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Effects of high-protein high-fiber meal replacements on weight loss and dietary composition in overweight women: A randomized controlled trial

Esti Nurwanti[1,2], Harry Freitag Luglio Muhammad[1,6], Ngan Thi Kim Nguyen[3], Naufal Muharam Nurdin[4,5]*

ABSTRACT

Background: Energy deficit is essential for weight loss; however, an effective weight loss program should also focus on improving dietary composition.

Objective: This study aims to evaluate the effects of high-protein, high-fiber dietary supplements on weight loss and body composition improvements in overweight individuals.

Methods: This experimental study utilized a randomized controlled trial (RCT) design. Participants were women and were randomly assigned to either a control group or an intervention group. Criteria of this study are: Female aged 20-30 years; Body Mass Index (BMI) between 25 and 30 kg/m²; No allergies, including soy allergies; Fasting blood glucose level (FBG) < 100 mg/dL. The control group received 2 sessions of nutritional counselling by nutritionists to follow a low-calorie diet, while the intervention group received the same counselling along with a daily meal replacement containing 184 kcal energy, 17 grams of protein and 5 grams of dietary fiber.

Results: After an 8-week weight loss program, participants in the intervention group experienced significantly greater weight loss (-3.4 ± 0.43 kg) compared to the control group (-2.4 ± 0.5 kg) ($p = 0.047$). Additionally, a higher proportion of participants in the intervention group (62%) achieved the 5% weight loss threshold compared to the control group (28%) (Chi-Square $p = 0.033$). The intervention group also showed improvements in macronutrient composition compared to control, with a greater reduction in fat intake (-7.1 vs 2.1, $p = 0.013$) and increased consumption of protein (5.9 vs 1.8, $p = 0.002$) and fiber (7.21 vs 4.26, $p = 0.026$).

Conclusion: The use of high-protein, high-fiber meal replacements was associated with improvement of weight loss compared to standard low-calorie diet counselling alone.

Keywords: Diet; meal replacement; obesity; weight loss

BACKGROUND

Obesity has been identified by the World Health Organization (WHO) as one of the leading causes of chronic diseases in adults.[1] This condition is associated with an increased risk of mortality, reduced life expectancy, and various co-morbidities, including cardiovascular diseases, type 2 diabetes, hypertension, certain types of cancer, and sleep disorders.[2] According to the National Basic Health Research (RISKESDAS), the prevalence of obesity in Indonesia increased from 21.8% in 2018 to 23,4% in 2023.[3] One of the contributing factors to the rising prevalence of obesity is the environmental condition that promotes increased energy intake and decreased physical activity.[4] Therefore, addressing obesity is crucial to improving public health and preventing more severe complications.

Weight loss programs based on diet consultations and physical exercise have been shown to help overweight individuals reduce their weight.[5,6] However, sustaining these dietary changes through continuous education and counselling remains a challenge, often leading to weight rebound after the cessation of low-calorie diets.

The phenomenon of weight rebound, or the yo-yo effect, has been reported by numerous researchers studying weight loss programs.[7] The energy intake during and after weight loss programs is a critical component in determining the extent of weight loss achieved and the likelihood of weight rebound. Research indicates that protein and fiber consumption can enhance the release of anorexigenic gut hormones which play a role in suppressing appetite as well as energy metabolism.[8] Maintaining or increasing protein and fiber intake

[1]Gizi Nusantara Research Center, PT. Inovasi Gizi Nusantara, Jakarta Barat, DKI Jakarta, Indonesia
[2]Department of Nutrition, Faculty of Health, Universitas Aisyah Pringsewu, Pringsewu, Lampung, Indonesia
[3]Programs of Nutrition Science, School of Life Science, National Taiwan Normal University, Taipei, Taiwan.
[4]Department of Community Nutrition, Faculty of Human Ecology, IPB University, Bogor, West Java, Indonesia
[5]Faculty of Medicine, IPB University, Bogor, West Java, Indonesia
[6]Departement of Nutrition, Universitas Dhyana Pura, Badung, Bali, Indonesia
***Correspondence:** naufal@apps.ipb.ac.id

while lowering overall caloric intake can help individuals with obesity more effectively adhere to nutritionist- or dietician-guided calorie-deficit plans.

