An observational study comparing the effects of whey and vegan meal replacements containing PolyGlycopleX® over 12-weeks in healthy adults

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Abstract

Purpose – Background/Objectives: Protein-based meal replacements (MR) with viscous soluble fibre are known aids for weight loss. This study aims to compare the effects of new whey and vegan MR containing different amounts of PGX (PolyGlycopleX) on weight loss over 12 weeks, along with a calorie-restricted diet.

Design/methodology/approach – Subjects/Methods: Sixty-eight healthy adults of both sexes (53 women; 15 men; average age 47.1 years; BMI $31 \pm 7.1\,kg/m^2$ and weight $85.05 \pm 23.3\,kg$) were recruited. Participants consumed a whey or vegan MR twice/d (5–10 g/day PGX) with a low-energy diet (1,200 kcal/day), over 12 weeks. Weight, height, waist and hip circumference were recorded (four time periods).

Findings – Results: Forty-four participants completed the study. Results showed significant reductions in average body weight and at week 12, whey group was [$-7.7\,kg \pm 0.9$ (8.3%), $p < 0.001$] and vegan group was [$-4.5\,kg \pm 0.8$ (6.2%), $p < 0.001$)]. All participants ($n = 44$; BMI 27 to $33\,kg/m^2$) achieved significant reductions in body measurements from baseline to week 12; $p < 0.001$. Conclusions: Supplementation of protein-based MR with PGX and a balanced, low-energy diet, appears to be an effective approach for short-term weight loss.

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Institutional review board statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Canadian SHIELD Ethics Review Board, Ontario, Canada (protocol code 2021-04-003; date of approval June 16, 2021).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Conflicts of Interest: JS is an employee of Isura and declares no other conflict of interest. RJG is the owner of the Factors Group of Companies and holds various patents on PGX. SW receives consulting fees from InovoBiologic Inc. and has an InovoBiologic Inc patent pending on PGX.

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Research limitations/implications – As the authors were evaluating if the MR as a whole (i.e. with PGX) caused weight loss from baseline over the 12 weeks, no comparators, i.e. just the MR without PGX, were used. Formulation of these new MRs resulted in a whey product with 5 g PGX and a vegan product with 2.5 g PGX. Only 2.5 g PGX could be formulated with the vegan protein due to taste and viscosity limitations. Study participants were not randomized and no control groups (e.g. no MR or MR without PGX but with energy restricted diet) were used. Furthermore, it is not clear whether the sort of protein alone or the combination with a higher amount of PGX (whey with 5 g PGX/serving vs vegan with 2.5 g PGX/serving) has contributed to these significant greater weight-loss effects. This was something the authors were testing, i.e. could only 2.5 g PGX/serving have an effect on weight loss for a vegan MR. These limitations would be somethings to evaluate in a subsequent randomized controlled study. Hence, the results of this study may serve as a good starting point for further sophisticated randomized controlled trials that can demonstrate causality – which the authors acknowledge as one of the fundamental limitations of an observational study design. Participants tracked their calories but adherence and compliance were self-assessed and they were encouraged to keep their exercise routine consistent throughout the study. Hence, these are further limitations. No control group was used in this study to observe the effect of the dietary intervention and/or physical activity on weight loss alone. However, a goal of the authors was to keep this study as close to a real-life situation as possible, where people would not be doing any of these measurements, to see if with minimal supervision or intervention, people can still lose weight and alter their body composition. Furthermore, differences in gender and the corresponding weight loss effects in response to MR-protein-based treatments could be evaluated in follow-up studies.

Practical implications – This study indicates that the consumption of protein-based (animal, whey or plant, pea protein) MR incorporating the highly soluble viscous PGX is beneficial for weight loss when combined with a healthy-balanced, calorie-restricted diet. MRs at either 2.5 g or 5 g per serving (RealEasy™ with PGX) proved to be a highly effective as a short-term solution for weight loss. The observed results are encouraging, however, further long-term studies (i.e. randomized clinical trials RCT) are needed to confirm the clinical relevance. RCTs should focus on the individual effects of PGX and/or the different protein sources used in MRs, on weight loss and the maintenance of the reduced body weight, and should measure detailed blood parameters (lipid profiles, glucose etc.) as well as collect detailed exercise and food consumption diaries.

