Will the Daily Ingestion of High Protein Nutrition Bars

(With or Without Added Fiber) for One Week

Impact 24-h Energy Intake and Satiety in Healthy Young Adults?

by

Minghan Pang

A Thesis Presented in Partial Fulfillment
of the Requirements for the Degree
Master of Science

Approved April 2022 by the
Graduate Supervisory Committee:

Carol Johnston, Chair
Christina Shepard
Christy Alexon

ARIZONA STATE UNIVERSITY

May 2022

ABSTRACT

Objective: This research examined the impact of daily ingestions of commercial high protein nutrition bars (with or without added fiber) on 24-h energy intake and satiety for one week among free-living young healthy adults.

Design: In a 4-week double-blind, randomized crossover trial, 21 normal and overweight participants (Mean BMI 23.9 ± 2.7 kg/m^2), free of chronic diseases, were randomized assigned to HP (high protein: 21 g protein) or HPHF (high protein high fiber: 20g, 14 g fiber) nutrition bars. Participants were included in the trial if they meet the criteria for non-smoking, and not taking prescribed medication for chronic diseases. Participants were instructed to consume commercial nutrition bars daily for seven consecutive days. Body composition was measured with a bioelectrical impedance scale at weeks 1, 3, and 5. Dietary data was recorded by the MyFitnessPal app on Wednesday, Friday, and Sunday of each week.

Results: The mean energy intake for the weeks HPHF bars were consumed is significantly higher compared to baseline (1998 ± 534 vs. 1806 ± 537 respectively; $p = 0.035$). The mean fat mass following one week of HPHF bar consumption was significantly higher than the baseline value (18.8 ± 6.8 vs. 18.3 ± 6.7 respectively; $p = 0.023$) and trended higher (18.8 ± 6.8 vs. 18.3 ± 6.7 respectively; $p = 0.057$) in comparison to the value following one week of HP bar consumption. For the high physical activity level group (n = 10), the mean energy intakes for the baseline week and the weeks the HP and HPHF bars were consumed were 1883 ± 597 kcal, 2154 ± 712 kcal, and 2099 ± 603 kcal respectively ($p < 0.04$; energy intakes for both bars were significantly different from baseline). Nutrient intakes differed significantly mirroring the nutrient profile for each specific bar. There are significant effects after both bars on satiety, but there were no differences between each bar.

Conclusions: Sales of nutrition bars gained rapid growth and may represent a unique source for specific nutrients. However, ingestion of commercial high protein nutrition bars may increase the risk of gaining fat mass and eventual body mass over time.

DEDICATION

I dedicated this thesis to my family, who provide me with a great opportunity to study abroad throughout this hard time. I am also dedicated to my future goal, which is to become a registered dietitian that improves the overall health status of the elder population in China.

ACKNOWLEDGMENTS

I would like to first thank my mentor, Dr. Carol Johnston, for her generous time, support, encouragement, feedback and provided the idea for my thesis. She accepted me as a master's student and provided me with great instructions throughout the thesis, so I can complete the program in nine months. In addition, I would like to extend my sincere appreciation to my committee members Dr. Catherine Trier and Dr. Christy Alexon. Both professors give me the enthusiasm to finish the thesis and never wavered in their commitment to providing support. Furthermore, I am grateful to GPSA who award me a jumpstart reward, and all my participants who participated in my research. Lastly, I am grateful to ASU IRB which accepted my research, and all the ASU professors and staff who helped me through my bachelor's and master's degrees.

TABLE OF CONTENTS

Page

LIST OF TABLES vii

LIST OF FIGURES ix

CHAPTER

1 INTRODUCTION 1

Purpose of Study 2

Research Aim and Hypothesis 3

Delimitations and Limitations 3

Definitions 3

2 REVIEW OF LITERATURE 5

Overview of Obesity 5

Factors Associated with Obesity 5

Appetite and Obesity 8

Strategies to Treat Obesity 9

Tools to Measure and Manage Obesity 15

Protein and Satiety 17

Protein Quality 21

Fiber and Satiety 23

Soluble and Insoluble Fiber 24

Fiber and Weight Loss 25

CHAPTER Page

High Protein and High Fiber Studies 27

Energy Bars 29

3 METHODS 34

Participants 33

Sample Size estimate 34

Study Protocol 35

Laboratory Analysis 36

Statistical Analysis 36

4 RESULTS 37

5 DISCUSSION 44

REFERENCES 48

APPENDIX

A IRB APPROVAL 61

B INFORM OF CONSENT 64

C SAMPLE SIZE CALCULATION 67

D FOOD PICTURE AND NUTRITION LABEL 69

E MYFITNESSPAL DATA AND EVALUATION 72

F STUDY FLOW CHART 74

G STUDY FLOW DIAGRAM 76

H HEALTH HISTORY QUESTIONNAIRE 78

I SATIETY RATING 81

LIST OF TABLES

Table Page

1. Composition of Nutrition Bars....35

2. Subject Baseline Characteristics....37

3. Subject Characteristics for Each Treatment 38

4. Energy and Nutrient Intake Comparisons for Each treatment....41

5. Satiety Rating Comparisons for Each Treatment 43

LIST OF FIGURES

Figure Page

1. Fat Mass 38

2. Total Energy Intake 40

3. Satiety Rating 41

CHAPTER 1

INTRODUCTION

Between 1999 to 2017, the prevalence of obesity increased dramatically from 30.5% to 42.4%, and severe obesity increased from 4.7% to 9.2%.[1] According to recent data, nearly 74% of adults are overweight or obese in the United States. In addition, almost 40% of children and adolescents are considered overweight or obese, and the rate of obesity has increased over the recent decades.[2] Obesity is a major risk factor for cancer, diabetes, cardiovascular diseases, and other health problems.[3] Many weight-loss programs were developed, but these programs remain unsuccessful due to individuals following protocols inconsistently. New approaches for slowing the progression of obesity are urgently needed. Focusing on simple, convenient, and practical strategies to help individuals control energy intake and appetite may be an effective approach for reducing the risk of obesity.

Although early studies showed many factors could contribute to obesity, such as psychological factors, policy, and genetics, the main leading cause for obesity is energy imbalance.[3-8] Multiple strategies have been developed to treat obesity, including dietary guidelines, dietary reference intakes, popular diet programs, meal replacements, and drugs.[2,9-17] Some strategies are successful, and some strategies may associate with adverse effects. For instance, one meta-analysis of popular diet programs found that the randomized control trials evaluating low carbohydrate diets reported adverse effects such as headache, and dizziness.[17] Some FDA-approved anti-obesity drugs such as Lorcaserin have adverse effects including dizziness, nausea, headache, and upper respiratory tract infection.[18] In contrast, several studies indicated meal replacements had shown impacts on weight loss successfully without any adverse effects.[11-12]

Energy bars that share characteristics with meal replacement may be considered a practical approach for weight management. The global energy bars market was valued at $645.0 million in 2020 and is estimated to reach $1,010.9 million by 2028, with a compound annual growth rate of 6.4% from 2021 to 2028.[24] Convenience is the main reason for the increasing demand for energy bars.[24] However, few studies have examined the health impact of energy bar consumption, particularly in regards to overall energy intake and satiety. The commercial nutrition bar provides energy and essential nutrients such as protein and fiber. There is substantial evidence that protein and fiber have the potential to suppress satiety and energy intake.[25-29] Although many studies found that protein and fiber suppress satiety and reduce energy intake in the short term, only a few studies examined the effects of long-term satiety on body weight in free-living individuals. Most of these studies utilized protein and fiber supplements in a liquid form.[30-31] Based on our knowledge, only one study has investigated the long-term impact of the energy bar on appetite and energy intake in free-living individuals.[32] However, the effect of commercial energy bars that combine high protein and high fiber (HPHF) on appetite and energy intake remain unclear.

Purpose of Study

This study examined daily consumption for seven consecutive days of HPHF energy bars compared to high protein energy bars on 24-h energy intake and satiating effects in the free-living health adults in the Phoenix metropolitan area.

Research Aims and Hypothesis

Hypothesis 1

Daily HPHF energy bars ingestion will result in greater satiating effects as compared to the placebo treatment (high protein energy bars) in healthy adults.

Hypothesis 2

Daily HPHF energy bars ingestion will result in a greater reduction in 24-h energy intake as compared to the placebo treatment (high protein energy bars) in healthy adults.

Limitation and Delimitation

The participants are healthy volunteers from the Phoenix metropolitan area who responded to an online survey. Respondents who met the inclusion and exclusion criteria were eligible to participate in this study. Cigarette use, alcohol status, food allergy, extreme athletes, and dieting status exclude individuals from participation. The limitation includes self-reported dietary data. Additionally, the inability to use the gold standard for measuring body composition, energy intake, and satiety are study limitations. Finally, participants may not follow the study protocol.

Definitions

Satiety: a feeling or condition of being full after eating the food; measured using a VAS: 0 mm (extremely hungry) -100 mm (extremely full)

Nutrition bar: a functional food that contains energy and perceived as a source of nutrients such as protein and fiber.

24-h energy intake: total energy intake from food in 24 hours; measured by using MyFitnessPal

CHAPTER 2

REVIEW OF LITERATURE

Overview of Obesity

According to the World Health Organization (WHO), obesity is abnormal excessive accumulative body fat harmful to health. For adults, WHO defined overweight as Body Mass Index (BMI) greater than or equal to 25, and obese as BMI greater or equal to 30. WHO statics estimated that in 2016, more than 1.9 billion adults (18 years old or older) were overweight, and over 650 million adults were obese.[33] The data from the National Health and Nutrition Examination Survey (NHANES) in 2017-2018 estimated 42.5% of U.S. adults age 20 years and over are obese. The survey indicated a slight upward trend for obesity rates among men and women aged 20-74 years old from 1960-1980. This trend had changed markedly from 1980, when obesity prevalence was 12%, to 2017-2018, when the prevalence of obesity reached 42.5%.[1] The major risk factors associated with overweight and obesity are cancer, diabetes, cardiovascular diseases, and many other health problems.[3]

Factors associated with Obesity.

Although many factors are associated with obesity, such as genetic, environmental, and policies, a positive energy balance is the leading cause of obesity.[3] According to Dietary Reference Intake (DRI), energy is essential for maintaining many body functions. Carbohydrates, protein, fat, and alcohol from food provide energy to the human body. The energy balance for an individual depends on energy intake and energy expenditure. The components of energy expenditure include Basal Metabolic Resting Metabolic Rate (RMR), Thermic Effect of Food (TEF), thermoregulation, and physical activity.[9] A positive energy balance will cause weight gain, and a negative energy balance will cause weight loss.