To improve the successfulness of a weight loss program and to prevent weight rebound, alternative interventions are being developed, including the use of functional foods. The aim is to help individuals with obesity manage their energy intake more effectively, thereby optimizing weight loss programs. Studies have shown that increasing the intake of fiber and protein can aid in controlling energy intake and enhancing weight loss outcomes.[9] To support these findings and evaluate the efficacy of our developed products, this research aims to assess the effects of high-protein and high-fiber dietary supplements on energy intake, weight loss and improvement of body composition in overweight individuals.

MATERIAL AND METHODS

Study Design and Subjects

This study was experimental research using a randomized controlled trial (RCT) design. The subjects were divided into two groups, control group and intervention group. In control group subjects received nutritional counselling to follow a low-calorie diet. In intervention group, subjects received nutritional counselling to follow a low-calorie diet and were provided with a meal replacement product containing protein and fiber to be consumed once daily. This study has been approved by Ethical Committee of IPB University No. 1232/IT3.KEPMSM-IPB/SK/2024. Informed consent was obtained from all individual participants included in the study.

The population for this study consisted of overweight adults residing in Bogor City, West Java, Indonesia. The study subjects were individuals from this population who registered to participate in the weight loss program via the website gizinusantara.com. Subjects were selected using simple random sampling through the website randomizer.org. Inclusion Criteria of this study are: Female employees and students aged 20-30 years; Body Mass Index (BMI) between 25 and 30 kg/m²; No allergies, including soy allergies; Fasting blood glucose level (FBG) < 100 mg/dL. Women were selected as criteria in this study because proportionally the prevalence of obesity in women is higher than those in men (Indonesian Health Survey, 2023).[3] The exclusion criteria are: Pregnant or breastfeeding women; individuals with chronic diseases; individuals with a history of surgery within the last six months; individuals currently following specific diets (e.g., keto diet, Ramadan fasting) or using weight loss supplement/drug or regularly participating in physical activity or exercise sessions. The dropout criteria are subjects experiencing gastrointestinal issues during the study; subjects diagnosed with infectious diseases during the study period.

The sample size calculation was performed using the sample size formula from Cohen (2013).[10] With mean difference of 1.2 kg between intervention and control group based on previous study (Luglio *et al*., 2017)[6], $\alpha = 0.05$, $\beta = 80\%$, standard error of mean = 2.9 kg, effect size = 0.414 the minimal number of subjects in each group is 23 in each group.

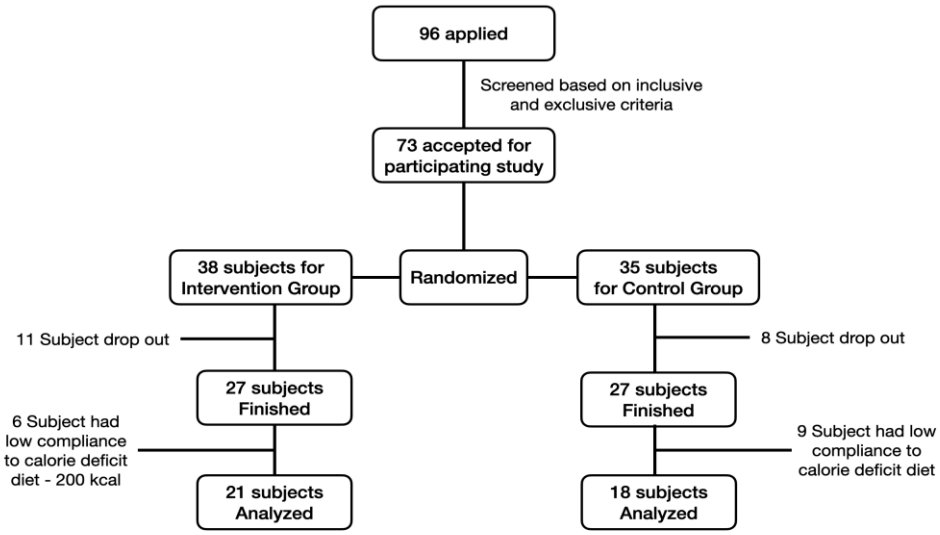

Figure 1. Research flow diagram

Randomisation and Blinding

Subjects were randomly assigned to one of the four groups using a computer-generated randomization list. The randomization process ensured that each group had an equal number of participants. Blinding was maintained throughout the study by ensuring that the researchers conducting the measurements and assessments were not aware of the group assignments.