Originality/value – To the authors' knowledge, this is the first study comparing a whey versus vegan, (as pea) protein-based MR that is supplemented with fibre PGX; thus, this work adds information to the already existing literature on fibre (such as PGX) and MRs regarding their combined weight loss effects. The purpose of this study was to observe if the novel protein-based (either whey or vegan versions) MR RealEasy™ with PGX at 2.5 or 5 g in addition to a calorie-restricted diet (total of 1,200 kcal/day) would aid in weight loss in individuals over a 12-weeks period. Adding increasing amounts of whey protein and soluble fibre can help reduce subsequent ad libitum energy intake which could help adherence to energy restricted diets, but whether similar effects are seen with vegan protein is unclear – this study does aim to address this.

Keywords Overweight, Weight loss, Obesity, Fibre, Meal replacement, PolyGlycopleX®

Paper type Research paper

1. Introduction

It is well known that being overweight or obese [body mass index (BMI) $\geq 25\ kg/m^2$] can lead to numerous health concerns and conditions such as cardiovascular disease (CVD), type 2 diabetes and certain forms of cancer (Centers for Disease Control and Prevention, 2021). The obesity epidemic is not just restricted to industrialised countries but often progresses even faster in developing countries (World Health Organization, 2021). As countries become wealthier, the number of people with obesity or overweight increases significantly worldwide, which is partly due to the increased intake of more energy-dense and nutrient poor foods – rich in sugars and saturated fats (Crino *et al.*, 2015). While genetic disposition is one important factor in determining susceptibility to weight gain, energy balance defined by calorie intake and physical activity significantly affects the weight status.

Effective weight management for individuals and those who are at risk of developing obesity involves a range of long-term strategies. These include prevention, weight

maintenance and management of co-morbidities and weight loss. One approach that aids in the reduction of calories while providing optimal amounts of macro- and micronutrients is a safe and sustainable method of weight loss/management by the use of meal replacements (MR). Formulated MRs have played an important role in the management of people with obesity or overweight (BMI$\geq$ 25 kg/m^2) for more than 40 years (Howard, 1981; Maston *et al.*, 2020). MR have been prescribed in the form of a very-low-energy diet but can also be used during a low-energy diet [4,200 to 5,000 kJ, (1,000 to 1,200 kcal)] as a combination with energy-controlled food-based meals (Maston *et al.*, 2020). Numerous clinical trials from the early 1980s and ongoing have proven that MR-based diets containing high-quality protein are a highly effective weight loss intervention in the management of obesity by reducing food cravings and providing a long-lasting feeling of satiety (Astbury *et al.*, 2019; Howard, 1981; Noakes *et al.*, 2004; Maston *et al.*, 2020; Pattinson *et al.*, 2021). Asbury *et al* reviewed 23 studies with 7,884 adults and concluded that:

> Programmes incorporating meal replacements led to greater weight loss at 1 year than comparator weight loss programmes and should be considered as a valid option for management of overweight and obesity in community and health care settings (Astbury *et al.*, 2019).

By law in Canada (Canadian Food Inspection Agency, 2019), where this study was performed, MR products must provide the recommended amount of nutrients needed for good health and their composition must conform to certain standards (i.e. the food and drug regulations set by the government of Canada). Replacing meals with MR shakes (typically formulated to provide high-quality protein) should help reduce daily calories and, therefore, assist in losing weight in the short and long-term. One concern regarding MR diets is how to re-introduce a healthy food-based diet after weight loss (Maston *et al.*, 2020; Pattinson *et al.*, 2021). However, a recent study conducted on postmenopausal obese women found that either a total MR diet or a food-based diet can lead to long-term (1 year) improvements in diet quality. The authors also emphasize the importance of adding more vegetables, whole grains, dairy products, as well as calcium supplementation to the diet to meet dietary recommendations (Pattinson *et al.*, 2021). The role of fibre is considered a critical aspect in the diet due to its numerous health benefits – such as reducing blood lipids, improving glucose levels and enhancing satiety, which can reduce food intake and, thus, help with weight loss (Lambert *et al.*, 2014). Even though data in adults suggest the importance and the possible beneficial effects of fibre intake on various health outcomes, relatively few individuals achieve the recommended daily target, with the current recommendations for dietary fibre intake for adults between 30 and 35 g per day for men and 25–32 g per day for women (Barber *et al.*, 2020). Since these recommendations are difficult to reach through dietary means alone, fibre supplementation, especially with soluble fibre products, may present a convenient option to help increase daily fibre intake (Barber *et al.*, 2020).