Moreno et al. conducted a 12-month study to evaluate the effectiveness of the very low kcalorie ketogenic diet (VLCK) with obese participants ($\geq$30 kg/m^2 BMI). 53 participants were randomized into control group (kcalorie values are 10% below the metabolic expenditure, 45–55 % carbohydrates,15–25 % proteins, and 25–35 % fat for macronutrient intake); whereas, the VLCK group had a three-stage process (Stage1: 600-800 kcal/day VLCK diet, Stage 2: 800-1500 kcal/day low calories diet, Stage 3: 1500-2250 kcal/day balanced diet). Both groups received physical activity and nutrition counseling throughout the study. The result indicated that the VLCK group lost 13.6 ± 3.9 kg at two months versus 4.8 ± 2.7 kg in the control group ($p \leq 0.0001$). The VLCK group lost 19.9 ± 12.3 kg at 12 months versus 7.0 ± 5.6 kg in the control group($p \leq 0.0001$). Although the VLCK groups were associated with higher adverse effects, the study suggested that VLCK is an effective strategy to induce weight loss in one year.[34]

Psychological factors may also associate with obesity. Degirmenci et al. investigated the relationship between depression level and anxiety symptoms in obese patients.[4] Both the test group (n=52, $\geq$30 kg/m^2 BMI) and the control group (n=43, $\leq$25 kg/m^2 BMI) were subjected to the Hamilton depression rating scale (HAM-D_{17}) and Hamilton anxiety scale (HAM-A). The results indicated that the control group had a score of 2.46±3.34 and the test group had a score of 9.44±4.76 ($p<0.05$) on HAM-D_{17}, and on HAM-A test scores were 4.13±4.64 and 15.05±8.27 for the control and test groups, respectively ($p<0.05$). These results indicated that anxiety and depression levels were significantly higher in the obese patients than in the control group. The researchers suggested psychiatric evaluations are necessary for obese patients. In addition, sociological factors may relate to obesity. One cross-sectional study measured the association between exposure to television advertisements and adult fast-food consumption. The study found a significant positive relationship between the participants who watched commercial TV for ≥3 h/day and fast-food consumptions at dinner.[5] Other socitial factors such as the marketing of sugar-sweetened beverages may contribute to obesity. According to Vartanian et al., soft drink consumption became a controversial public health problem related to food policy. A meta-analysis of 88 studies was conducted to examine the association between soft drink consumption and health outcome. They found a strong association between soft drink consumption and increased energy intake, and most of the studies indicated a positive correlation to weight gain. The study suggested that the increasing energy intake associated with soft drink consumption was linked to the risk of developing health conditions such as diabetes.[6] Policy changes have been proposed to lesson the impact of social media and marketing on energy intake.[7]

Genetics is another factor that may cause obesity. One genome-wide association study conducted by Frayling et al. identified a variant rs9939609 in FTO (fat mass and obesity-associated) gene associated with BMI and obesity among 2,939 control subjects. The study also indicated that each A allele of rs9939609 was associated with increased

BMI 0.36 kg/m^2 (range 0.34 to 0.46 kg/m^2) among the adult population.[8] However, two studies found no evidence that rs9939609 increases the risk of obesity among the Chinese Han and Africa American population.[35-36] One study suggested that the difference between genetic architecture and allele frequencies are the possible reasons for the lack of association.[35]

Appetite and Obesity

Appetite is essential in the human body to regulate hunger and satiety. According to Heisler et al., the brain is the main organ for regulating appetite and body weight.[37] Two groups of neurons have opposing functions in the hypothalamus: the appetite-stimulating neuron triggers hunger, and the appetite-suppressing neuron triggers satiety. Moreover, hormones play a vital role in the sense of appetite. The variety of hormones could signal the brain and release feelings of hunger and satiety.[38-40] More specific details about hormones will be discussed in the protein and satiety sections.

One of the most popular tools to measure the satiety level is the visual analogue scale (VAS). The VAS measures the magnitude of a characteristic or attitude, which is not easily measured objectively. For instance, the bipolar VAS of hunger-fullness consists of top and bottom endpoints labeled extremely hungry and full, and the unipolar hunger scale consists of top, and bottom endpoints labeled extremely hungry and not at all hungry.[41] However, VAS has some limitations, including non-linearity, a limit to a single measurement dimension, ambiguous language, and the reluctance of subjects to select extreme responses.[42-43] One recent study investigated the energy intake of breakfast eggs compared to cereals in overweight women.[44] The study used VAS to measure hunger, satisfaction, fullness, level. The study indicated that eating eggs for breakfast had significantly lower energy intake at ad libitum lunch than eating cereals (4518 ± 1593 kJ vs. 5284 ± 1814 kJ, p =0.001). The study also indicated that all participants felt less hungry, more satisfied, and more full after egg breakfast.

Strategies to Treat Obesity

Dietary Guideline and Dietary Reference Intake. The U.S. Departments of Agriculture (USDA) and Health and Human Services (HHS) collaboratively developed Dietary Guidelines for Americans (DGA) in 1980 and updated every five years based upon the evolvement of nutritional science.[45] For the macronutrients, the current 2020-2025 dietary guideline suggests that 10%-35% kcal of energy should come from protein, 45%-65% kcal of energy should come from carbohydrates, 20%-35% kcal of energy should come from fat.[2] Dietary Reference Intake (DRI) was proposed in 1997 to present comprehensive recommendations for U.S. health individuals and populations by the Food and Nutrition Board of the Institute of Medicine (IOM). Estimated Energy Requirements (EER) complement the DRI to determine the average energy intake to maintain energy balance by defining age, gender, weight, height, and level of physical activity. Acceptable Macronutrient Distribution Ranges (AMDRs) were developed to estimate the macronutrient intake for healthy individuals and populations based on the evidence from the clinical trials of chronic diseases. Both AMDR and EER were adapted in the DGA as dietary recommendations for people.[2,9]

Ge et al. conducted a systematic review and meta-analysis to examine the effectiveness of macronutrient patterns and popular diet programs for weight loss and cardiovascular factors improvement among overweight and obese participants. The study included 21942 patients from 121 randomized trials and reported 14 popular diets and three control diets. Fourteen diets were assigned to three categories: low carbohydrates (≤ 40% carbohydrates, 30% protein, 30-55% fat), which included Atkins, South Beach, Zone diets; moderate macronutrients (55-60% carbohydrates, 15% protein, 21-≤30% fat) which included Biggest Loser, DASH, Jenny Craig, Mediterranean, Portfolio Slimming World, Volumetrics, Weight Watchers diets; and low fat (60% carbohydrates, 10-15% protein, ≤20% fat) which included Ornish, the Rosemary Conley diets and the paleolithic diet, all considered moderate macronutrients and low carbohydrates diet. The control group maintained their usual diet and received diet advice (education brochures, dietary guidelines, or consultation with dietitians) promoting a low-fat diet (⩽30% fat with or without advice about lowering calories). The results indicated low carbohydrate, low-fat, and moderate macronutrient diets had mean weight reductions of 4.63kg, 4.37kg, and 3.06kg, respectively, at six months (± three months). 18.2% of 121 randomized control trials evaluated the low carbohydrate diet had adverse effects (headache). The study suggested that weight loss was facilitated by all diets, low carbohydrate, low fat, and moderate macronutrients, but that adverse symptom may occur with low carbohydrate diets supporting the higher carbohydrate recommendations by the DGA.[46]

Meal Replacement. Astbury, Nerys et al. defined meal-replacement as products that replace the food usually consumed at mealtime to achieve the goal of weight loss and weight maintenance after weight loss.[10] One well-organized randomized controlled trial indicated the meal replacement was an effective strategy to produce short-term weight loss. These researchers randomized 90 obese participants (BMI > 30.0 $kg/m^2 \leq 50.0 kg/m^2$ included diabetes patients) to either an MD group (the Medifast 5 & 1 Plan meal replacement) or a FB group (isocaloric food-based plan) with around 1000 kcal calories for both groups in first 16 weeks for weight loss. Energy intakes were adjusted to support weight maintenance for the final 24 weeks. A total of 48 participants completed the 16-week phase of the trial. The 28 participants in the MD group lost an average of 12.3% of body weight (13.5 ± 5.9 kg) versus 6.7% weight loss (6.5 ± 6.8 kg) noted for the 20 participants in the FB group (p = 0.002). At week 40, 2 participants dropped from the MD group and the MD group regained 4.8 ± 5.8 kg (p<0.0001) versus the FB group 0.8 ± 4.8 kg (p = 0.467). Although there is a significant difference between the regained weight between groups, the weight in MD group remained reduced from baseline by 7.8% versus 5.9% in the FB group (p = 0.15). However, there is no difference between the satiety level assessed in week 16 regarding post-meal fullness. The study also suggested improvements in the health parameters during the weight maintenance phase in the meal replacement group.[11]

Lowe et al. conducted a study to evaluate the effectiveness of meal-replacement and home food environment intervention for long-term weight loss. The study randomized 262 participants (BMI>27 $kg/m^2 \leq 45 kg/m^2$) to three groups in 36 months: behavior therapy (BT), behavior therapy plus meal replacement (BT+MP), modifying the home food environment (HFE). The result indicated that all three groups had significant weight loss in month 12; BT, BT+MP, and HFE group's percentage weight loss was 9.41% ± 7.92%, 10.37% ±7.77%, and 10.97% ± 7.79%, respectively. Although all three groups regained their weight at month 36, compared percentages were 4.21% ± 8.64%, 3.06% ± 6.93%, and 4.49% ± 7.83%. The study indicated that meal replacement is an effective strategy.[12]

A recent meta-analysis of 23 randomized controlled trials consisting of 8253 subjects was conducted to evaluate the effect of one-year weight loss intervention trials incorporating meal replacements (MR) on weight change in overweight and obese adults.[34] The 23 studies classified into five comparisons: MR diet vs diet only, MR diet + support vs. diet + support, MR diet + support vs diet only, MR diet + enhanced support vs. diet + support, and MR diet + support vs. minimal intervention (3 studies). All of these groups lost more significant weight compared to the control groups. Two studies found there is no relationship between adverse effects and meal replacement products. This meta-analysis provides evidence that MR is an effective weight loss strategy for overweight and obese adults in one year.[10]

Drugs. Anti-obesity pharmacological research has been conducted for more than a century, but many of these drugs were associated with severe side effects. Orlistat was one of the U.S. Food and Drug Administration (FDA) approved anti-obesity drugs.[47] According to Hvizdos et al., the mechanism of the Orlistat is to inhibit the lipase enzyme, which breaks down triglycerides to fatty acids and glycerol in the pancreas and stomach. This process can slow down the rate of fat absorption up to 30%.[48] The adverse effects of Orlistat include steatorrhea, bloating, and oily discharge due to the malabsorption of fat in the gastrointestinal tract.[49] Smith et al. designed a 24-week randomized placebo-controlled trial to determine the effect of intake of Orlistat (60 mg) on visceral adipose tissue (VAT). A total of 131 participants (BMI 25–34.9 kg/m^2) were randomized to either Orlistat 60 mg/day or placebo capsules. All participants were instructed to consume a hypocaloric, low-fat diet (50% carbohydrate, 30% fat, and 20% protein) and encouraged to exercise (30–45min walk, five times weekly). Of the 93 participants who completed the trial, both groups significantly decreased VAT from baseline to week 24 ($p < 0.001$). However, the Orlistat group had a more significant mean reduction than the placebo group (-15.7% vs.-9.4%, $p < 0.05$). The Orlistat group also had a more significant adjusted mean weight reduction than the placebo group (−5.93 ± 0.63 kg vs. −3.94 ± 0.64 kg, $P < 0.05$). The most commonly observed adverse effect is GI disorder, and the incidence for Orlistat and placebo group are 66.7% versus 26.6% of participants. The results also indicated improvements in other outcomes, including waist circumference, total fat mass, % body fat of the Orlistat group.[50]

Lorcaserin is an anti-obesity drug that activates the serotonin or 5-hydroxytryptamine (5-HT).[50] According to Heisler et al., serotonin is involved in regulating the appetite suppressing process and promoting satiety. There was an inverse relationship between the serotonin level and food intake.[51] The common adverse effects of Lorcaserin include dizziness, nausea, headache, and upper respiratory tract infection.[15] Fidler et al. designed a 52-weeks randomized, placebo-controlled, double-blind clinical trial to determine the efficiency, safety dosage of Lorcaserin for obese and at-risk overweight patients.[15] A total of 4008 patients (BMI 30–45 kg/m2 or 27–29.9 kg/m2 with health risk conditions) were randomized to one of three conditions: 10 mg lorcaserin twice daily (BID), 10 mg lorcaserin once daily (QD), or placebo. Nutrition and physical activity counseling were provided throughout the study. The result indicated that patients in the BID and QD group lost at least 5% of body weight from baseline (47.2 and 40.2%, respectively) compared to the placebo group (25%, $p < 0.001$). Adverse effects occurred in 82.6% of the BID group, 81.5% of the QD group, and 75.3% of the placebo group. The common adverse effects in BID and QD groups were headaches, upper respiratory infection, nausea, dizziness, and fatigue. The result indicated that intake of Lorcaserin for 1 year relates to significant weight loss among obese and overweight patients.