Nutritional Counselling and Menu Planning

All subjects received personalized nutritional counselling aimed at achieving a caloric deficit suitable for weight loss. The counselling sessions were designed to ensure that subjects adhered to a low-calorie diet tailored to their individual energy needs. The menus provided were calculated to ensure an appropriate caloric intake for weight loss, considering each subject's basal metabolic rate and physical activity level.

Dietary Intervention

To closely mimic real-world conditions, subjects were not provided with meals by the research team, except for the meal replacement products. They were responsible for obtaining their own food, following the guidelines provided during the nutritional counselling sessions. The meal replacement used in this study for intervention group is Flimeal, a product approved by the Indonesian Food and Drug Administration NUMBER MD830531454367. Flimeal was used once a day to replace one of the subjects' meals, with subjects free to choose which meal they wanted to replace (breakfast, lunch or dinner). This product is already available in the market. Subjects received the product for at least 56 days consumption.

Flimeal is composed of various ingredients, including whey protein concentrate, multigrain, skim milk powder, oat powder, cocoa powder, malt extract, whey powder, inulin, fruit and vegetable extracts, instant soy, chocolate flavoring, vanilla powder, vitamin premix, sucralose, and anti-caking agent silicon dioxide. Each serving of Flimeal provides a balanced nutritional profile, containing 184 kcal, 1 g of fat, 17 grams of protein, 27 grams of carbohydrates, and 5 grams of dietary fiber. This product was selected for its comprehensive nutrient content, which supports the dietary needs addressed in our research.

Lifestyle Education Program

All subjects, regardless of group, participated in the Lifestyle Education Program, which included the following components: 1) Nutrition Consultations: Each subject received two nutrition consultations. These consultations involved calculating daily energy requirements and recommending a calorie deficit of 500 kcal. Subjects were advised to follow a low-calorie diet plan consisting of three main meals and two snacks per day. 2) Meal plans and educational materials: Subjects were provided with meal plans, a list of food exchanges, and leaflets detailing a low-calorie diet. 3) Digital Content: a total of 56 nutrition and health articles (300 words each) were distributed online. Additionally, 28 educational videos on nutrition and health, 16 home workout videos, and one dedicated webinar for meal replacement participants were shared. 4) Personalized Support: Subjects received personalized support through the Gizi Nusantara app, with consultations provided based on individual needs. 5) Offline Activities: Four offline Zumba sessions were organized to promote physical activity.

Data Collection

Anthropometric, physical-clinical, and dietary intake measurements were taken at baseline (pre-test) and at the end of the study (post-test). These measurements body weight, body mass index (BMI), body composition, waist circumference; blood pressure; physical activity and dietary intake 24-hour food records recall (3 times). Data were collected at baseline and at the end of the intervention period. Parameters assessed included dietary intake, body weight, and other relevant health indicators. Data analysis involved comparing pre- and post-intervention metrics to evaluate the effectiveness of each intervention.

Body weight was measured to assess general adiposity. Subjects performed self-weighing using a scale under the guidance of the research team. The weight measurement was recorded in kilograms (kg). Waist circumference was measured as an indicator of central obesity. This was taken at the midpoint between the lower border of the last palpable rib and the top of the iliac crest using a standard measuring tape. The waist circumference was recorded in centi-meter (cm). Body composition, includes body fat mass, fat free mass, skeletal muscle mass, percent body fat, was assessed using a bioelectrical impedance analyzer (INBODY 210/270 PT InBody Global Healthcare, Jakarta, Indonesia). The components measured included total body fat percentage, subcutaneous fat percentage, visceral fat percentage, and muscle mass percentage, with a precision of 0.1%.