Epidemiological evidences indicate that dietary fibre in either soluble or insoluble form can help reduce weight in adults with obesity or overweight and, thus, may be beneficial in tackling obesity and obesity-related cardio-metabolic diseases (Ruheea and Suzuki, 2018; Bozzetto *et al.*, 2018). In this study, the MRs have been carefully formulated to balance as many vitamins, minerals etc. as possible to meet Canadian regulations. More importantly, PGX has been added as an excellent source of fibre to complement a MR diet. PGX® (PolyGlycopleX®) is a highly soluble viscous fibre complex manufactured from three types of soluble fibre using a proprietary process (EnviroSimplex®): konjac (glucomannan), sodium alginate and xanthan gum. Based on research, PGX provides similar benefits to other soluble fibre products such as psyllium (Jane *et al.*, 2019). Previous studies have found that PGX not only has favourable results for weight loss/management (Reichert *et al.*, 2013)

but also has beneficial effects on lipids and glycaemia (Solah *et al.*, 2016; Pal *et al.*, 2017), satiety (Solah *et al.*, 2017; Kacinik *et al.*, 2011), blood pressure and arterial stiffness (Pal *et al.*, 2021). However, only a few studies have investigated the weight loss effects of MR-protein based shakes combined with fibre such as PGX. A recent study by Glynn *et al.* found that overweight participants who consumed a high-protein shake (a whey and pea protein blend) supplemented with 6 g fibre (a source of cocoa, pea fibre, xanthan gum, inulin, flaxseed, chicory root and chia seed powder) twice-daily – lost a significant amount of weight over the study period (Glynn *et al.*, 2022).

To our knowledge, this is the first study comparing a whey versus vegan, (as pea) protein-based MR that is supplemented with fibre PGX; thus, this work adds information to the already existing literature on fibre (such as PGX) and MRs regarding their *combined* weight loss effects. The purpose of this study was to observe if the novel protein-based (either whey or vegan versions) MR RealEasy™ with PGX at 2.5 or 5 g in addition to a calorie-restricted diet (total of 1200 kcal/day) would aid in weight loss in individuals over a 12-weeks period.

2. Materials and methods

2.1 Participants

Sixty-eight healthy adults of both sexes (53 women; 15 men; average age 47.1 years), with a mean BMI of 31 ± 7.1 kg/m^2 and mean weight of 85.05 ± 23.3 kg, were recruited through a series of advertisements placed in company flyers (Factors Group, British Columbia, Canada), recruiting people motivated to lose weight. Participants provided written informed consent before participation in this observational study. Participants (BMI of ≥25) who were ≥ 18 years old and of self-assessed good physical condition were included. As exclusion criteria, participants must not have any of the following diseases and/or health conditions: serious acute or chronic diseases – such as liver, kidney or gastrointestinal diseases – which may affect absorption, metabolism and/or elimination of the treatment. The presence of these diseases was self-reported and no proof of medical records was required. Female participants must not have been recently pregnant, planning to get pregnant or be breast-feeding. Participants had to complete an online health screening form upon enrolment to confirm this. Participants could decide to withdraw from the study at anytime – without giving a reason. The overall investigation was conducted in accordance with the ethical standards as set forth in the Helsinki Declaration of 1975 and the study was approved by the Canadian SHIELD Ethics Review Board (IORG0003491, IRB00004157), Ontario, Canada.

