case of illness requiring medical attention, participants were required to inform investigators of the details of the illness including: type of illness, any symptoms suffered, duration and severity of symptoms and any drug prescribed. Other exclusion criteria included pregnancy, abuse of illicit drugs or alcohol, smokers/ recent non-smokers and hypertension (bp >140mmHg systolic/ 90 mmHg diastolic). Volunteers with specific food avoidances or diets, and those that had participated in another experimental trial prior to screening were also excluded from the investigation.

a)



b)

	Screening	Trial 1	Trial 2
Health screening questionnaire	✓		
Informed Consent	✓		
Weight	✓		
Height	✓		
Waist circumference	✓		
Hip circumference	✓		
Blood pressure	✓		
Hunger and satiety questionnaire		✓	✓
Blood sample collection		✓	✓

Figure 3: A) Study Flow Diagram B) Participant Visit Details

2.3. Participants

A total of 22 individuals were contacted and able to pass screening for the study, receiving a detailed briefing of the study design and procedures as well as the aims. All prospective participants were screened on site at the Sport and Exercise Science Research Laboratory. Of the total, 17 participants met the criteria, agreed to participate, and completed the entire study. Due to personal circumstances, 5 volunteers were excluded from the study.

2.4. Intervention

Participants attended the Sport and Exercise Science Research Laboratory on three separate occasions; visit 1 (screening/ familiarisation), visit 2 (control trial), and visit 3 (test trial), respectively. During the screening visit, the participants were asked to sign a consent form and complete a health and safety questionnaire. Considering there was eligibility through screening, anthropometric measurements such as height, weight and hip and waist circumferences were obtained from prospective participants. To accurately record waist circumference, participants were requested to stand upright and exhale, with measurement obtained just above the navel at the smallest part of the waist, while for hip circumference, the distance around the widest part of the buttocks was measured. Participants' body composition was also assessed by bioelectrical impedance, using a Tanita BC-418 (Tanita corporation, Japan), recordings of blood pressure were also obtained (Nissei, model DS-1902, Japan Precision Instruments, Inc., Gunma, Japan). From recordings of height and body weight, and hip and waist circumference, calculations could be made to determine BMI and hip: waist ratio respectively (see **Table 2** for full characteristics). For each study day (visits 2 and 3), participants were required to perform an overnight fast (10 hours) before attending the lab, where they ingested one of two different solutions; trial 1: 250ml water and 50g dextrose, trial 2: 250ml water, 50g dextrose and 3g Slimbiome® (agglomerated glucomannan, CrPic and FOS). Blood samples were then collected at set time points for analysis. Participants were also required to fill out questionnaires which assessed their subjective perception of aspects of satiety and cravings (see **Table 1**).

TIME POINT (minutes)	ACTION TAKEN	TRIAL 1	TRIAL 2
-30	Blood sample	✓	N/A
-15	Blood sample	✓	N/A
0	Blood sample	✓	✓
	SATIETY QUESTIONNAIRE		
	SOLUTION CONSUMPTION (DEXTROSE / SLIMBIOME+DEXTROSE)		
15	Blood sample	✓	✓
30	Blood sample	✓	✓
45	Blood sample	✓	✓
60	Blood sample	✓	✓
75	Blood sample	✓	✓
	SATIETY QUESTIONNAIRE		
90	Blood sample	✓	✓
120	Blood sample	✓	✓
150	Blood sample	✓	✓
	SATIETY QUESTIONNAIRE		

Table 1: Data Collection Specification at Various Time Points Throughout Trial Visits

2.5. Response Variables

2.5.1a. Blood Glucose Concentration and Patterns

To measure the efficacy of the food supplement on managing blood glucose concentration, blood samples were collected in visits 2 and 3 and examined using a lactate and glucose analyser (Biosen C-line, EKF Diagnostics, Inc.,). After a brief period of applying heat to the hand (≈3 minutes), blood was collected using a lancet and a capillary tube, which was then placed in an EKF 'safe lock' reaction cup for analysis. In trial 1 (control solution), baseline glucose readings were recorded at time points, t = -30, -15 and then 0 minutes, where the glucose solution was ingested at t = 0. The timer was reset and restarted upon complete consumption of the solution, with subsequent blood glucose measurements being taken at 15, 30, 45, 60, 75, 90, 120 and 150 minutes after intake. In trial 2 (test solution), baseline glucose reading was measured at t = 0 minutes, where the solution was ingested, followed by a repeat of the blood collection and analysis time points of trial 1.