The combination of phentermine and topiramate is one of the prescribed appetite suppressant drugs.[52] According to Rothman et al., the mechanism of phentermine is to stimulate noradrenaline to reduce food consumption and increase satiety level. The mechanism of topiramate is undefined. The adverse effects of this combination drug include insomnia, dizziness, dry mouth, paresthesia, and dysgeusia.[53] Allison et al. designed a 56-weeks randomized, placebo-controlled, double-blind clinical trial to determine the efficiency and safety of phentermine/topiramate (PHEN/TPM) in obese participants and metabolic improvements. A total of 1267 obese participants (BMI $\geq$35kg/m^2) were randomized assigned to three groups: placebo, PHEN/TPM 3.75/23mg, and PHEN/TPM 15/92mg. The result indicated that participants who received 15/92, 3.75/23, and placebo lost 10.9%, 5.1%, and 1.6% of body weight from baseline, respectively ($p < 0.0001$). The common adverse effects include paresthesia, dry mouth, constipation, dysgeusia, and insomnia. The result indicated that intake of phentermine/topiramate for one year relates to significant weight loss among obese patients.[16]

Other strategies for obesity, including high protein diets, high fiber diets, and combined protein and fiber diets, will be demonstrated in protein and fiber sections.

Tools to measure and manage obesity

Dietary assessment tools include food frequency questionnaire (FFQ), food record (or diary), and 24-hour dietary recall are established to monitor food intake and diet patterns. Although nutrition professionals commonly use these tools to track food intake, these tools highly rely on the participants' memory, ability to estimate portion sizes, and consistency of reporting.[18-19] However, many studies indicated that new innovative technologies, including computers and mobile phones, effectively improve the self-monitoring processes.[54] To evaluate the effectiveness of the dietary self-monitoring process between the smartphone and traditional dietary assessment methods, one study enrolled 57 participants (BMI 25–40 kg/m^2) in an 8-weeks weight-loss trial. Participants were randomized into three groups: the APPs group (Lose it! Apps, n=19), the memo group (ME, n=18), and paper group (PA, n=20). The APP group recorded their dietary data in the Lose it! Apps, which recorded the data and provided nutrition feedback immediately. The ME and PA groups received nutrition counseling at the beginning of the trial and weekly emails for nutrition advice. 47 participants finished the trial, but 5 ME and 5 PA participants did not complete the trial. The results indicated that the APP and ME group had a higher number of complete days than the PA group (43.0 ± 2.5, 34.8 ± 3.5 and 30.7 ± 4.6 days, respectively; p=024), but there is no significant difference between the APP and ME groups. The study also determined that there was substantial weight reduction across three groups at the end of the trial (- 3.5±1.0, - 6.5±1.4, and -

4.4±1.2 lb. for AP, ME, and PA groups, respectively; $p<0.05$). The investigators suggested that the short-term self-monitoring process through smartphones is more feasible than traditional dietary assessment methods.[21]

One study evaluated the effectiveness of tracking dietary modification between the smartphone Apps and paper journals and enrolled 30 participants (BMI 25.6 ± 4.3 kg/m^2) in a 4-week randomized parallel trial. Participants were randomized into two groups: the MyFitnessPal App group and the paper journal group, and both groups were instructed to reduce sodium intake to ≤ 2300 mg/day. The paper journal group received a journal and additional nutrition education materials regarding sodium intake. Participants were instructed to collect 24-h urine voids to determine the 24-h sodium excretion. The result indicated that 24-h sodium excretion differed between two groups: - 838 ± 1093 and + 236 ± 1333 mg ($p=0.010$) for the Apps and paper journal groups. In addition, the satisfaction of the App users was significantly higher than that for the paper journal group for recording diet intake and enjoyment of the method. Although the study was small and of short duration, the data suggest that commercial Apps could be a valuable tool to improve communication between clients and health practitioners.[22]

In addition, one systematic review analyzed the effectiveness of self-regulatory strategies by smartphone application in overweight and obese adults. The study reviewed six studies and found that all studies reported participants who used smartphone applications lost weight. Although it is challenging to conclude that smartphone applications are more effective than other self-regulatory tools, smartphone applications still represent a valuable tool for weight management and diet reporting. The study also suggested that setting goals are essential for weight management by using smartphone applications.[23]

Protein and Satiety

Protein is the major component of cells. According to DRI, the AMDR for protein is 10-35% of total energy for adults, and the recommended dietary allowance (RDA) is 0.8g/kg/d for males and females. Protein from animal sources is considered complete protein, which provides all the essential amino acids. Protein from plant sources is considered incomplete protein, generally deficient in one or more essential amino acids.[9] Investigations for the effect of the protein on satiety and energy balance have been conducted for many decades. Together these studies indicate that the high protein diet is a potential tool to lose weight. The possible mechanisms include increasing diet-induced thermogenesis, regulating the satiety hormone, and maintaining fat-free mass.[55-56]

Diet-induced Thermogenesis. Diet-induced thermogenesis (DIT), also called the thermic effect of food, reflects the energy expenditure involved in the metabolism processes of nutrients. Protein has the highest DIT (20-30%) compared to carbohydrate (5-10%) and fat (0-5%).[9] Westerterp et al. indicated there is a positive relationship between DIT and satiety level. The possible mechanism is that increased oxygen demand to conduct metabolism processes for protein.[26]

Lejeune et al. conducted a randomized crossover trial to investigate the 24-h satiety, hormone, and energy metabolism in a respiration chamber for a high protein diet. Twelve healthy women (BMI 20–25 kg/m^2) were randomized to adequate-protein group (AP: 10% protein, 60% carbohydrate, and 30% fat of energy) and high-protein group

(HP: 30% protein, 40% carbohydrate, and 30% fat of energy). The result indicated that the HP group had higher DIT (0.91 ± 0.25 MJ/d) than the AP group (0.69 ± 0.24 MJ/d, $p<0.05$). HP groups had a higher sleeping metabolic rate (6.40 ± 0.47 MJ/d) than AP group (6.12 ± 0.40, $p<0.05$). Compared with AP group, the hunger score group was significantly lower, and the satiety score was significantly higher during HP diet before and after dinner. The study suggested that a high protein diet had a higher 24-h satiety level, DIT level, and sleeping metabolic rate than an adequate protein diet without difference in energy intake.[25]

Oliveira et al. conducted two randomized crossover trials to evaluate the high protein intakes on energy metabolism for healthy adults of both sexes. Forty-three healthy adults (BMI 18.5–24.9 kg/m2) were randomized to two prescribed diets: control diet (CON: 55% carbohydrate, 15% protein, and 30% fat) and high protein replacement diet (HP-TDR: 35% carbohydrate, 40% protein, and 25% fat). The participants received prescribed diets for 32 h while inside the whole-body calorimetry to evaluate the energy metabolism. The result indicated that the HP-TDR group had a higher total energy expenditure than the CON group (2143 ± 268 versus 2061 ± 243 kcal/d, $p <0.001$). The HP-TDR group had an energy imbalance (–112 ± 85 kcal/d; $p <0.001$) compared to the CON group. There was an inverse relationship between protein and fat balance in the HP-TDR group ($r = –0.57$, $P <0.001$). The study suggested that HP-TDR leads to higher total energy expenditure among both sexes, promoting fat loss than conventional diets.[57]

One meta-analysis of five randomized controlled trials consisting of 111 participants was conducted to assess the association between DIT and appetite among adults. The study found no association between satiety and DIT at 15% of energy intake from protein; the possible reason is that the protein intake is too low to trigger the satiety effect. However, the study suggested possible associations may present with a higher level of protein intake.[58]

Satiety Hormones. Other possible mechanisms to relate high protein diets to satiety are the satiety hormones. The satiety hormones play a vital role in regulating the control of food intake via several mechanisms.[59] Glucagon-like peptide 1 (GLP-1), cholecystokinin (CCK), and peptide YY (PYY) increase in response to high protein intake.[60] GLP-1 inhibits gut motility and secretion, which could suppress the appetite and food intake. CCK is a peptide hormone that modifies intestinal motility and inhibits gastric empty which could reduce food intake and increase satiety. PYY is an appetite hormone that down-regulates the appetite through the hypothalamus.[61] One randomized crossover trial investigated the effect of a high protein diet on appetite hormone and appetite rating. Twenty-five male participants were randomized into three groups: normal protein (NP: 14% of energy from protein), medium-high protein (MHP: 25% of energy from protein), and high protein (HP: 50% of energy from protein). The researchers found that compared to NP group, MHP and HP group had 10% and 20% higher 4-hour GLP-1 levels, respectively. MHP and HP groups had 7% and 14% higher responses for PYY. HP group had a higher CCK level at 180 min and 240 min after the meal. The study suggested that protein diets increase satiety and appetite hormone levels and are essential for bodyweight regulation.[60]

Maintaining Fat-free Mass. Bodyweight reduction includes fat mass (FM) reduction and fat-free mass (FFM) reduction; the latter has been shown to reduce energy expenditure and decrease energy requirement. In addition, maintaining the FFM is essential to basal energy expenditure, limiting energy expenditure reduction.[62] Mettler et al. conducted a randomized parallel control trial to examine the effect of dietary protein on lean body mass during short-term weight loss in athletes. Twenty athletes had examined energy expenditure for one week with a mixed diet (15% protein, 100% energy) and randomized to two hypoenergetic diets (60% of the habitual energy intake), which included 15% protein (CP: control group) or 35% protein (HP: high protein group) for two weeks. The result indicated that the total weight loss was -3.0 ± 0.4 versus -1.5 ±0.3 kg ($p = 0.036$), and lean body mass loss was -1.6 ± 0.3 versus -0.3 ±0.3 kg ($p = 0.006$) for CP and HP. The study suggested that a high protein diet better maintains lean body mass during short-term weight loss.[63]

Griffin et al. conducted a 12-month randomized control trial to compare the effect of two energy-restricted diets on body composition. A total of 71 participants (BMI ≥27.5 kg/m^2) were randomized into high protein (HP: 32% protein, 41% carbohydrates, 25% fat) and high carbohydrate (HC: 20 protein, 58% carbohydrates, 21% fat) diets. The result indicated that HP completers had more significant weight loss than HC completers at 6 months but not 12 months ($p = 0.034$). Absolute fat loss was significantly higher in HP at 6 months ($p = 0.022$). Both groups had a ≤1kg reduction of lean body mass. The study suggested that a high protein diet had a more significant effect on reducing fat mass and maintaining lean body mass compared to conventional diets.[64]

Furthermore, Wycherley et al. conducted a systematic review and meta-analysis to compare high protein low-fat diets (HP) with standard protein and low-fat diets (SP) on weight loss, body composition and resting energy, satiety, and appetite. The result indicated that HP diets reduced body weight, fat mass, and mitigation reduction in resting energy expenditure compared to SP diets. Greater satiety in HP diets was reported in 3 of 5 studies.[65]

Protein Quality

In addition to satiety hormones, Pal et al. conducted a 12- weeks randomized parallel control trial to evaluate the effect of whey and casein protein on appetite. Seventy overweight and obese adults (BMI 25–40 kg/m^2) were randomized to glucose control, casein protein, and whey protein groups. The participants were asked to limit alcohol consumptions and keep their regular diet throughout the study. The results indicated that the percentage of carbohydrate was significantly lower ($p<0.0001$), and protein intake was significantly higher ($p<0.0001$) in the casein and whey protein groups than the control group at week six. The VAS of satiety measured before lunch indicated significantly higher satiety in the whey group than the casein ($p=0.017$) and control group ($p=0.024$) in week six. In addition, the increased rating of satiety in the whey group was observed compared to the casein and control group at week 12. The study suggested that whey protein supplements appear to have a positive effect on overweight and obese adults.[66]

Veldhorst et al. conducted a randomized control trial to compare the effects of casein, soy, and whey protein on appetite, hormones, amino response, and energy intake.