2.2 Study design

Study participants could freely decide which protein-based MR they wanted to consume. One group consumed a proprietary MR powder (RealEasy™ with PGX®) containing 25 g whey protein and 5 g of PGX per serving [230 calories (945 kJ)]; and the second group consumed a proprietary MR powder (RealEasy™ with PGX) containing 22 g vegan pea protein and 2.5 g of PGX per serving [230 calories (945 kJ)]. MR were naturally sweetened with stevia, organic cane sugar and xylitol and were available in Vanilla and Chocolate flavours (the formulations are proprietary). The difference in PGX amounts was due to formulation constraints to obtain a palatable product that also met Canadian regulations. MR (RealEasy™) with PGX were taken twice per day (5 or 10 g/day PGX) in place of any two meals, for 12 weeks. Each MR was consumed along with water (250 – 375 mL). Study participants were advised to follow a low-calorie diet, consisting of low-fat, low-glycaemic-index (GI) foods as snacks and another meal for a total of 1,200 kcal/day. A booklet containing simple tips for a healthy diet written by dietitians was provided to participants. Participants tracked their calories throughout the study period; compliance and adherence were self-assessed. All participants were encouraged to keep

their exercise routine consistent throughout the study period. Study participants were evaluated at four different time points: baseline and then on a three-week basis for weight (kg), height, waist and hip (cm) measurements. Waist and hip measurements were recorded using a standard medical-type tape measure at consistent anatomical locations: approximately mid-way between the lowest rib and the iliac crest for the waist and at the level of the greater trochanter around the hip. Body weight, height and anthropometric measures were taken by study assistants at the research facility (PGX Centre, Coquitlam, BC, Canada). The outcome assessors for the evaluations (e.g. weight measurements) were not blinded to the participants. BMI scores were calculated using an online BMI calculator available through the US Department of Health and Human Services (www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm). Any side effects (adverse events and positive side effects) were recorded across different time points e.g. through direct questioning at every visit (research site location) and/or via health surveys at the end of the study period. As we were evaluating if the MR in combination with PGX caused weight loss from baseline over the 12 weeks, no control group was used that compared the effects of MR alone – without the addition/supplementation of PGX. Formulation of these new MRs resulted in a whey product with 5 g PGX and a Vegan product with 2.5 g PGX. Only 2.5 g PGX could be formulated with the Vegan protein due to taste, texture and viscosity limitations. Hence, we were further evaluating if only 2.5 g PGX/serving could have an effect on weight loss for a vegan (pea) MR. Pea protein has been selected as a high-quality plant-protein source (nongenetically modified) in the vegan MR due to its availability, cost-effectiveness, allergenicity, high nutritional value and health benefits.

2.3 Statistical analysis

Results were expressed as difference of means ± SD. Between group differences across different time points (at baseline, week 4, 8 and 12) were analysed with two-way, repeated measures (RM), mixed-factor (between and within subjects' factor) ANOVA and post hoc tests for pairwise comparison (Bonferroni). Changes within group (within subjects) over the different time periods were analysed with one-way RM ANOVA and post hoc tests (pairwise comparison; Bonferroni). As for differences in individual baseline characteristics of the two groups independent t tests were performed for each single characteristic (such as weight, waist, hip and BMI). Data were considered significant at $p < 0.05$. All statistical analyses were completed using IBM SPSS Statistics for Windows (USA, IBM Corp.) and provided figures were developed using GraphPad (CA, USA).

3. Results

3.1 Demographic characteristics

Sixty-eight healthy individuals, primarily female (78%) 47.1 years old, were recruited of which 34 consumed Whey MR and 34 consumed the Vegan MR based on their personal preference (Table 1). After four weeks (phase 1), 16 participants decided to discontinue the study. After eight weeks (phase 2), another eight people dropped out of the study. Overall, 44 participants completed the entire 12-weeks study. There were significant differences in the individual baseline characteristics between participants in the Whey and Vegan group ($p < 0.01$; independent t tests; Table 1). As a group, participants in the Whey MR group showed a significant higher amount of weight (19.3%), BMI (16.9%) and waist and hip circumferences (10.6 and 8.3%) from the baseline ($p < 0.01$ and $p < 0.001$; independent t tests, Table 1).

3.2 Effects of protein-based meal replacements with PolyGlycopleX on body measurements

All participants ($n = 44$; BMI 27 to 33 kg/m^2) significantly lost weight and reduced waist and hip circumferences and BMI over the 12-weeks study period ($p < 0.001$; ANOVA, Tables 2 and 3).