2.5.1b. Glycaemic Index and Iauc

A key comparison can be made by the glycaemic index (GI) value of a test solution in comparison to a control. The glycaemic index is established using the incremental area under the blood glucose-response curve (iAUC) above the baseline only, after the test food is consumed (Slimbiome® formulation), divided by the corresponding iAUC after the control (dextrose solution) is consumed. The value is multiplied by 100 to represent a percentage of the control food, expressing the equation: GI = ($iAUC_{test\ food}/iAUC_{glucose}$) x 100. The iAUC itself is an estimation of the total area under a curve, calculated by applying the trapezoidal rule. Linking this rule to a blood glucose response graph, simplifies to the equation: $\left(A+B+C+\frac{D}{2}\right)t+\frac{D^2t}{2}(D+|E|)$, where A – E represent areas of positive blood glucose increments in comparison to the baseline and t represents the time interval between blood sample collection (in minutes)

2.5.2. Hunger, Satiety and Cravings

To assess any changes in subjective perceptions of hunger and satiety, a questionnaire consisting of 5 questions was created, reflecting various aspects of satiation and hunger. The questions set were: 'how hungry do you feel?', 'how full do you feel?', 'how strong is your desire to eat?' 'How much food do you think you can eat?' and 'how thirsty do you feel?'. Response was scaled in increments of 10, with 0 representing the absolute minimum, while 100 represented the absolute maximum. The questionnaire was completed at three different points (t = 0, 75 and 150 minutes) in both the control and test solution trials.

Characteristics	Values*
Age (y)	26.35 ± 5.18
Weight (kg)	73.24 ± 13.23
Height (cm)	171 ± 11.22
BMI (kg/m2)	24.89 ± 2.72
Body fat percentage (%)	28.95 ± 9.39
Waist circumference (cm)	81.59 ± 9.20
Hip circumference (cm)	101.65 ± 8.68
Waist: Hip ratio (waist/hip)	0.81 ± 0.06

Systolic blood pressure (mmHg)	118.35 ± 8.39
Diastolic blood pressure (mmHg)	72.89 ± 8.21
*Data expressed as mean ± SD	

Table 2: Clinical Characteristics of Participants at Baseline, who Completed the Study (N=17)

2.6. Data Analysis

All statistical analysis was performed using SPSS v.28.0.15 (IBM SPSS® Statistics, UK). The mean value for baseline readings of glucose in dextrose trials (t = -30, -15) was calculated and used for the statistical analysis. Glucose response data were expressed as means ± standard deviation as reported in **Table 3**. In order to characterise the sample, response variables were tested for normality using the Shapiro-Wilk test. Following the establishment of normal distribution, paired sample t-tests were used to comparatively assess changes between baseline, mid-trial and post-trial, in the subjective scores of questionnaire responses. Additionally, to test for any differences in responses between genders, appropriate t-tests were performed. For the analysis of the difference in changes in glucose response between the control group and each test group, the Mann-Whiney U test was used, after failing normality confirmation with the Shapiro-Wilk test. Statistical significance was set at $p \leq 0.05$.

3. Results

3.1. Participants

A total of 17 participants completed the entire study. There was not a significantly predominant sex group, as the total constituted of 8 men and 9 women. Participants represented a variety of racial and ethnic groups and the age ranged between 19 – 40 years, with a mean of 26.35 years. Participant BMI ranged between 20.3 – 31.3 kg/m2, with a mean of 24.89 kg/m^2. Of the total study group, 10 were classified as normal (18.5 – 24.9 kg/m^2), 5 as overweight (BMI 25–29.9 kg/m^2) and 1 as obese (BMI 30 – 34.9 kg/m^2). A total of 22 participants were contacted and began trials for the study, however 4 were excluded as a result of a change in clinical approach, while 1 was excluded for failure to adhere to protocol. Blood pressure was normal for all participants (<140/90 mmHg) when measured at screening, and there were no reports of health conditions that may have affected the outcomes of the investigation.