Twenty-five healthy adults (BMI 25±0.3 kg/m^2) were randomized to casein, soy, or whey groups with either normal protein group (10/55/35 En% protein/carbohydrate/fat) and high protein group (25/55/20 En% protein/carbohydrate/fat). The researcher found that hunger suppression increased more after whey breakfast than casein breakfast in the normal protein group. However, there is no difference in hunger rating between the three groups. They found significantly higher plasma glucose after breakfast with casein than soy. In addition, the GLP-1 level in the whey is substantially higher than in the casein and soy at both normal and high protein groups. The energy intake for lunch in the whey group was lower than that for the casein and soy groups. The study suggested that breakfast with whey triggered a stronger satiety response than breakfast with casein and soy sources.[67]

Safety and Efficacy

Jose et al. conducted an 8-weeks randomized crossover trial to evaluate the effect of a high protein diet on clinical markers of health in young males with extensive resistance training experience. Twelve healthy participants were randomized to an 8-week habitual diet (2.6 ± 0.8 g/kg/day of dietary protein) or an 8-week high protein diet which included protein powder (3.3 ± 0.8 g/kg/day of dietary protein). Each participant followed their regular training programs. The result indicated that the high protein group consumed significantly higher energy and protein than the normal protein group. There were no harmful effects associated with high protein consumption.[68]

Hernandez-Alonso et al. conducted a PREDIMED study to evaluate the efficacy and safety of long-term high dietary protein intake among older adults at high cardiovascular risk. They found long-term high protein diets were associated with increased body weight (BW) and total death risk. The food-frequency questionnaire was used to assess the dietary intake. They found a significant positive relationship between higher BMI and dietary protein intake (animal sources and animal-to-vegetable protein) but not vegetable protein intake. In addition, a positive association between intake of >1.5 g protein/kg BW/d at risk of cardiovascular diseases and all-cause death compared to 1.0-1.5 g/kg BW/d of protein intake. These findings are only related to long-term protein intake and only for animal sources. These data suggested that dietary protein intake from animal resources should not exceed 1.5g/kg/ BW/d.[69]

Fiber and Satiety

According to DRI, dietary fiber is defined as a nondigestible carbohydrate or lignin that is intrinsic and intact in plants; functional fiber is defined as a nondigestible carbohydrate with beneficial physiological effects in humans. Total fiber incorporates both dietary fiber and function fiber. The adequate intake (AI) for total fiber is 38 g/d for males and 25 g/d for females.[4] Total fiber can be categorized into soluble fiber and insoluble fiber. The soluble fibers, such as β-glucan commonly found in oats and barley, appear to benefit serum lipids. The insoluble fibers, such as cellulose found in legumes and whole grains, appear to benefit laxtations.[70] Possible mechanisms of high fiber for inducing weight loss include slowed glycemic response, regulated laxtation, and delayed gastric emptying.[71-72]

Soluble and Insoluble Fiber.

One randomized control trial assessed the effect of the cooked white rice β-glucan barley on appetite and energy intake compared to white rice alone. A total of 21 healthy participants (BMI 23.3±0.7 kg/m^2) were randomized into two groups: white rice group (WR) and white rice with high β-glucan barley group (BAR). The results indicated that the energy intake at lunch was significantly lower in BAR compared to WR (3,061 ± 681 kJ versus (3,280 ± 617 kJ p=0.035). The cumulative energy intake (lunch + dinner) was significantly lower in BAR compared to WR (4,963±1,209 kJ versus 5,374±1,079 kJ p=0.021). Furthermore, the hunger score and fullness score of BAR were significantly higher aqt 240 min compared to WR, and the satiety score of BAR was significantly higher at 60 and 480 min compared to WR. Although the study had small sample sizes, these data suggested that β-glucan may be associated with appetite control and reduced energy intake.[73]

Samra et al. conducted a randomized crossover trial to evaluate the effect of insoluble fiber on appetite, short-term food intake, and blood glucose (BG) in healthy males. The study consisted of two experiments. Experiment one evaluated the insoluble fiber on appetite, food intake, and postprandial plasma glucose at an ad libitum pizza meal consumed 75 min later. A total of 16 healthy participants (BMI 20 –27 kg/m^2) were randomized into four groups: high fiber cereal (HF: 33g insoluble fiber), low-fiber cereal (LF), white bread (WB), and 500ml water for the control group. Experiment two evaluated the appetite and BG after consuming a preset pizza meal (850 kcal: 2 deluxe pizzas, 1 pepperoni pizza, and 1 three-cheese pizza). The result of experiment one indicated that the energy of ad libitum lunch of HF and WB was lower than LF and water (937 ± 86, 970 ± 65, 1109 ± 90, 1224 ± 89 kcal, respectively; $p < 0.001$) The appetite of HF was lower than WB but not differ from LF. The post-BG increased after WB and LF, but not in HF. The result of experiment two indicated that the HF had the lowest BG (3.6 ± 14.2 mmol. min) compared to LF (42 ± 12.5 mmol. min) and WB (26.9 ± 12.4 mmol. min). The fullness was significantly higher in HF (2536.0 ± 412.3 mm.min) compared to WB (1736.0 ± 486.5 mm.min) and LF (1582.0 ± 364.7 mm. min; $p<0.05$). The study suggested that insoluble fiber may suppress appetite, lower food intake, and improve post-glucose response.[74]

Fiber and Weight Loss

One cohort study was conducted to investigate the effect of dietary fiber on weight and waist circumference in Europe. A total of 89,432 participants aged 20-78 y and free of cancer, cardiovascular disease, and diabetes followed for an average of six years were included in the study. Food-frequency questionnaires were used to assess the dietary data. The results indicated that total fiber was inversely associated with waist circumference and weight. A 10 g/d of higher total fiber intake was associated with annual weight change -39 g/y and -0.08 cm/y for annual waist circumference. A 10 g/d of higher fiber intake from cereal was associated with annual weight change -77 g/y and -0.10 cm/y for annual waist circumference. Although fruit and vegetable fiber was positively associated with an annual weight change (2 g/y), it was negatively associated with annual waist circumference (-0.08 cm/y). The study suggested higher intake of fiber is beneficial for preventing abdominal obesity among Europeans.[75]

Abutair et al. conducted an 8-week randomized control trial to determine whether soluble fiber supplements from psyllium improve the glycemic response and body weight among type 2 diabetic patients. A total of 40 patients were randomized to the intervention group (7.0 g of psyllium 15 min before lunch and 3.5 g of psyllium 15 min before dinner) and control group (remain their regular diet). Both groups were instructed to follow their regular diet and lifestyle. Of 36 participants finished trial, the results indicated that the mean body weight (-2.7 kg versus 0.8 kg, $p < 0.001$), BMI (-0.9 kg/m^2 versus 0.3kg/m^2 $p < 0.001$), waist circumference (-2.7 cm versus 0.3 cm, $p < 0.001$), hip-circumference (-2.6 cm versus 0.5 cm, $p < 0.001$) was significantly lower than baseline in intervention group compared to control group. The mean fasting blood sugar (-43 mg/dl versus -5 mg/dl $p < 0.001$), HbA1c (-1% versus 0 % $p = 0.013$), insulin level (-8.2 μIU/mL versus 3.1 μIU/mL, $p < 0.001$), C-peptide (-2 ng/ml versus 1.1 ng/ml $p < 0.001$), HOMA.IR. (-5.5 versus 0.8 $p < 0.001$) and HOMA.B% (37.8 versus 17 $p < 0.001$) were significantly improved from baseline in the intervention group. The study suggested that the soluble fiber from psyllium with normal diets is beneficial to body weight and glucose metabolism among type 2 diabetic patients.[76]

In addition, a systemic review consisting of 32 randomized control trials investigated the impact of fiber-based supplementation on body weight and fatness. The result indicated that the dietary fiber supplementation on the body weight, BMI, and waist circumference is inconsistent across studies. The study suggested that the possible reason for inconsistency among these studies are variations in interventions, participants' characteristics, and overall methodological quality.[77] Furthermore, one systemic and meta-analysis investigated the effect of viscous fiber on body weight independently of a calorie-restricted diet found viscous fiber as monotherapy has insufficient evidence for weight loss. However, the study suggested combined viscous fiber and caloric restricted diet provide a more effective approach.[78]

Safety and Efficacy

Williams et al. conducted a review to investigate the safety and adverse effects on types of fiber consumed among U.S. children and adolescents.[69] The study found that high dietary fiber intake is associated with a slight loss of energy, protein, and fat. The study also indicated that high fiber intake might compromise caloric consumption among children and adolescents. However, the loss of these nutrients is unlikely to have adverse effects when they consume adequate and balanced diets. The study suggested that a moderately increased fiber induces more benefits than harms.[79]

Davidson et al. found inulin intake associated with gastrointestinal distress, and the most symptoms are bloating, cramping, and loose stool.[80] According to DRI, a high fiber diet may cause Gastrointestinal distress, but the symptom always subsides with time. People who suffer from excess gastric gas are suggested to consume a low dietary fiber diet.[9]

High Protein and High Fiber Studies

One recent randomized crossover control study assessed the acute effect of high protein and high fiber beverage (HP/HFb: 160 kcal, 17g protein, and 6g fiber) as a preload compared to an isocaloric low protein and low fiber beverage (LP/LFb: 160 kcal, 1g protein, and 3g fiber) on appetite ratings and subsequent energy intake at an ad libitum meal in obese and overweight adults. A total of 50 overweight and obese adults (BMI 29.6 ± 0.3 kg/m2) received either HP/HFb or LP/LFb in two randomized occasions. After consumption of two beverages for 30 minutes, the participants received ad libitum pizza meal. The VAS was used to assess the appetite rating. The result indicated that HP/HFb leads to a significantly higher reduction in desire to eat and hunger than LP/LFb ($p < 0.05$). Subsequent meal energy intake for HP/HFb was lower than LP/LFb ($p=0.09$). The study suggested that high protein and high beverages consumption tend to have a lower desire to eat, hunger level, and subsequent energy intake than low protein and low fiber beverages.[30]

Dina et al. conducted a randomized crossover trial to assess the effect of beverages containing soy protein and soluble corn fiber on satiety, appetite, and hunger in healthy young men. A total of 30 healthy participants with normal weight (BMI 23.6 ± 1.6) consumed four beverages on different days with a 3-days washout period: one carbohydrate control (B: 0g protein and 2g fiber), high protein (HP: 30g protein and 2g fiber), high fiber (HF: 0g protein and 11g fiber) and high protein high fiber (HPHF: 30g protein and 11g fiber). VAS was used to assess appetite, hunger, and satiety. Subsequent energy intake was measured after an ad libitum lunch. The result indicates that HP, HF and HPHF showed a higher satiety effect than B ($p=0.02$). HP showed the most prolonged effect on satiety after four hours($p=0.02$). There is no difference between each treatment on appetite control, but B showed a significantly higher appetite than other treatments. There is no difference in subsequent energy between each treatment.