Characteristics	Whey group $n = 34$	Vegan group $n = 34$
Gender (F/M)	25/9	28/6
Age (years)	47.4 ± 11.5	46.7 ± 10.9
Weight (kg)	94.3 ± 27.2*	76.1 ± 14.0*
Waist (cm)	101.7 ± 15.5*	90.9 ± 11.2*
Hip (cm)	117.8 ± 18.0*	108.0 ± 10.4*
BMI (kg/m^2)	33.8 ± 8.2**	28.1 ± 4.2**
Drop-out (%)	35	35

Table 1.
Baseline characteristics

Notes: Values are mean ± SD with $n = 34$ participants; significant difference between groups *$p < 0.01$; **$p < 0.001$ (independent t tests); Drop-out rate (%) calculated after 12 weeks; BMI = Body mass index; PGX®
Source: Author's own work

The BMI scores in both the whey and the vegan group showed a significant reduction from baseline of −2.2 ± 0.5 kg/m^2 ($p < 0.001$; Table 2) and −1.2 ± 0.2 kg/m^2 ($p < 0.001$; Table 3), respectively. Participants in both groups reduced their BMI, weight, waist and hip circumferences, in a similar steady manner between Phase 1 (4 weeks) to Phase 3 (12 weeks). A one-way (within subjects) RM ANOVA indicated that the change in body measurements (such as BMI, weight, waist and hip circumferences) was significantly different during at least one of the time points; post hoc tests revealed that all body measurements significantly changed across the four time points (from the baseline to week 4, 8 and 12; $p < 0.001$, Tables 2 and 3). Participants in the whey group (BMI 33) lost 0.6 kg (1.3 lb) on average per week (Table 2); participants in the vegan group (BMI 27) lost on average 0.4 kg (0.9 lb) per week (Table 3) over the 12-week study

Whey group	Baseline	4 weeks	Change	8 weeks	Change	12 weeks	Change
Weight (kg)	92.5 ± 19.4	86.9 ± 18.5	−5.6 ± 1.0	85.1 ± 18.9	−7.4 ± 1.5	84.8 ± 17.9	−7.7 ± 0.9
Waist (cm)	100.1 ± 16.0	96.7 ± 16.9	−3.4 ± 0.8	94.9 ± 16.5	−5.2 ± 1.8	94.5 ± 15.5	−5.6 ± 1.0
Hip (cm)	116.7 ± 19.0	114.7 ± 18.8	−2.0 ± 0.4	112.8 ± 17.4	−3.9 ± 0.7	112.7 ± 16.8	−4.0 ± 0.8
BMI (kg/m^2)	33.0 ± 2.0	31.6 ± 1.6	−1.4 ± 0.9	30.9 ± 1.7	−2.1 ± 0.4	30.8 ± 1.8	−2.2 ± 0.5

Table 2.
Body measurements of PGX® whey meal replacement group

Notes: Body weight, waist and hip circumference measurements and BMI (body mass index) at baseline, 4, 8 and after 12 weeks. Change from baseline. Data represents mean ± SD with $n = 22$ participants; significant difference in body measurement changes over time $p < 0.001$ (RM ANOVA and post hoc tests)
Source: Author's own work

Vegan group	Baseline	4 weeks	Change	8 weeks	Change	12 weeks	Change
Weight (kg)	73.0 ± 8.6	70.4 ± 8.9	−2.6 ± 0.7	69.2 ± 8.7	−3.8 ± 0.5	68.5 ± 8.0	−4.5 ± 0.8
Waist (cm)	87.2 ± 7.8	86.1 ± 8.0	−1.1 ± 0.3	85.7 ± 8.9	−1.5 ± 0.6	85.0 ± 8.8	−2.2 ± 0.4
Hip (cm)	104.2 ± 8.6	102.7 ± 8.1	−1.5 ± 0.9	101.9 ± 8.3	−2.3 ± 0.7	101.4 ± 8.6	−2.8 ± 1.0
BMI (kg/m^2)	27.0 ± 1.2	26.1 ± 1.7	−0.9 ± 0.1	26.0 ± 1.9	−1.0 ± 0.3	25.8 ± 1.8	−1.2 ± 0.2

Table 3.
Body measurements of PGX® vegan meal replacement group

Notes: Body weight, waist and hip circumference measurements and BMI (Body mass index) at baseline, 4, 8 and after 12 weeks. Change from baseline. Data represents mean ± SD with $n = 22$ participants; significant difference in body measurement changes over time $p < 0.001$ (RM ANOVA and post hoc tests)
Source: Author's own work

period. There was a significant difference between the two groups ($p < 0.001$; two-way, mixed factorial, RM ANOVA) in weight-loss over time (Figure 1).