3.2a. Blood Glucose Concentration

Figure 4 reports the changes in blood glucose concentration following the ingestion of either the control or test formulation. Consumption of both control and test solutions resulted in a significant difference in post prandial blood glucose concentration, by an average of 172% and 168% from baseline to peak in control and test solutions respectively (**Figure 6**) ($P = < .001$ *and* $P = < .001$). After homogeneity was established, the Tukey test yielded that there was statistically significant difference between baseline and peak glucose concentration, but not between baseline and post when observing the control solution ($P = .001$ *and* $.072$ respectively). A similar result was also produced for the test solution, however, the difference between peak concentration and post concentration was even less statistically significant (baseline – peak, $P = .001$; baseline – post-trial, $P = .460$). When looking at differences between men and women (**Figure 5, a - b**), men had a 166% and 177% increase from baseline to peak blood glucose concentration in control and test solutions respectively, which were significant ($p = < .001$). Computing the significance of the difference in the means of control and test solution when administered in men, reveals that the difference between them is both statistically significant and important (Cohen's d = 1.32833). Women had a 178% and 161% increase from baseline to peak blood glucose concentration after ingestion of both solutions ($P = < .001$). The difference in percentage increase from baseline to peak glucose concentration in women after solution ingestion, though also significant, reflected a smaller effect size in comparison to men (Cohen's d = .61622).

3.2b. Glycaemic Index and Iauc

Applying the calculation for iAUC, the estimated area under the blood glucose response curve for the control solution equates to 168mmol.min/L, whereas the test solution was shown to have a value of 156mmol.min/L. Substituting these values into the GI formula $\left(\left(\frac{156}{168}\right) \times 100\right)$ results in an average GI value of 92.9%. When examining GI differences in genders, men had an iAUC value of 143.1mmol.min/L and 181.8mmol.min/L for control and test solutions, respectively. The test solution therefore has a GI value $\left(\left(\frac{181.8}{143.1}\right) \times 100\right)$ of 127% of the control in men. In women, the iAUC values were 215.25mmol.min/L and 161.025mmol.min/L for control and test solutions, respectively. GI value $\left(\left(\frac{161.025}{215.25}\right) \times 100\right)$ of the test solution is therefore 74.8% of the control in women.

3.3. Hunger, Satiety and Cravings

Descriptive statistics of the mean score, standard deviation, and standard error means were run for each question, representing participants' subjective rating of various aspects of satiety, in both control and test solution trials (see **Table 3**). Comparisons of mean responses to all parameters of hunger satiation and cravings after consumption can be visualised in **Figure 7** for both the control and test solutions. No statistically significant differences were observed in the response scores for the level of hunger felt and feeling of fullness at 75 minutes post consumption of the test solution, however there was a significant difference between these response scores at 150 minutes after consumption ($P = .001$). There was no statistically significant difference found in the mean change in scores for how much food participants thought they could eat and their desire to eat following ingestion of the test solution at both mid-trial and post-trial levels of assessment. There was however a significant difference in the mean change in how thirsty participants felt following ingestion of the test solution at both mid-trial ($P = .002$) and post-trial levels ($P = .002$). Questionnaire response showed a significant and very strong positive correlation between feelings of hunger and the desire to eat at 75 minutes

after test solution consumption (*r = .800**, P = < .001*), and a slight positive correlation between the desire to eat and the amount of food believed could be eaten, though this was statistically insignificant. The strong positive correlation between desire to eat and feelings of hunger increased further at 150 minutes after test solution consumption, which was again statistically significant (*r = .895**, P = <.001*). The desire to eat and the amount of food believed could be eaten were moderately, negatively correlated, with statistical significance (*r = .752**, P = <0.001*). There were no significant associations between levels of thirst and any other variable.