Although the study found no synergistic satiety of fiber plus protein, it suggested that beverages in high soluble corn fiber and high soy protein significantly affected satiety in healthy men compared to carbohydrate beverages.[31]

Energy Bars

The global energy bars market was valued at $645.0 million in 2020 and is estimated to reach $1,010.9 million by 2028, with a compound annual growth rate of 6.4% from 2021 to 2028.[24] One of the critical factors that contribute to increased demand for energy bars is convenience.[24] Energy bars not only provide energy value but also provide essential nutrients and food benefits. The average energy bars available in the market generally contain 150-400 calories, 25-30 grams of carbohydrate, 10-20 grams of protein, 5-10 grams of fat, and 5-10 grams of fiber. The sources of protein in the energy bars are varied, such as soy, whey, casein. The purpose of the energy bars includes weight management, meal replacement, strength muscle.[81] Although the market size of energy bars is enormous, few studies have examined the health impact of energy bar consumption, particularly in regards to overall energy intake and satiety.

Chow et al. conducted a randomized crossover trial to assess the satiety effect of energy bars containing viscous fiber on overweight and obese type 2 diabetic patients. A total of 99 patients were received a 300 kcal lunch consisted fiber-containing nutrition bars (VF: 9.1g fiber, 12g protein, and 7.5g sugar) or control bars (CH: 6.4g fiber, 12.9g protein, and 19g sugar). The study found VF had a 27.1% higher increase in fullness ($p < 0.05$), 15.8% decrease on perspective consumption ($p < 0.001$) and 14.2 decrease on hunger ($p < 0.001$) in 120-240 min areas under the curve compared to CH. The data suggested that nutrition bars containing viscous fiber may be helpful for weight management of type 2 diabetic patients.[82]

Trier et al. conducted a randomized crossover trial to assess 24-h energy intake in free-living college students ingesting nutrition bars high in carbohydrate or protein for the breakfast meal. Fifty-four participants were randomized to one of the two nutrition bars: high carbohydrate bars (HC: 260 kcal, 4 g protein,6 g fat, and 4 g fiber) and protein bars (HP: 280 kcal, 30 g protein, 7 g fat, and 1 g fiber). The participants were instructed to consume the bars one hour after waking and not to consume any other calorie-containing food or beverage at that time and for one hour after consuming the bars. The participants were instructed to follow their regular diets and complete a 24-h dietary recall on the remainder of the day. The result indicated that the daily energy intake assessed on the same day during the study did not differ significantly. The mean energy intake was 1752 ± 99 kcal, 1846 ± 75, and 1891 ± 110 kcal at baseline and for HP and HC respectively. Physical activity level was assessed by using MET tertiles and categorized into two groups: MET scores > 66 and MET scores < 66. The participants who reported high physical activity had a significantly higher energy intake compared to the control day for HC bar day (+45% or 709 ± 281 kcal, p = 0.03) and HP bar day (+22% or 346 ± 145 kcal, p=0.038). Although the ingestion of the nutrition bar high in protein or carbohydrate did not impact 24-h energy intake, the participants with high physical activity had a significantly higher energy intake than low physical activity participants on HC and HP bar day. In addition, the study suggested that nutrition bars may be helpful to increase nutrition status for young adults.[83]

One randomized crossover study evaluated the acute and chronic effects of a whey protein and polydextrose (PPX) energy bar and an isoenergetic carbohydrate bar on appetite, energy intake (EI), metabolic and endocrine responses in free-living males. Ten lean males (BMI 19-25) participated in the study. For the acute phase, participants consumed a standardized meal (30% of daily energy need: 48%, 36%,16% of energy from carbohydrate, fat, and protein) at 20:00 on the night before each experimental day (day 1 and 15). On the experiment day, fasting glucose and VAS for satiety were collected, and participants were provided a standardized meal at 7:45. At 150 minutes post-meal, researchers collected blood samples and conducted VAS for satiety, and participants consumed one energy bar. After 90 minutes, participants were provided an ad libitum pasta meal. Post-meal, the blood sample and appetite rating were repeated, and the participants were instructed to record all dietary data for the remainder of the day. For the chronic phase, participants consumed one bar as a mid-morning between-meal snack on 14 consecutive days for two intervention periods. There was a 14-day washout period between each intervention period. Participants were instructed to keep their regular diets throughout the study. On day 1, the result indicated that both ad libitum EI at lunch (4085 ± 365 kJ versus 4880 ± 459 kJ, $p<0.05$) and total EI (9248 ± 782 kJ versus 11,466 ± 738 kJ, $p<0.05$) were significantly lower for PPX than the control. On day 15, both ad libitum EI at lunch (4330 ± 359 kJ versus 5344 ± 424 kJ, $p<0.05$) and total EI (10,214 ± 954 kJ versus 12080 ± 775 kJ $p<0.05$) were significantly lower after consumption of PPX than the control. The mean self-report free-living daily EI was significantly lower than control (7904 ± 610 kJ versus 9041 ± 928 kJ, $p<0.05$). In addition, the hunger value was significantly lower than the control ($p<0.05$). The PPX was associated with lower glucose and ghrelin higher glucagon-like peptide 1 and peptide tyrosine-tyrosine. Although the study included a small sample size (n=10), the study suggested that replacing regular snack bars with protein and polydextrose may be considered a potential weight loss strategy.[84]

CHAPTER 3

METHODS

Participants

Men and women volunteers were recruited from the campus community at Arizona State University in Phoenix metropolitan area through posters, listservs, and class announcements. The inclusion criteria for eligible volunteers include age, 18-35y, body mass index (BMI), 18.5 to 30 kg/m^2, no history of serious diseases, not pregnant or lactating, not currently dieting, and no competitive athletes. The participants were excluded if they experienced weight loss or gain (± 3 kg in the past six months). The study was conducted between February and April 2022, and participants received $50 financial compensation for participating in the study (APPENDIX G). Written informed consent was obtained from the participants, and the study was approved by Arizona State University Institutional Review Board. IRB Approval and the informed consent are shown in APPENDIX A and B.

Participants completed an online short health history questionnaire that included dieting history, current health status, medication use, alcohol and smoking status, physical activity status, body weight history, and height. The total physical activity was calculated using metabolic equivalent (MET) derived using the Godin questionnaire (APPENDIX H).[35]

Sample Size estimate

Early studies examining the satiety in subjects with protein and fiber provided data for sample size calculations.[30-31,76,86] Anticipating a change in satiety score of 1.5 with an SD of 2.6, the calculated sample size is 47 participants per group, assuming a probability of .05 and 80% power. The actual sample size in these studies averaged 22 participants per group. The sample size evaluation is shown in APPENDIX C.

Study Design

This study was a double-blind, randomized, cross-over trial that spanned a total of 28 days. Week 1 is the baseline week, and the following two 7-d intervention phases were separated by a 7-d washout period. Participants made three visits to the laboratory, scheduled for the 1st or 2nd day of week 1 and 3 and 1st or 2nd after the 7th day of week 4 (see Appendix F).

Test Food

There were two test foods in the study: a high protein (HP) bar and a high protein and high fiber (HPHF) bar. The test food composition and ingredients are shown in **Table 1**. The picture of the test food and original nutrition label are shown in APPENDIX D. The bars were packaged in opaque bags with randomly assigned codes: A or B. The investigator was blind to the code, and the study was not unblinded until the study was completed and all data analyzed.

Table 1

Composition of Nutrition Bars	HP	HPHF
Energy (kcal)	180	180
Protein (g)	21	20
Total Carbohydrate (g)	17	24
Added Sugar (g)	2	0
Fat (g)	4.5	7
Fiber (g)	2	14

HP: high protein bar; HPHF: high protein and high fiber bar
HP ingredients: protein blend (milk protein isolate, whey protein isolate, whey protein concentrate), hydrolyzed collagen, glycerin, cocoa, water, maltitol, maltitol syrup, fractionated palm kernel oil, sugar, whey protein concentrate, milk, unsweet chocolate, cocoa butter, cocoa (processed with alkali), natural flavor (include annatto and turmeric added for color), partially defatted peanut flour, calcium carbonate, soy lecithin, butterfat, almond butter, sucralose
HPHF ingredients: protein blend (milk protein isolate, whey protein isolate), soluble corn fiber, water almonds, erythritol, unsweetened chocolate, natural flavors, cocoa processed with alkali, cocoa butter, contain less than 2% of the following: sea salt, sunflower lecithin, stevia sweetener.

Study Protocol

Participants recorded all their food, drinks, and exercise status each Wednesday, Friday, and Sunday throughout the four weeks using MyFitnessPal, a smartphone diet tracker. The primary function of the MyFitnessPal includes setting the goal for dietary and exercise, estimating energy and nutrient intake. MyFitnessPal utilizes the USDA food database to help users develop weight goals, track their food and exercise status.[87] All participants received verbal and written instructions on using MyFitnessPal. The data entry and nutrient evaluation examples are shown in APPENDIX E.

During week 2, participants were randomly assigned to one of two test foods: HP bar or HPHF bar. The bars were consumed within 1 hour of waking. The participants were instructed to refrain from consuming any other energy-containing food or beverage at that time and for an additional hour after consuming the bars. The participants consumed their regular diet for the remainder of the day. For week 3, they were instructed to follow their regular diet for seven days as a washout period. During week 4, participants were provided with alternative bars and followed the same procedures as week 2. The appetite rating was measured by using online 100-mm VAS scale (APPENDIX I). The participants measured daily satiety when they woke up for week 1 and 3 and measures when they woke up and 1 hour after consuming the bars in week 2 and 4 (see APPENDIX F for flow chart).

Laboratory Analysis

Body composition measures were collected at each visit (weight in light clothes and body fat percentage). Waist circumferences were measured umbilicus by using a flexible tension tape.

Statistical Analysis

Data were reported as mean ± SD, and the statistical analysis was completed using Statistical Package for the Social Sciences (SPSS V27, IBM Corporation, Somers, NY) with significance ≤ 0.05. The normality was assessed, and outliers were removed as necessary, and repeated measure ANOVA was conducted to compare daily energy and nutrient intake and when the bars were consumed. The post hoc test was assessed at baseline and after consumption of each bar.

CHAPTER 4

RESULTS

There were 79 responses to the online screener, and 30 participants qualified for the study; however, only 21 participants completed the study entirely (6 males; 15 females). Subject characteristics were presented in TABLE 2. No adverse events were reported during the study. Gender, age, BMI, body weight did not differ significantly between completers and non-completers. Age ranged from 19 to 30 y (21.9 ± 2.6 y) and weight ranged from 49.8 to 89.7 kg (80.5 ± 7.2 kg and 63.2 ± 10.6 kg for men and women respectively); and none of participants classified as obese (BMI ≥ 30 kg/m^2), 30% participants classified overweight (24.9 < BMI < 29.9 kg/m^2).