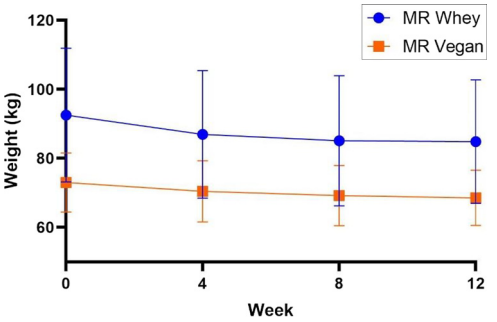
3.3 Side effects

No significant differences were observed between the two treatment groups (whey vs vegan) regarding the reported side effects ($n = 44$; $p > 0.05$, ANOVA); all adverse events (27%, $n = 12$) and positive effects (98%, $n = 43$) are summarised in Table 4. Minor to moderate adverse events ($n = 11$) were gastrointestinal in nature (e.g. bloating, constipation, diarrhoea), which are typical with increased fibre consumption. Participants in both groups reported several positive effects (98%, $n = 43$) besides weight loss (Table 4).

4. Discussion

The aim of this study was to compare the weight-loss effects of RealEasy™ whey and vegan protein-based MR with additional soluble viscous fibre in the form of PGX® along with a healthy-balanced, low-calorie diet, with minimal intervention (e.g. behavioural support; changes to physical activity). The results suggest that both whey and vegan MR containing PGX at 2.5 or 5 g/serving can have beneficial effects for weight loss over a period of 12 weeks. On average, participants who consumed the whey MR containing 5 g/serving PGX and 25 g/serving whey protein lost 8.3% (−7.7 kg ± 0.9) of their initial body weight. Those participants who consumed the vegan MR containing 2.5 g/serving PGX and 22 g/serving pea protein lost 6.2% (−4.5 ± 0.8) of their initial body weight. Noteworthy, participants in the Whey MR group showed significant higher baseline characteristics such as initial weight (19.3%), BMI (16.9%) and waist and hip circumferences (10.6 and 8.3%) than those in the vegan group but they were consuming twice the amount of PGX. The discrepancy between baseline characteristics is because of non-matched groups – as participants (with varying BMIs) could freely decide which protein-based MR they wanted to consume at study start.

Furthermore, participants in the whey MR group consumed a higher amount of PGX (10 g/day) compared to the vegan group (5 g/day PGX). This is because, in the development of these MR, developing viscosity, once liquid is added, should take about 15–20 mins before the MR is unpalatable for drinking. When trying 5 g PGX/serving in the vegan product, the



Source: Author's own work

Figure 1.
Changes in weight after the consumption of Meal Replacement (MR) whey and MR vegan with PGX, over a 12-week study period; values are changes in weight reduction of each group over the 12 weeks and are mean ± SD; $n = 44$; $p < 0.001$ (two-way, mixed factorial, RM ANOVA)

	Symptoms	Whey MR	Vegan MR
Number of participants (*n*)		*22*	*22*
Participants reporting AE (*n*)		*6* (27.3%)	*6* (27.3%)
Participants reporting type of AE (*n*)	Bloating (feeling of fullness)	*6* (27.3%)	*6* (27.3%)
	Constipation	*5* (22.7%)	*4* (18.2%)
	Diarrhoea	*4* (18.2%)	*3* (13.6%)
	Pain, cramps or a knotted feeling in abdomen	*3* (13.6%)	*2* (9.1%)
	Headache	*1* (4.5%)	*1* (4.5%)
	Other (unrelated to treatment)	*2* (9.1%)	*1* (9.1%)
Total AE by severity (*n*)	Mild	*3*	*4*
	Moderate	*2*	*2*
	Severe	*1*	*0*
Participants reporting positive E* (*n*)		*22* (100 %)	*21* (95.5%)
	Feeling of satiety	*22* (100%)	*21* (95.5%)
Participants reporting type of positive E* (*n*)	Improved sleep (quality and duration)	*21* (95.5%)	*21* (95.5%)
	Improved skin health	*21* (95.5%)	*21* (95.5%)
	Improved mental health (higher energy levels)	*20* (91.0%)	*20* (91.0%)
	Improved gut health (digestion/stool frequency)	*19* (86.4%)	*19* (86.4%)