	Control (Dextrose solution)				**Test (dextrose+ Slimbiome® formulation)**			
	Mid-trial (75 minutes)		**Post-trial (150 minutes)**		**Mid-trial (75 minutes)**		**Post-trial (150 minutes)**	
	Mean ± SD	**SEM**	**Mean ± SD**	**SEM**	**Mean ± SD**	**SEM**	**Mean ± SD**	**SEM**
How hungry do you feel?	56 ± 29	6.9	76 ± 23	5.6	44 ± 19	4.6	58 ± 24	5.9
How full do you feel?	31 ± 28	6.9	15.2 ± 15	3.5	42 ± 18	4.5	31 ± 19	4.7
How strong is your desire to eat?	59 ± 26	6.3	79 ± 25	6	46 ± 22	5.4	61 ± 26	6.3
How much food do you think you can eat?	60 ± 22	5.2	76 ± 22	5.4	53 ± 16	3.8	61 ± 21	5.1
How thirsty do you feel?	38 ± 21	5.1	48 ± 20	4.9	44 ± 24	5.9	36 ± 23.2	5.6

Table 3: Mean ± Sd and Sem of Questionnaire Data Parameters, Measuring Various Aspects of Hunger, Satiety, and Craving Scores after the Administration of Control and Test Solutions (*N* = 17)

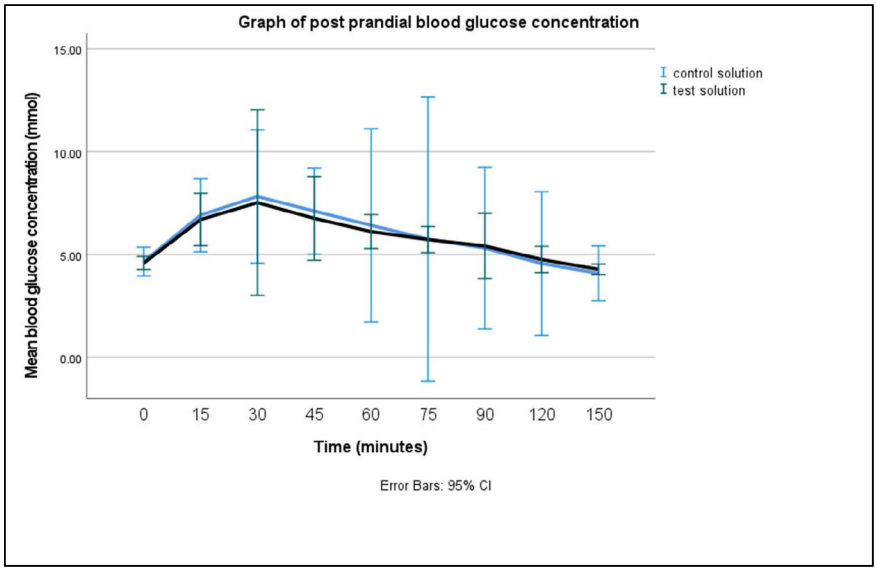


Figure 4: The Effects of a Formulation Containing Slimbiome® (A Combination of Glucomannan, Crpic and Fos) and Dextrose on Post Prandial Blood Glucose Concentrations Following an Overnight Fast

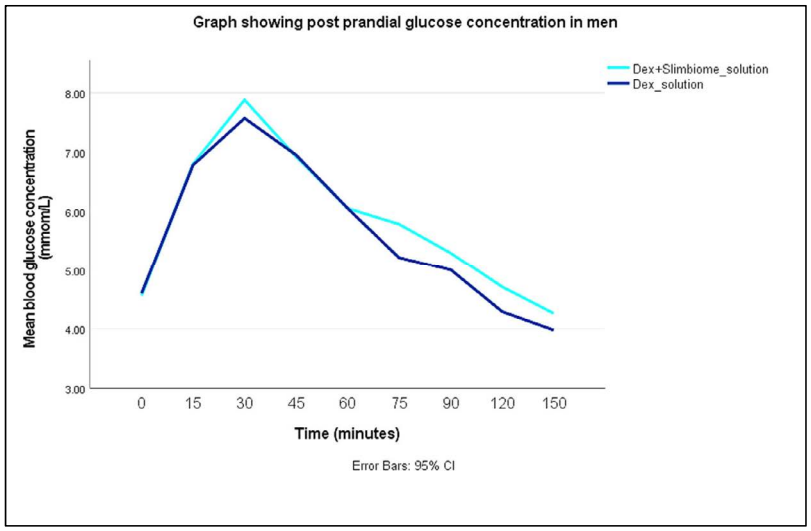


Figure 5a: The Effects of a Formulation Containing Slimbiome® on Post Prandial Blood Glucose Concentration in Women. Test Solution Resulted in a 161% Increase in Baseline Blood Glucose Concentration to Peak (p < .001)