TABLE 2
Subject Baseline Characteristics[1] (n = 21)

	Values
Age (y)	21.9 ± 2.6
Height (cm)	168.4 ± 11.9
Weight (kg)	68.2 ± 12.4
BMI (kg/m^2)	23.9 ± 2.7
Waist Circumference (cm)	77.6 ± 9.6
Fat-Free Mass (kg)	50.9 ± 11.6
Fat Mass (kg)	17.2 ± 6.8

[1] Data are presented as mean ± STD.

Participant characteristics at the end of each treatment week did not differ from baseline or between treatments except for mean fat mass (TABLE 3). The mean fat mass following one week of HPHF bar (treatment B) consumption was significantly higher than the baseline value (p = 0.023) and trended higher (p=0.057) in comparison to the value following one week of HP (treatment A) bar consumption. Data was presented in FIGURE 1.

TABLE 3

Subject Characteristics for Each Treatment (n = 18)

	Baseline	HP	HPHF	p-value
Weight (kg)	69.5 ± 12.3	70.1 ± 13	69.9 ± 12.4	0.232
Waist Circumference (cm)	78.8 ± 9.3	78.3 ± 9.0	78.8 ± 8.9	0.436
Fat-Free Mass (kg)	51.2 ± 11.7	51.4 ± 11.9	51.1 ± 11.8	0.801
Fat Mass (kg)	18.3 ± 6.7	18.8 ± 6.8	18.8 ± 6.8*	0.039

Data are presented as mean ± STD. Asterisk indicates a significant difference from baseline.

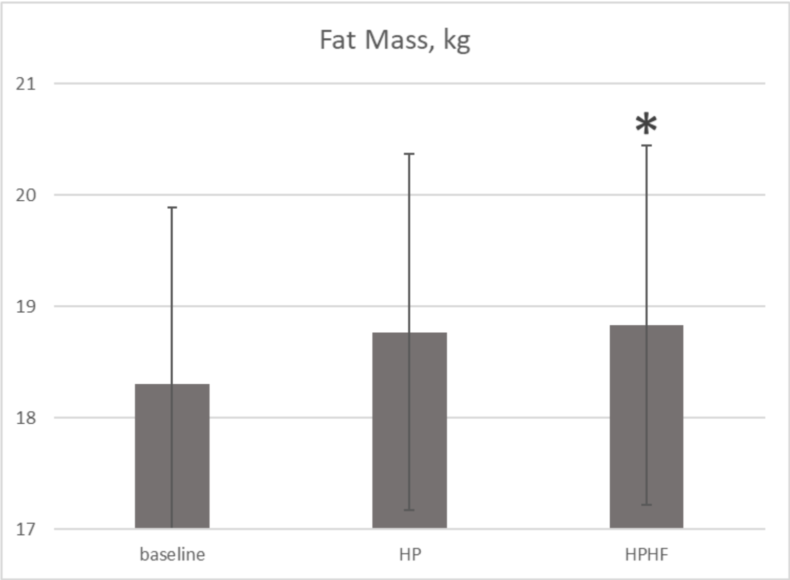


FIGURE 1. Mean fat mass (kg) in comparison for each treatment. Baseline and treatment A showed an upward trend (p=0.057). Baseline and treatment B is differed (*p = 0.023). Data are presented as mean ± STD.

Mean energy intake at the baseline week and the washout week did not differ significantly; furthermore, the order of the treatment did not impact energy intake. The mean energy intake during the study ranged from 1806 ± 537 kcal for the baseline week to 1902 ± 634 kcal and 1998 ± 534 kcal for the weeks the HP and HPHF bars were consumed respectively (FIGURE 2). The mean energy intake during the week the HPHF bar was consumed was significantly greater than that for the baseline week (p = 0.035). Gender, age, and BMI did not impact the result. However, physical activity level did impact these results (p = 0.034). For the low physical activity level group (n = 11), the mean energy intake for the baseline week and the weeks the HP and HPHF bars were consumed were 1735 ± 495 kcal, and 1673 ± 475 kcal and 1906 ± 472 kcal respectively ($p = 0.253$). For the high physical activity level group ($n = 10$), the mean energy intakes for the baseline week and the weeks the HP and HPHF bars were consumed were 1883 ± 597 kcal, and 2154 ± 712 kcal and 2099 ± 603 kcal respectively ($p < 0.04$; energy intakes for both bars were significantly different from baseline). Hence, highly active participants did not compensate for energy intake during the weeks the bars were consumed, but energy compensation appeared to occur for the low active participants.

Protein intakes were significantly increased in the subjects for the weeks the HP bars and HPHF bars were consumed. Similarly, fiber intakes were significantly increased in participants for the week the HPHF bar was consumed. Fat intakes were significantly increased in the participants for the week the HPHF bars were consumed. Data were not impacted by gender or physical activity level (TABLE 4).

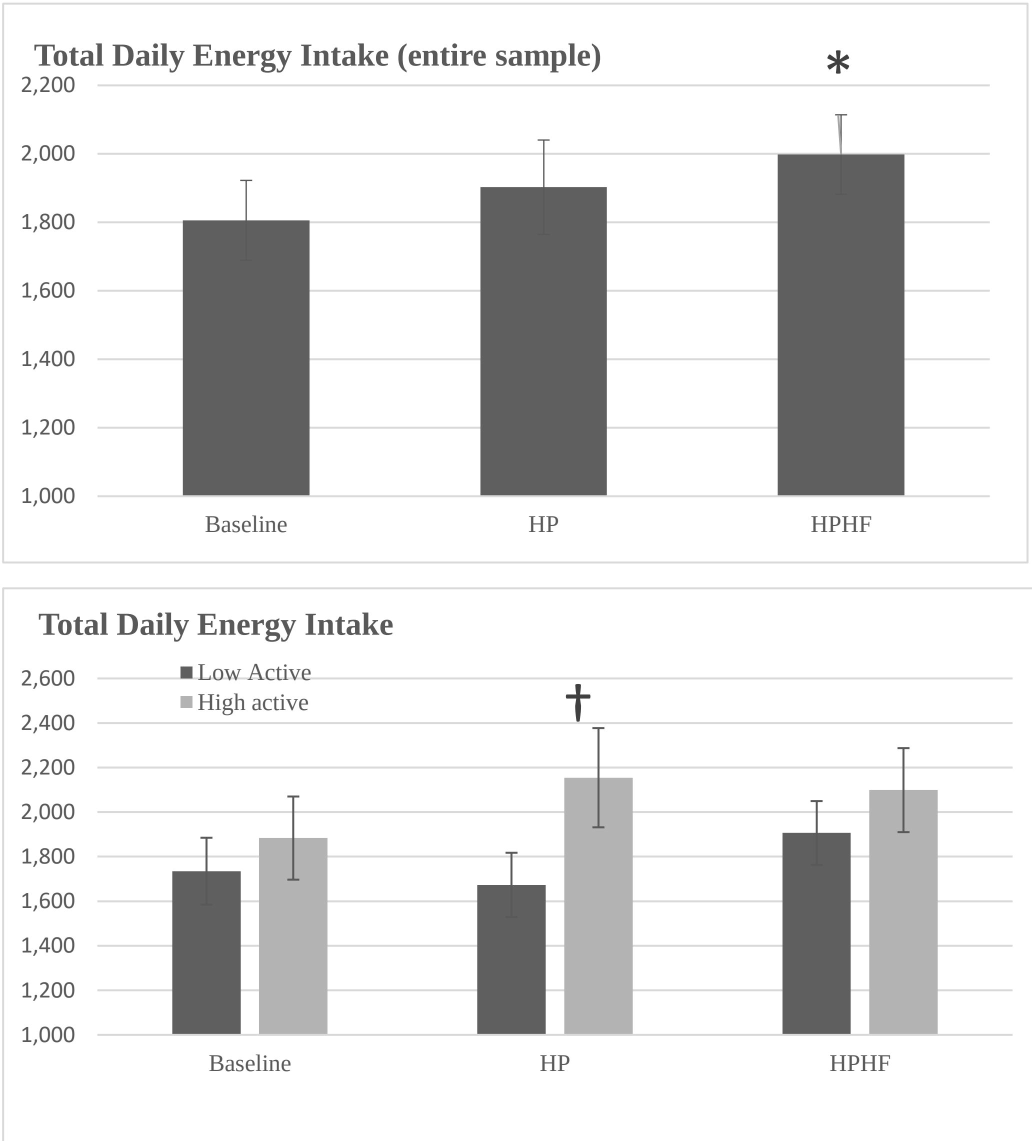


FIGURE 2. Mean energy intakes (kcal) in comparison for each treatment (n = 21). Baseline and HP and HPHF is differed (*p = 0.035). Data are presented as mean ± STD. For participants who were more physically active, daily energy intakes showed an upward trend from the low active group (†p=0.082).

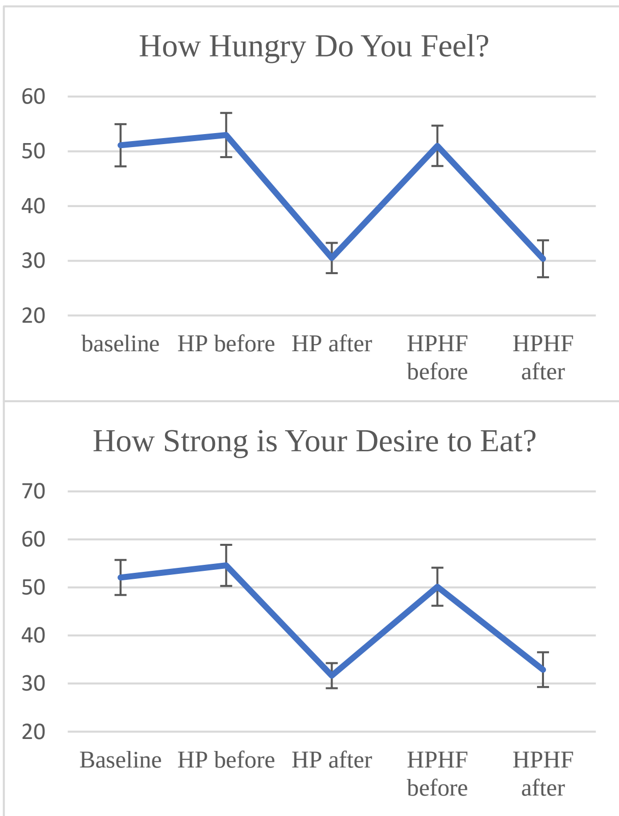
Table 4

Energy and Nutrient Intake Comparisons for Each Treatment (n = 21)

	Baseline	HP	HPHF	p-value
Energy (kcal)	1806 ± 537	1902 ± 634	1998 ± 534*	0.035
Carbohydrate (g)	206 ± 79	221 ± 63	216 ± 63	0.402
Protein (g)	80 ± 37	101 ± 43*	108 ± 36*	< 0.001
Fat (g)	62 ± 26	67 ± 28*	78 ± 26*	0.035
Fiber (g)	17 ± 14	18 ± 11	29 ± 9*	< 0.001

Data are presented as mean ± STD. Asterisk indicates differences from baseline.