Table 4.
Health status survey. Summary of side effects (SE) or positive outcomes (E)

Notes: MR = (Meal replacement); Abbreviation = AE = Adverse events; SE: effects; (positive effects * reported besides weight loss); parentheses denote the percentage from the total number of participants
Source: Author's own work

product thickened far too quickly as suggested by Harding *et al.* who showed novel interaction at junction zones for the novel PGX product (Harding *et al.*, 2011). We postulate in this current study that due to the different proteins in whey and pea, PGX may be interacting at different secondary and tertiary sites in these molecules, causing different developing viscosity profiles. This being said, it is interesting that only 2.5 g PGX per MR serving still has significant beneficial effect for weight loss and body measurements. Furthermore, the different sources of protein (animal vs vegan) may have a significant effect on weight loss. In comparison with whey protein, vegan protein sources e.g. pea protein lack sulphur-containing amino acids, such as methionine and cysteine (Qin *et al.*, 2022). In general, animal (whey) protein has a higher protein quality e.g. based on the essential amino acid content as well as digestibility (>95%) and bioavailability than pea protein (Qin *et al.*, 2022) – which results in greater satiety.

Based on the findings of this present study, participants in the whey MR group with PGX®, lost a significant higher amount of weight after 12 weeks (−7.7 kg) as compared to the vegan MR group (−4.5 kg) – which is most likely due to the discrepancies, discussed earlier. The weight loss results of the current study are considerably greater than those of other study outcomes. For example, in a similar study participants achieved a weight loss of −3.3 kg over 12 weeks by consuming a high-protein shake (a blend of whey and pea protein) containing 6 g fibre (a source of cocoa, pea fibre, xanthan gum, inulin, flaxseed, chicory root and chia seed powder) twice-daily (Glynn *et al.*, 2022). Interestingly, there are no studies on vegan (pea) protein-based MRs and the effects on weight reduction. One study compared the effects of 3 per day animal-based (casein) and 3 per day vegan (soy) MR, along with an entrée, fruit and vegetable for a total of 4.2–5 MJ/d on weight reduction, obese female

participants (n = *43*) in both groups lost weight in a similar fashion of 12.5% and 11.3%, after 16 weeks; however, no significant differences in weight loss and body composition changes were observed between the two treatment groups (Anderson *et al.*, 2007). However, soy protein as a vegan, plant-based source differs from pea vegan protein in terms of the protein digestibility-corrected amino acid score, which evaluated the protein quality (soy: 0.92–1.00 vs pea: 0.66–0.91), as well as digestibility in the human body after consumption (soy: 95–98% vs pea: 83–90%; Qin *et al.*, 2022).

According to guidelines, the initial goal of weight loss therapy is to reduce body weight by approximately 10% from baseline, with 6 months of therapy being considered a reasonable time line [NHLBI Obesity Education Initiative Expert Panel on the Identification, Evaluation, and Treatment of Obesity in Adults (US), 1998]. For overweight and obese patients (BMIs in the range of 27 to 35) a decrease of 300 to 500 kcal/day should result in weight loses of about 1/2 to 1 lb (0.23 kg – 0.45 kg) per week and, thus, a 10% loss in 6 months [NHLBI Obesity Education Initiative Expert Panel on the Identification, Evaluation, and Treatment of Obesity in Adults (US), 1998]. In this current study, participants with an average BMI of 33 lost 0.6 kg (1.3 lb) per week which resulted in an 8.3% loss in three months. Similarly, those participants with an average BMI of 27 lost 0.9 lb (0.4 kg) per week accounting for a 6.2% loss over the study period. In both MR groups, participants lost a significant amount of weight and reduce their waist and hip circumferences and BMI, in a similar steady manner from week 4 to week 12. In summary, during this 12-week programme, participants in the Whey group attained a 5.6% reduction in waist (-5.6 ± 1.0) and a 3.4% reduction in hip (-4.0 ± 0.8) circumferences, while those in the Vegan group achieved a 2.5% reduction in waist (-2.2 ± 0.4) and a 2.7% reduction in hip (-2.8 ± 1.0) measurements.