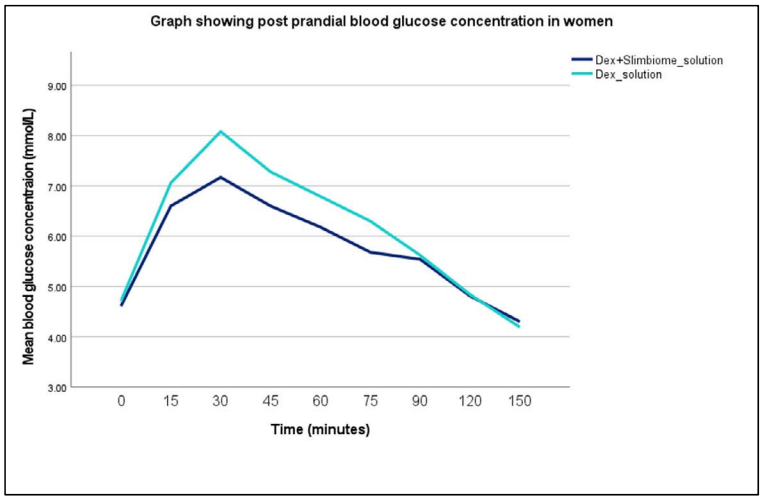
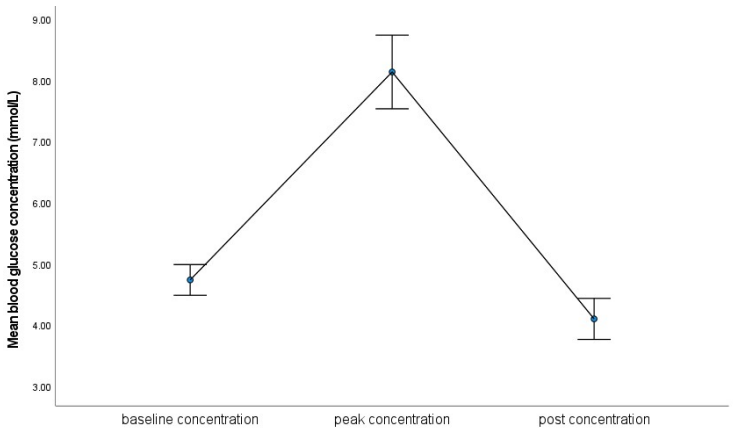


Figure 5b: Graph Showing Effects of a Formulation Containing Slimbiome® on Post Prandial Blood Glucose Concentration in Men. Test Solution Resulted in a 177% Increase in Baseline Blood Glucose Concentration to Peak (*p < .001*)

Control solution

Slimbiome® formlation



Control solution

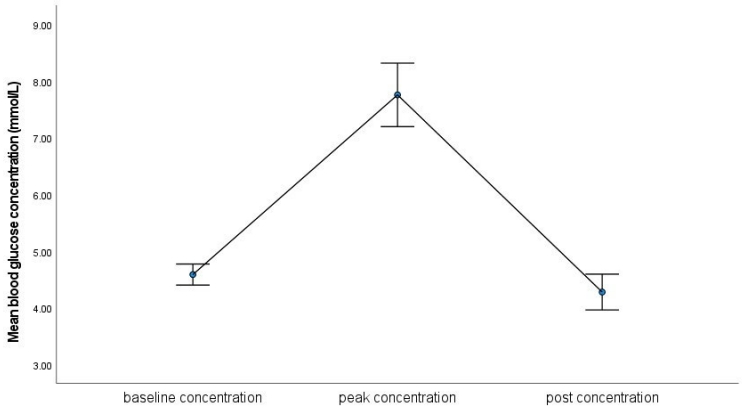


Figure 6: Average Changes in Blood Glucose Concentration from Baseline to Peak to Post Trial in Both Control and Test Solutions. (*p = <.001, p = < .001*)