Dietary intake, including the types and amounts of foods consumed, was assessed using a semi-quantitative food frequency questionnaire. This questionnaire had been validated and previously used in Indonesia. It provided information on the subjects' dietary habits over the past month. Physical activity was assessed by the number of steps measured using a digital pedometer (Xiaomi Smart Band 9, Jakarta, Indonesia).

Statistical Analysis

All statistical analyses were conducted using JASP software 0.19.3, University of Amsterdam, The Netherlands (JASP Team, 2020). The normality of the data was assessed using the Kolmogorov-Smirnov test. To evaluate the changes in measured variables within each research group, an individual t-test was employed. This test compared the means of the same group at two different times (pre- and post-intervention) to determine if there were statistically significant different in the variables of interest. An additional analysis using Analysis of Covariance (ANCOVA) was performed to further examine the differences between groups while controlling for potential confounding variables. This method allowed us to adjust for the influence of these confounders (corrected for age, height, energy intake at week 4 and physical activity) and provided a clearer understanding of the effect of the intervention. Additionally, a chi square test was done to examine whether those in intervention group had higher percentage in achieving 5% weight loss during 8 weeks of intervention compared to control group.

RESULTS

A total of 96 subjects participated in this study based on screening. The initial screening was conducted based on age, body mass index, and fasting blood glucose levels. After the screening process, the subjects who were eligible randomly assigned to two groups: the intervention group (n=38) and the control group (n=35). Both groups received in person dietary counselling as well as online guidance sessions.

Table 1. Baseline Characteristic of Subjects

	Intervention Group (n=21)		Control Group (n=18)		
	Mean	**SE**	**Mean**	**SE**	***p****
Age (years)	26.7	1.3	24.8	1.3	0.327
Height (cm)	153.4	1,1	156.9	1.4	0.049
Anthropometric measures					
Body weight (kg)	68.0	1.6	71.3	1.6	0.153
Body mass index (kg/m2)	28.8	0.5	28.9	0.5	0.885
Waist circumference (cm)	90.9	1.8	92.0	1.9	0.153
Body fat mass (kg)	29.2	1,1	31.2	1.1	0.672
Fat free mass (kg)	38.8	0.9	40.1	0.8	0.211
Percent body fat (%)	42.8	0.9	43.6	0.8	0.288
Dietary intake					
Energy (kcal)	1704	59	1839	63	0.128
Protein (g)	64.4	2.9	72.7	4.5	0.115
Fat (g)	77.2	4.6	77.4	5.1	0.986
Carbohydrate (g)	194.0	13.6	208.6	10.5	0.412
Fiber (g)	8.4	1.2	8.3	0.8	0.950
Physical activity - Steps/day	5954	708	6366	1302	0.765

*Independent t-test

All subjects were women. Baseline characteristics of the participants are presented in Table 1. There were no significant differences in anthropometric measures, body composition, blood pressure, dietary intake and physical activity between the control and intervention groups. Subjects in control group had higher height than those in intervention group. Of those who participate in this study only 21 subjects in intervention group

and 18 subjects in control group finished 8 weeks of all intervention as well as comply with the intervention protocols. In the intervention group, three subjects reported constipation, two experienced bloating, one had diarrhoea, and one reported nausea. In the control group, one subject had diarrhoea and one subjects had constipation.

After 8 weeks of weight loss intervention, there was a significant reduction in body weight and waist circumference in all groups ($p<0.05$) (Table 2). Changes in anthropometric measurements are presented in Table 2. In this study, we showed that weight changes in the intervention group were higher than those in control group (week 4, $p=0.008$; week 8, $p=0.047$). There were no significant difference in changes of waist circumference and body composition between those groups (all $p>0.05$).