Mean satiety for the baseline week and washout week did not differ significantly. The satiety rating of five questions indicated a significant effect for each bar consumed (TABLE 5) in comparison to baseline and the 'before' values; however, there were no differences between bars for any of the 'after' satiety ratings (FIGURE 3).



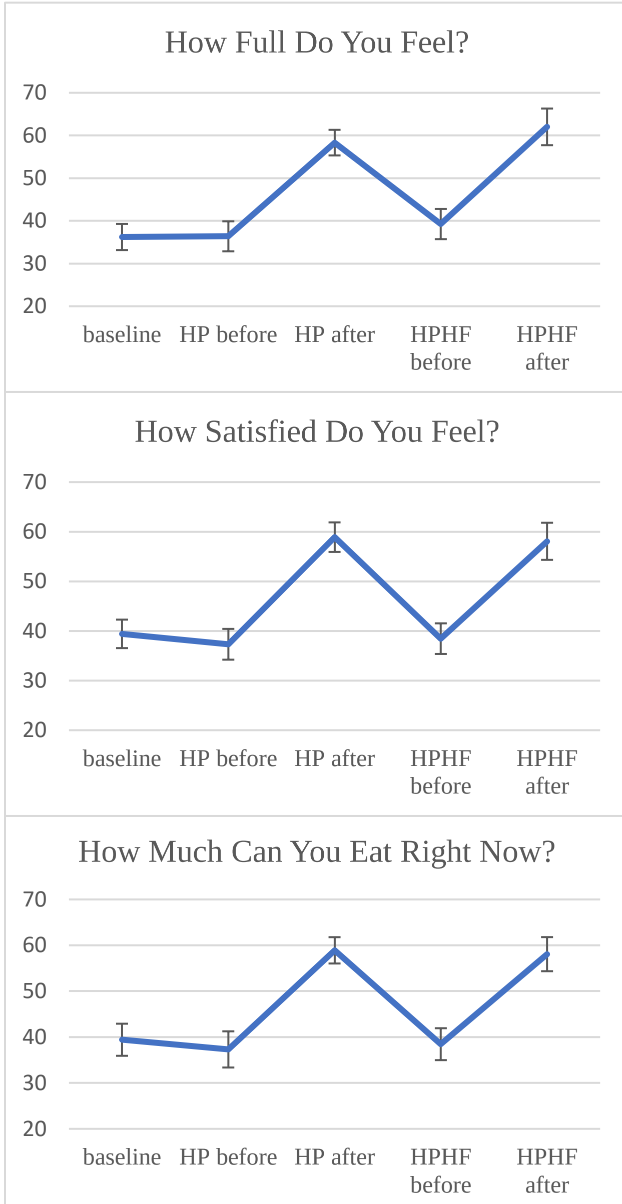


FIGURE 3. Satiety rating comparisons for each treatment. HP after and HPHF after did not differ. Data are presented as mean ± STE.

Table 5
Satiety Rating Comparisons for Each Treatment (n = 20)

	Baseline	Before HP	After HP	Before HPHF	After HPHF	p-value
How strong is your desire to eat?	52.1 ± 16.3	54.6 ± 19.1	31.7 ± 11.7*	50.2 ± 17.7	32.9 ± 16.2*	0.001
How hungry do you feel?	51.1 ± 17.2	53 ± 18	30.5 ± 12.4*	51 ± 16.5	30.3 ± 15.1*	0.002
How full do you feel?	36.2 ± 13.7	39.4 ± 15.7	58.3 ± 13.4*	39.3 ± 15.8	62 ± 19.2*	0.002
How satisfied do you feel?	39.4 ± 13.1	37.3 ± 14.2	58.9 ± 13.7*	38.5 ± 14.1	58.1 ± 17.1*	< 0.001
How much do you think you could eat right now?	55.7 ± 15.6	56 ± 17.6	34.9 ± 12.8*	54.3 ± 15.5	35.8 ± 16.6*	0.002

Data are presented as mean ± STD. Asterisks indicate significant differences from baseline and 'before' values.
Satiety rating by using VAS 1-100

CHAPTER 5

DISCUSSION

Although the data indicated both protein bars increased short-term satiety in one-hour after ingestion, the average total 24-h energy intake was raised above baseline for the seven days of daily bar consumption (HP or HPHF). Hence, the short-term satiating effects noted at one hour following bar consumption did not extend across the entire day. Trier et al. confirmed the same results and suggested that the satiating effects from ingestions of nutrition bars may be canceled by food intake later in the day among free-living adults.[83] Indeed, McKiernan et al indicated that single meals may not be precise to assess the compensatory responses and long-term energy balance since free-living adults regulate 24-h energy intake more consistently than individual eating occasions.[88]

Data indicated a small but significant increase in body fat mass following one-week ingestion of HPHF bars and an upward trend following one-week ingestion of HP bars compare to the baseline. BMI was not related to the change of energy intake on the week HP and HPHF treatment was consumed. These data suggested that the extra energy content from the protein bars may accumulate in the adipose tissues. Others have documented that short-term overfeeding has a minimal effect on energy intake among free-living adults and it may contribute to fat mass gain without changing physical activities.[89] In addition, Whybrow et al. indicated that there is a non-significant trend for weight gain and increased fat content with increasing energy intake from snacks within two weeks of mandatory snacks consumption among free-living adults.[90]

Consumption of protein bars may impact nutrient intake among free-living adults. On the week HP bars were consumed, the average protein intake increased by an average of 26%; whereas on the week HPHF were consumed, the average protein intake increased by

35%. The average fat intake increased by 8% and 26% on the week HP bars and HPHF bars were consumed. The average fiber intake increased by 70% on the week HPHF bars were consumed. Thus, protein bars may be considered a source to improve nutrition health among free-living adults. The global energy bars market was valued at $645.0 million in 2020 and is estimated to reach $1,010.9 million by 2028, with a compound annual growth rate of 6.4% from 2021 to 2028.[24] Consumers may perceive nutrition bars as convenient, healthy, or nutrient-rich, but they may not consider nutrition bars as energy-dense meal-replacements. The increasing sales of nutrition bars are parallel with the increasing obesity rate in the U.S.; hence, future long-term intervention trials are necessary to conduct among free-living populations.

According to the data, the mean 24-h energy intake did not differ between the weeks HP and HPHF bars were consumed. However, Astbury et al. indicated that 24-h energy intake is significantly lower when PPX (whey protein and polydextrose) bars were consumed (250 kcals, 17 g carbohydrate, 14 g fat, 13 g protein).[84] These results imply that the additional energy, carbohydrate, and fat content may contribute to the compensatory effect and lower energy intake. In comparison, the nutrition bars in the present study contained only 180 kcals and little carbohydrate or fat, and there were no compensation effects in our study. It is important to note that the data indicated that physical activities impact the average energy intake for both protein bars. The individuals with high activity levels reported average energy intakes that were significantly elevated on the weeks the protein bars were consumed. These data indicated that individuals with high activity levels may not effectively compensate for the increased energy intake. Ptomey et al. indicated that moderate to vigorous physical activity is associated with slightly increased energy intake in the 12-month weight maintenance intervention.[91] In addition, Barutcu et al. indicated a higher energy intake was observed after planned fasted aerobic exercise, but the increased energy intake did not compensate for the energy expended on the exercise.[92] However, these data do not align with the finding reported herein. Interestingly, Martins et al. found that medium-term exercise could increase the drive to eat in the fasting state, but it will be balanced improved satiety response and sensitivity of the appetite control system.[93]

The satiety rating of five questions indicated a significant satiating effect for both HP and HPHF bars one hour after consumption. The satiating effect between HP bars and HPHF did not differ significantly. The results rejected our hypothesis that HPHF will have a higher satiating effect compared to HP bars due to the soluble fiber content. Willis et al. indicated that mixed fiber in muffins for breakfast did not influence satiety, gut hormones, or food intake and researchers suggested that higher fiber intakes (>12 g) may be necessary to have satiety effects.[94] In addition, the food volumes may affect the satiating effect. Rolls et al. indicated volume of the food could influence satiety through sensory processes, and these are associated with gastric stimulation.[95]

The attribution rate for the study is 30%; however, the gender, age, BMI, and body weight did not differ significantly between completers and non-completers. The limitations of the study include self-report health status and dietary data, and the inability to use the gold standard for measuring body composition, energy intake, and satiety. The long-term effects may not be presented in the study. The commercial nutrition bars in the study may not generalize to other products in the market. Cutrufello et al. indicated that acute fluid consumption had a significant effect on multifrequency bioelectrical impedance analysis.[96] Therefore, participants came in different schedules which may increase the error rate for bioimpedance. Participants were healthy volunteers from the Phoenix metropolitan area and receive incentives. Several data were missing due to the school holiday schedule and participants may not follow the protocols throughout the study. However, the crossover nature of the study reduced the confounding variables and free-living conditions were not manipulated the external validity.

In conclusion, nutrition bars represent a convenient functional food category that has gained rapid market growth in the recent decade, and consumers many perceive these foods as a source of specific nutrients, such as protein or fiber. However, nutrition bars may not be perceived as a significant energy source and may increase the risk of gaining fat mass and eventual body mass over time. Nutrition bars should be viewed as a snack or meal replacement to facilitate compensation for their caloric content. Future studies are necessary to determine the long-term effects of the commercial nutrition bars.

REFERENCES

1. Centers for Disease Control and Prevention. (2021, September 30). Adult obesity facts. Centers for Disease Control and Prevention. Retrieved April 11, 2022, from https://www.cdc.gov/obesity/data/adult.html

2. Home: Dietary guidelines for Americans. Home | Dietary Guidelines for Americans. (n.d.). Retrieved April 11, 2022, from https://www.dietaryguidelines.gov/

3. Romieu, I., Dossus, L., Barquera, S., Blottière, H. M., Franks, P. W., Gunter, M., Hwalla, N., Hursting, S. D., Leitzmann, M., Margetts, B., Nishida, C., Potischman, N., Seidell, J., Stepien, M., Wang, Y., Westerterp, K., Winichagoon, P., Wiseman, M., & Willett, W. C. (2017). Energy balance and obesity: What are the main drivers? Cancer Causes & Control, 28(3), 247–258. https://doi.org/10.1007/s10552-017-0869-z

4. Degirmenci, T., Kalkan Oguzhanoglu, N., Sozeri Varma, G., Ozdel, O., & Fenkci, S. (2015). Psychological symptoms in obesity and related factors. Noro Psikiyatri Arsivi, 52(1), 42–46. https://doi.org/10.5152/npa.2015.6904

5. Scully, M., Dixon, H., & Wakefield, M. (2009). Association between commercial television exposure and fast-food consumption among adults. Public Health Nutrition, 12(1), 105–110. https://doi.org/10.1017/s1368980008002012

6. Vartanian, L. R., Schwartz, M. B., & Brownell, K. D. (2007). Effects of soft drink consumption on nutrition and health: A systematic review and meta-analysis. American Journal of Public Health, 97(4), 667–675. https://doi.org/10.2105/ajph.2005.083782

7. Fernandez, M. A., & Raine, K. D. (2019). Insights on the influence of sugar taxes on obesity prevention efforts. Current Nutrition Reports, 8(4), 333–339. https://doi.org/10.1007/s13668-019-00282-4

8. Frayling, Timpson, N. J., Weedon, M. N., Zeggini, E., Freathy, R. M., Lindgren, C. M., Perry, J. R. B., Elliott, K. S., Lango, H., Rayner, N. W., Shields, B., Harries, L. W., Barrett, J. C., Ellard, S., Groves, C. J., Knight, B., Patch, A.-M., Ness, A. R., Ebrahim, S., … McCarthy, M. I. (2007). A Common Variant in the FTO Gene Is Associated with Body Mass Index and Predisposes to Childhood

and Adult Obesity. Science (American Association for the Advancement of Science), 316(5826), 889–894.