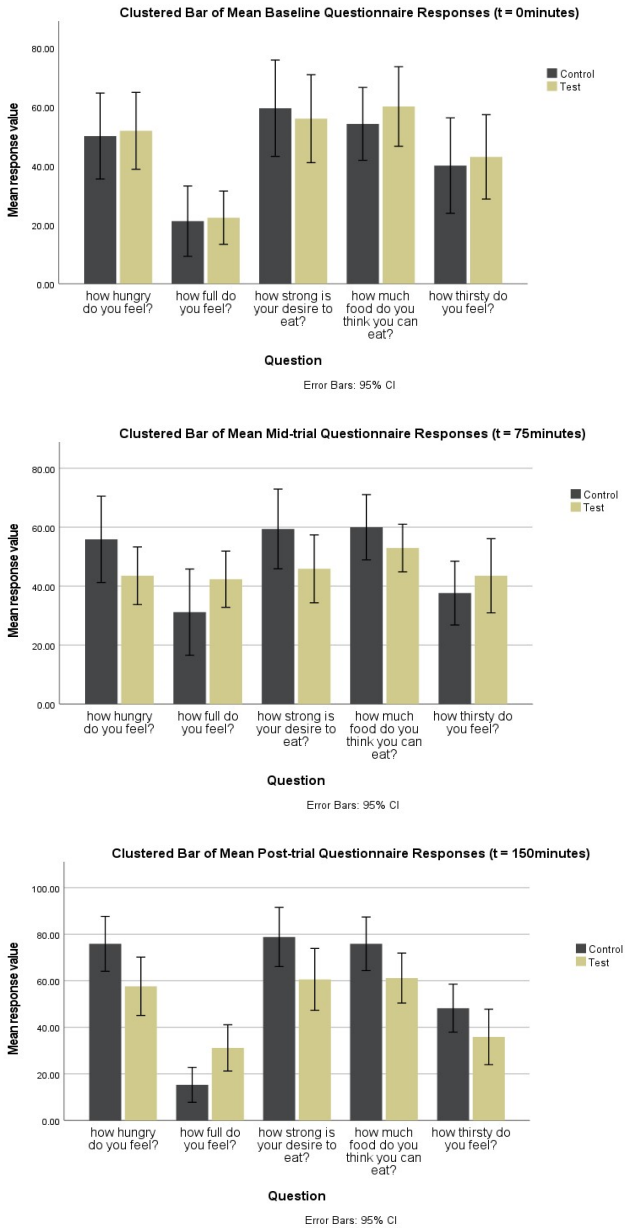


Figure 7: Changes in Reported Levels of Hunger, Satiety, and Craving. Clustered Bar Charts Show Means and ± sd for Control and the Test Groups at Different time Point (t = 0, 75 and 150 minutes). Correlation Response Scores Showed a Significant, Strong Positive Correlation between Feelings of Hunger and the Desire to eat at 75 and 150 Minutes after Test Solution Consumption (*r = .800, p = < .001 and r = .895, p = <.001*)

4. Discussion

This preliminary study aimed to explore the effect of a food supplement formulation, containing a combination of agglomerated glucomannan, chromium picolinate and fructooligosaccharides on post-prandial blood glucose concentration, and hunger and satiety in healthy adults. The data revealed that though the Slimbiome® formulation resulted in a peak glucose concentration that was comparatively, on average, lower than the control solution, the positive effect was not statistically significant. This contrasts the anticipated impact which a solution containing chromium is understood to have. CrPic has been shown to facilitate insulin action and improve glycaemic control in patients with T2DM, with multiple studies reporting significant improvement in glycaemic control through chromium mono-supplementation [33,42,43]. This investigations' results deviating from this trend may possibly be explained by the enrolment of healthy individuals. Many of the previous studies used exclusively obese and overweight participants, including participants already with, or at elevated risk of obesity related disorders. These studies may have shown CrPic to have a higher positive impact on glucose response parameters, as the corresponding mechanisms such as insulin and glucose sensitivity were already limited/ impaired by the study sample. Another plausible reason may be due to the dose of CrPic in the test solution. Earlier studies that mirrored a lack of the expected effect from CrPic on response variables, such as anthropometric characteristics, LDLs and HbA1c, were able to attribute this to the administered CrPic dosage [32].