Table 2. Anthropometric Changes After 8 Weeks of Weight Loss Program on Intervention and Control Groups

Anthropometric changes	Intervention Group (n=21)			Control Group (n=18)			*p*^	*p**	*p*^^
	Mean	SE	% Change	Mean	SE	% Change			
Body Weight (kg)									
Week 4 - Week 0	-2,6	0,38	-3,8	-2,1	0,3	-2,9	0.563	0.080	0.008
Week 8 - Week 0	-3,4	0,43	-5,0	-2,4	0,5	-3,4	0.135	0.061	0.047
Waist Circumference (cm)									
Week 4 - Week 0	-3,4	0,61	-3,7	-3,1	0,8	-3,4	0.855	0.383	0.828
Week 8 - Week 0	-5,4	0,51	-5,9	-5,0	1,0	-5,4	0.789	0.449	0.309
Body Composition									
Body Fat Mass (kg)									
Week 4 - Week 0	-1,7	0,32	-5,8	-1,4	0,3	-4,5	0.463	0.215	0.120
Week 8 - Week 0	-2,2	0,46	-7,5	-1,5	0,6	-4,8	0.231	0.275	0.167
Fat Free Mass (kg)									
Week 4 - Week 0	-0,9	0,19	-2,3	-0,7	0,3	-1,7	0.672	0.353	0.450
Week 8 - Week 0	-1,2	0,25	-3,1	-0,9	0,3	-2,2	0.778	0.213	0.542
Percent body fat (%)									
Week 4 - Week 0	-0,9	0,32	-2,1	-0,8	0,4	-1,8	0.735	0.574	0.422
Week 8 - Week 0	-1,2	0,51	-2,8	-0,7	0,6	-1,6	0.345	0.554	0.342

^uncorrected, *corrected for age and height; ^^corrected for age, height, energy intake at week 4 and physical activity (Steps) at week 4

Dietary intake and physical activity during the weight loss period was analyzed. In this study, we found that subjects in both groups had a significant reduction in total energy and overall micronutrient intake (all $p<0.05$). We found no significant difference in changes of energy, protein and carbohydrate intake between intervention and control groups (all $p>0.05$) while subjects in the intervention group had a greater reduction in fat intake (week 4, $p=0.042$) and greater increment in fiber intake (week 8, $p=0.027$). There were no difference in changes of physical activity between groups (Table 3).

Energy corrected analysis was done to evaluate changes in macronutrients composition relative to total energy intake. In this study we showed a significant difference in macronutrients pattern between groups. Those in the intervention study had a greater reduction of fat (week 4, $p=0.013$; week 8, $p=0.030$) and greater increment in protein composition (week 4, $p=0.002$; week 8, $p=0.082$) compared to control group. In this study we showed that changes in fiber relative to energy intake among intervention group was higher than those in control group (all $p=0.026$).

Table 3. Changes in Dietary Intake and Physical Activity During a Weight Loss Program on Intervention and Control Groups

	Intervention Group (n=21)			Control Group (n=18)			*p*
	Mean	**SE**	**% changes**	**Mean**	**SE**	**% changes**	
Energy (kcal)							
Week 4 - Week 0	-650,2	66,8	-38,2	-659,4	75,1	-35,9	0.945
Week 8 - Week 0	-622,5	71,3	-36,5	-666,4	61,7	-36,2	0.626
Absolute intake							
Protein (g)							
Week 4 - Week 0	-8,9	3,6	-13,8	-20,9	4,6	-28,7	0.071
Week 8 - Week 0	-9,5	3,8	-14,8	-19,7	4,1	-27,1	0.111
Fat (g)							
Week 4 - Week 0	-37,4	4,4	-48,4	-25,0	6,8	-32,3	0.042
Week 8 - Week 0	-37,0	3,9	-47,9	-27,6	6,5	-35,7	0.215
Carbohydrate (g)							
Week 4 - Week 0	-76,2	15,9	-39,3	-71,1	13,6	-34,1	0.878
Week 8 - Week 0	-70,6	15,4	-36,4	-73,8	11,7	-35,4	0.707
Fiber (g)							
Week 4 - Week 0	4,1	1,3	48,8	2,1	1,3	25,3	0.147
Week 8 - Week 0	3,7	1,5	44,0	0,9	0,9	10,8	0.027
Energy corrected							
Protein (% Energy)							
Week 4 - Week 0	5,9	0,8	39,0	1,8	0,9	11,4	0.002
Week 8 - Week 0	5,2	1,1	34,4	2,7	0,9	17,1	0.082
Fat (% Energy)							
Week 4 - Week 0	-7,1	2,3	-17,4	2,1	2,6	5,5	0.013
Week 8 - Week 0	-7,4	1,7	-18,1	-0,3	2,8	7,4	0.030
Carbohydrate (% Energy)							
Week 4 - Week 0	-0,18	2,80	-0,4	1,44	4,50	3,2	0.756
Week 8 - Week 0	0,17	2,20	0,4	0,89	3,80	2,0	0.867
Fiber (g/1000 kcal)							
Week 4 - Week 0	7,21	0,80	146,3	4,26	1,10	94,4	0.026
Week 8 - Week 0	6,50	0,90	131,9	3,59	0,80	79,5	0.026
Physical activity - Steps/day							
Week 4 - Week 0	-232	946	-3,9	-738	870	-11,6	0.877
Week 8 - Week 0	-1541	1111	-25,9	-771	1143	-12,1	0.710