However, limitations of this observational study are that participants were not randomized and no control group (e.g. no MR or MR without PGX but with energy restricted diet) were used. Furthermore, it is not clear whether the sort of protein alone or the combination with a higher amount of PGX (whey with 5 g PGX/serving vs vegan with 2.5 g PGX/serving) has contributed to these significant greater weight-loss effects. This was something we were evaluating, i.e. could only 2.5 g PGX/serving have an effect on weight loss for a vegan MR. These limitations would be somethings to evaluate in a subsequent study. Hence, the results of this study may serve as a good starting point for further sophisticated randomized controlled trials that can demonstrate causality – which we acknowledge as one of the fundamental limitations of an observational study design (Wang *et al.*, 2015). As mentioned above, participants were advised to follow a low-calorie diet and booklet containing simple tips for a healthy diet was provided. Participants tracked their calories but adherence and compliance were self-assessed and they were encouraged to keep their exercise routine consistent throughout the study. Hence, these are further limitations. No control group was used in this study to observe the effect of the dietary intervention and/or physical activity on weight loss alone. However, a goal of ours was to keep this study as close to a real-life situation as possible, where people would not be doing any of these measurements, to see if with minimal supervision or intervention, people can still lose weight and alter their body composition. Furthermore, differences in gender and the corresponding weight loss effects in response to MR-protein based treatments could be evaluated in follow-up studies.

One critical aspect for a successful weight loss therapy and overconsumption is to maintain satiety while following a low-calorie diet (Halford and Harrold, 2012). In this study, participants reported a greater feeling of satiety (>95.5%) after the intake of these MR – regardless of the dose of PGX (5 g or 10 g/day) and the source of protein [whey or vegan (pea)]. This included a reduced appetite, hunger, food cravings and prospective calorie consumption, which is particularly helpful in managing obesity. This observation is

consistent with the results obtained by Douglas *et al.* comparing two high-quality protein sources (beef and soy) with fibre – with similar appetite and satiety responses, as well as similar daily food intakes regardless of the type of protein consumed (Douglas *et al.*, 2015). However, soy protein shares a similar amino acids composition (protein quality) and digestibility with that of whey protein (Hertzler *et al.*, 2020; Qin *et al.*, 2022). The combination of protein with fibre may have a synergistic effect on appetite, satiety and/or subsequent food intake as found in another study of Glynn *et al* (Glynn *et al.*, 2022).

In general, the use of viscous polysaccharides such as PGX (Lyly *et al.*, 2010) or the supplementation of polydextrose (Astbury *et al.*, 2013) can be a valuable addition as it increases satiety and effectively reduces subsequent energy intake in healthy adults. In this 12-week trial, participants supplemented with a total of 5–10 g/day of PGX generally tolerated the MR treatments well, with 12 of 44 (27%) subjects reporting mild to moderate gastrointestinal (GI) discomfort symptoms such as bloating. Overall, the adverse events were of mild to moderate intensity (92%, $n = 11$), except one severe episode of headache.

5. Conclusions

This study indicates that the consumption of protein-based (animal, whey or plant, pea protein) MR incorporating the highly soluble viscous PGX is beneficial for weight loss when combined with a healthy-balanced, calorie restricted diet. MRs at either 2.5 g or 5 g per serving (RealEasy™ with PGX) proved to be a highly effective as a short-term solution for weight loss. The observed results are encouraging, however, further long-term studies (i.e. randomised clinical trials RCT) are needed to confirm the clinical relevance. RCTs should focus on the individual effects of PGX and/or the different protein sources used in MRs, on weight loss and the maintenance of the reduced body weight, and should measure detailed blood parameters (lipid profiles, glucose etc.) as well as collect detailed exercise and food consumption diaries.

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