Furthermore, the idea of increasing CrPic supplementation to optimise its efficacy in improving blood glucose modulation, without adverse effects, may in fact be feasible. Previous research showed positive impact on fasting plasma glucose and HbA1c levels in T2DM patients, with daily supplementation ranging between 200µg - 1000µg [44]. However, this notion could be disputed by other findings, where varying the dosage of CrPic supplementation between 200µg - 400µg, showed that despite a statistically significant improvement in hormone modulation and body mass compared to the placebo group, there was no difference between the test groups [45,46]. The data suggests that, though the reduction in peak blood glucose concentration was nominal, this, combined with a lower difference between post-trial concentration and baseline, there is an overall more positive effect than implied. The more substantial impacts of the test drug appeared to be related to aspects of hunger, satiety and cravings. It was observed that the test group on average had lower response scores for how hungry they felt, and how strong their desire to eat was, at both mid-trial and post-trial time points. This can be attributed to the gelling properties of agglomerated glucomannan, resulting in sustained feelings of satiation. These results corroborate findings of previous studies exploring the use of supplementary glucomannan as a dietary intervention method to aid weight loss. In a randomised, 4-week intervention study, it was found that obese and overweight women measured a significant reduction in feelings of hunger after consumption of a solution containing Slimbiome® [41]. Not only does Slimbiome® show positive effect on reducing levels of hunger, but it may potentially play a role in delaying the onset of hunger. This can be also attributed to glucomannans ability to delay gastric emptying, by expanding in the stomach upon hydration it promotes nutrient displacement and improves feelings of satiation [23].

There does seem to be debate surrounding the ideal efficacious dose regarding glucomannan and weight loss, however, some studies have shown positive impacts of mono-supplementation at as low as 1.2g, with no significant difference in outcomes when this was increased to 4.3g [47]. Other studies found that introducing glucomannan in 1g dosages at 3 set time points throughout the day was effective and delivered the EFSA recommended 3g daily in conjunction with a calorie restricted diet [48]. Earlier research which found glucomannan to have insignificant effect on response variables: glucose parameters, satiation and body composition attributed their results' contrast to other studies to the absence of a regimented eating pattern [23]. A tailored dietary intervention does indeed have benefits in comparison to generic strategies, however, multiple studies have demonstrated positive associations even with the absence of caloric management, this present study further adding to that [24,48]. As a preliminary investigation, the current study does have limitations. Firstly, the adjusted sample (n = 17) was small. As smaller sample sizes are subject to type 2 error, this could potentially justify lower effects of test solution on parameters such as blood glucose concentration. Additionally, the investigation did not allow for evaluation of long-term impacts of intervention. Many studies have explored more moderate durations, with favourable results found within a 4-week period, but longer-term assessment is still outstanding. Despite these constraints, this investigation has highlighted the potential of a combination of agglomerated glucomannan, CrPic and FOS to have beneficial impacts as a dietary intervention method [41,49-53].

5. Conclusion

This preliminary study has shown that the supplementation of a mineral formulation containing glucomannan, CrPic and FOS, ingested in combination with dextrose, led to significant reduction in hunger levels and the desire to eat. This mixture delayed an increase in hunger levels, as participants felt more satiated for longer periods of time in comparison to the control solution containing dextrose only. Moreover, the effect on post-prandial blood glucose response is influenced by sex, with women having a lower percentage increase in blood glucose compared to men. These results could have potential applications in tackling weight loss and other obesity related concerns. These data are in line with the literature published to date, exploring the effects of monosupplementation, or when used in combination. Levels of obesity has steadily increased and as such, the need for efficient dietary interventions and weight loss approaches is imperative. Additional studies are required to determine the efficacy over the long term, with intervention on a larger scale population.

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