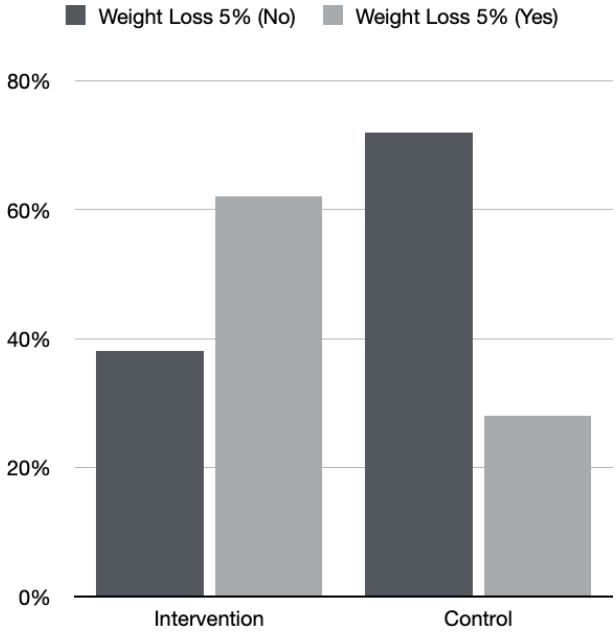

Figure 1. Proportion of Subjects Successfully Reduce at Least 5% of Initial Weight During 8 Weeks of Weight Loss Intervention

A Chi-Square test was conducted to assess whether the intervention group had a significant association with a higher likelihood of achieving a 5% weight loss during the 8-week intervention. Figure 01 illustrates the proportion of participants who achieved this weight loss in both the intervention and control groups. The results indicate that the intervention group had a higher proportion of individuals reaching the 5% weight loss threshold compared to the control group, a finding supported by the Chi-Square test ($p = 0.033$).

DISCUSSION

This study aimed to evaluate the effect of a high-protein and high-fiber meal replacement on body composition and dietary intake during a weight loss program. Subjects participated in a 8-weeks weight loss program that included in-person dietary counselling and online guidance. The objective of the weight loss program was to reduce energy intake to facilitate body weight reduction. Our findings demonstrated that using a meal replacement for 8 weeks in a weight loss program was associated with a significantly greater weight loss and a higher proportion of individuals reaching the 5% weight loss threshold compared to the control group. In addition, we also showed that despite similar in energy deficit, those in the intervention group had improvement of macronutrients compositions by reducing more fat, increasing more protein and fiber.

Energy deficit is a cornerstone and important aspect of a weight loss program.[11] However, adherence in calorie deficit during a weight loss program is an important issue to address.[12] This is one of the important protein that regulates appetite because it reduces energy intake once the blood level is increased. And increasing of energy intake during weight loss has been seen in several studies. This will hamper the successfulness of a weight loss program.[13,14]

One effective approach is to increase protein and fiber intake. It is generally accepted that when individuals with overweight and obesity reduce their caloric intake, they also tend to reduce the intake of other nutrients, including protein. This is because the primary focus of the diet is often on reducing the volume of food consumed. This trend was observed in our study as well. In both groups, there were a significant reduction in total protein intake alongside energy reduction. When analyzed as percent energy contributed from protein, we showed a significant increase in both groups. However, those in the intervention group had higher increment than those in the control group. This difference can be attributed to the high-protein, high-fiber meal replacement used in the intervention group.

In addition, for increase protein and fiber intake, subjects in the intervention group also experienced reduction fat intake especially percent fat to protein intake. This observation proved that the intervention can shift proportion of fat intake towards protein intake. This is beneficial because fat had a higher energy intake per-gram and provide less benefit in term of satiety and food induced thermogenesis.[15]

One of the proposed mechanism linking protein intake and weight loss is via regulation of appetite, increasing energy expenditure through thermogenesis, and maintaining fat-free mass.[16] Studies have shown that protein can increase the activation of anorexigenic hormones such as glucagon-like peptide-1 (GLP-1), cholecystokinin (CCK), and peptide tyrosine-tyrosine (PYY), which are gut-derived hormones that can reduce appetite.[16] By retaining or increasing protein intake while simultaneously reducing energy intake, individuals with obesity can better adhere to a calorie deficit program designed by nutritionists and dieticians. This was demonstrated in our study, where subjects in the intervention group who received high-protein, high-fiber meal replacements achieved a greater reduction body weight compared to control.

In addition to greater protein intake, other factors that might contribute to greater weight loss in the intervention group is higher fiber intake and lower fat intake. Fiber is an important component of dietary intake with is lacking among Indonesia. As presented in this study, the mean fiber intake at baseline is only 8,3 gram. This is also supported by larger epidemiology study showing Indonesians had median fiber intake 6,2 g per day, far below recommendation of 25 g fiber a day.[17] The biggest contribution of this inadequacy of fiber intake was insufficient of fruits and vegetables consumption among Indonesians. In 2018, the government conducted national food survey and found that 96,3% of Indonesian consume fruits and vegetables below recommendation.[18] It is shown that fiber has direct and indirect mechanisms to improve body weight including altered digestion and absorption, stimulation of gut hormones including GLP-1 and PYY, reduced appetite, and altered metabolism of bile and cholesterol.[19] The impact of fiber intake on the improvement of gut microbiome favoring for weight loss has also been proposed.[20]

This study not only reflects real consumer behavior, by allowing participants to self-select which meal to replace and self-selected diet, but also demonstrates how such autonomy strengthens the intervention's ecological validity. More importantly, the findings highlight how an integrative lifestyle-support system can shape weight-loss outcomes. By combining a market-available protein- and fiber-enriched meal replacement with a hybrid behavioral support structure (digital consultations, educational modules, and offline activities), the study shows that weight reduction is not merely the result of product use, but of the synergistic interaction between nutritional intervention, behavioral guidance, and participant engagement.

There are several limitations in this study. First, despite our efforts to select subjects with narrow characteristics, specifically young women with a BMI between 25-35 kg/m², several contributing factors might have influenced the final results. Because this study only involved women, results from this study cannot be generalized into broader population. Findings cannot be confidently applied to men or mixed-gender populations as biological, hormonal, metabolic, and behavioral differences between sexes mean the results may not represent broader groups. One such factor is physical activity, which we could not strictly control as subjects could engage in activities that might improve their weight loss. Second, the duration of this study was limited to only 8 weeks. This short duration restricts the potential for achieving significant long-term weight loss results. Third, because this study was limited to young women with a BMI between 25-35 kg/m², the findings cannot be generalized to the larger population.

CONCLUSION

In conclusion, this study demonstrated that adding a high-protein, high-fiber meal replacements was associated with a significantly greater weight loss and a higher proportion of individuals reaching the 5% weight loss threshold compared to the standard low calorie diet counselling method. This can be achieved due to greater increment in protein and fiber intake as well as reduction in fat intake despite of similar calorie deficit. Further study is needed to evaluate long term benefit of this meal replacement and its impact on weight changed during weight maintenance phase.

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