9. National Academies Press. (2005). Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids.

10. Astbury, N. M., Piernas, C., Hartmann-Boyce, J., Lapworth, S., Aveyard, P., & Jebb, S. A. (2019). A systematic review and meta-analysis of the effectiveness of meal replacements for Weight Loss. Obesity Reviews, 20(4), 569–587. https://doi.org/10.1111/obr.12816

11. Davis, L. M., Coleman, C., Kiel, J., Rampolla, J., Hutchisen, T., Ford, L., Andersen, W. S., & Hanlon-Mitola, A. (2010). Efficacy of a meal replacement diet plan compared to a food-based diet plan after a period of weight loss and weight maintenance: A randomized controlled trial. Nutrition Journal, 9(1). https://doi.org/10.1186/1475-2891-9-11

12. Lowe, M. R., Butryn, M. L., & Zhang, F. (2018). Evaluation of meal replacements and a home food environment intervention for long-term weight loss: A randomized controlled trial. The American Journal of Clinical Nutrition, 107(1), 12–19. https://doi.org/10.1093/ajcn/nqx005

13. Astbury, N. M., Piernas, C., Hartmann-Boyce, J., Lapworth, S., Aveyard, P., & Jebb, S. A. (2019). A systematic review and meta-analysis of the effectiveness of meal replacements for Weight Loss. Obesity Reviews, 20(4), 569–587. https://doi.org/10.1111/obr.12816

14. Smith, S. R., Stenlof, K. S., Greenway, F. L., McHutchison, J., Schwartz, S. M., Dev, V. B., Berk, E. S., & Kapikian, R. (2011). Orlistat 60 mg reduces visceral adipose tissue: A 24-week randomized, placebo-controlled, Multicenter Trial. Obesity, 19(9), 1796–1803. https://doi.org/10.1038/oby.2011.143

15. Murray, J. A. (2012). A one-year randomized trial of lorcaserin for weight loss in obese and overweight adults: The blossom trial. Yearbook of Medicine, 2012, 411–412. https://doi.org/10.1016/s0084-3873(12)00299-4

16. Allison, D. B., Gadde, K. M., Garvey, W. T., Peterson, C. A., Schwiers, M. L., Najarian, T., Tam, P. Y., Troupin, B., & Day, W. W. (2012). Controlled-

release phentermine/topiramate in severely obese adults: A randomized controlled trial (equip). Obesity, 20(2), 330–342. https://doi.org/10.1038/oby.2011.330

17. Ge. (2020). Comparison of dietary macronutrient patterns of 14 popular named dietary programmes for weight and cardiovascular risk factor reduction in adults: systematic review and network meta-analysis of randomised trials. BMJ, 370, m3095–m3095. https://doi.org/10.1136/bmj.m3095

18. Mclaren, McKay, G., & Fisher, M. (2013). Lorcaserin. Practical Diabetes (2011), 30(3), 136–137. https://doi.org/10.1002/pdi.1760

19. Thompson, F. E., & Subar, A. F. (2017). Dietary assessment methodology. Nutrition in the Prevention and Treatment of Disease, 5–48. https://doi.org/10.1016/b978-0-12-802928-2.00001-1

20. Thompson, F. E., Subar, A. F., Loria, C. M., Reedy, J. L., & Baranowski, T. (2010). Need for technological innovation in dietary assessment. Journal of the American Dietetic Association, 110(1), 48–51. https://doi.org/10.1016/j.jada.2009.10.008

21. Wharton, C. M., Johnston, C. S., Cunningham, B. K., & Sterner, D. (2014). Dietary self-monitoring, but not dietary quality, improves with use of smartphone app technology in an 8-week weight loss trial. Journal of Nutrition Education and Behavior, 46(5), 440–444. https://doi.org/10.1016/j.jneb.2014.04.291

22. Ipjian, M. L., & Johnston, C. S. (2017). Smartphone technology facilitates dietary change in healthy adults. Nutrition, 33, 343–347. https://doi.org/10.1016/j.nut.2016.08.003

23. Semper, H. M., Povey, R., & Clark-Carter, D. (2016). A systematic review of the effectiveness of smartphone applications that encourage dietary self-regulatory strategies for weight loss in overweight and obese adults. Obesity Reviews, 17(9), 895–906. https://doi.org/10.1111/obr.12428

24. Energy bar market share, size, growth: Global Industry Analysis 2028. Allied Market Research. (n.d.). Retrieved April 11, 2022, from https://www.alliedmarketresearch.com/energy-bar-market

25. Lejeune, M. P. G. M., Westerterp, K. R., Adam, T. C. M., Luscombe-Marsh, N. D., & Westerterp-Plantenga, M. S. (2006). Ghrelin and glucagon-like peptide 1 concentrations, 24-H satiety, and energy and substrate metabolism during a high-protein diet and measured in a respiration chamber. The American Journal of Clinical Nutrition, 83(1), 89–94. https://doi.org/10.1093/ajcn/83.1.89

26. Westerterp-Plantenga, M. S., Rolland, V., Wilson, S. A. J., & Westerterp, K. R. (1999). Satiety related to 24 h diet-induced thermogenesis during high protein/carbohydrate vs high fat diets measured in a respiration chamber. European Journal of Clinical Nutrition, 53(6), 495–502. https://doi.org/10.1038/sj.ejcn.1600782

27. Veldhorst, M. A. B., Nieuwenhuizen, A. G., Hochstenbach-Waelen, A., van Vught, A. J. A. H., Westerterp, K. R., Engelen, M. P. K. J., Brummer, R.-J. M., Deutz, N. E. P., & Westerterp-Plantenga, M. S. (2009). Dose-dependent satiating effect of whey relative to casein or soy. Physiology & Behavior, 96(4-5), 675–682. https://doi.org/10.1016/j.physbeh.2009.01.004

28. Aoe, S., Ikenaga, T., Noguchi, H., Kohashi, C., Kakumoto, K., & Kohda, N. (2014). Effect of cooked white rice with high β-glucan barley on appetite and energy intake in healthy Japanese subjects: A randomized controlled trial. Plant Foods for Human Nutrition, 69(4), 325–330. https://doi.org/10.1007/s11130-014-0437-6

29. Samra, R. A., & Anderson, G. H. (2007). Insoluble cereal fiber reduces appetite and short-term food intake and glycemic response to food consumed 75 min later by Healthy Men. The American Journal of Clinical Nutrition, 86(4), 972–979. https://doi.org/10.1093/ajcn/86.4.972

30. Sharafi, M., Alamdari, N., Wilson, M., Leidy, H. J., & Glynn, E. L. (2018). Effect of a high-protein, high-fiber beverage preload on subjective appetite ratings and subsequent ad libitum energy intake in overweight men and women: A randomized, double-blind placebo-controlled, crossover study. Current Developments in Nutrition, 2(6). https://doi.org/10.1093/cdn/nzy022

31. Sharafi, M., Alamdari, N., Wilson, M., Leidy, H. J., & Glynn, E. L. (2018). Effect of a high-protein, high-fiber beverage preload on subjective appetite ratings and subsequent ad libitum energy intake in overweight men and women: A

randomized, double-blind placebo-controlled, crossover study. Current Developments in Nutrition, 2(6). https://doi.org/10.1093/cdn/nzy022

32. Astbury, N. M., Taylor, M. A., French, S. J., & Macdonald, I. A. (2014). Snacks containing whey protein and polydextrose induce a sustained reduction in daily energy intake over 2 WK under Free-living conditions. The American Journal of Clinical Nutrition, 99(5), 1131–1140. https://doi.org/10.3945/ajcn.113.075978

33. World Health Organization. (n.d.). Obesity and overweight. World Health Organization. Retrieved April 11, 2022, from http://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight

34. Moreno, B., Bellido, D., Sajoux, I., Goday, A., Saavedra, D., Crujeiras, A. B., & Casanueva, F. F. (2014). Comparison of a very low-calorie-ketogenic diet with a standard low-calorie diet in the treatment of obesity. Endocrine, 47(3), 793–805. https://doi.org/10.1007/s12020-014-0192-3

35. Li, H., Wu, Y., Loos, R. J. F., Hu, F. B., Liu, Y., Wang, J., Yu, Z., & Lin, X. (2008). Variants in the fat mass–and obesity-associated (fto) gene are not associated with obesity in a Chinese Han population. Diabetes, 57(1), 264–268. https://doi.org/10.2337/db07-1130

36. Scuteri, A., Sanna, S., Chen, W.-M., Uda, M., Albai, G., Strait, J., Najjar, S., Nagaraja, R., Orrú, M., Usala, G., Dei, M., Lai, S., Maschio, A., Busonero, F., Mulas, A., Ehret, G. B., Fink, A. A., Weder, A. B., Cooper, R. S., … Abecasis, G. R. (2007). Genome-wide association scan shows genetic variants in the FTO gene are associated with obesity-related traits. PLoS Genetics, 3(7). https://doi.org/10.1371/journal.pgen.0030115

37. Heisler, L. K., & Lam, D. D. (2017). An appetite for life: Brain regulation of hunger and satiety. Current Opinion in Pharmacology, 37, 100–106. https://doi.org/10.1016/j.coph.2017.09.002

38. Drucker, D. J. (2005). Biologic actions and therapeutic potential of the proglucagon-derived peptides. Nature Clinical Practice Endocrinology & Metabolism, 1(1), 22–31. https://doi.org/10.1038/ncpendmet0017

39. Suzuki, K., Jayasena, C. N., & Bloom, S. R. (2011). The gut hormones in appetite regulation. Journal of Obesity, 2011, 1–10. https://doi.org/10.1155/2011/528401

40. Date, Y., Toshinai, K., Koda, S., Miyazato, M., Shimbara, T., Tsuruta, T., Niijima, A., Kangawa, K., & Nakazato, M. (2005). Peripheral interaction of ghrelin with cholecystokinin on feeding regulation. Endocrinology, 146(8), 3518–3525. https://doi.org/10.1210/en.2004-1240

41. Merrill, E. P., Kramer, F. M., Cardello, A., & Schutz, H. (2002). A comparison of satiety measures. Appetite, 39(2), 181–183. https://doi.org/10.1006/appe.2002.0496

42. Livingstone, M. B., Robson, P. J., Welch, R. W., Burns, A. A., Burrows, M. S., & McCormack, C. (2000). Methodological issues in the assessment of satiety. Näringsforskning, 44(1), 98–103. https://doi.org/10.3402/fnr.v44i0.1776

43. Cardello, A. V., Schutz, H. G., Lesher, L. L., & Merrill, E. (2005). Development and testing of a labeled magnitude scale of perceived satiety. Appetite, 44(1), 1–13. https://doi.org/10.1016/j.appet.2004.05.007

44. B Keogh, J., & M Clifton, P. (2020). Energy intake and satiety responses of eggs for breakfast in overweight and obese adults—a crossover study. International Journal of Environmental Research and Public Health, 17(15), 5583. https://doi.org/10.3390/ijerph17155583

45. Home: Dietary guidelines for Americans. Home | Dietary Guidelines for Americans. (n.d.). Retrieved April 11, 2022, from https://www.dietaryguidelines.gov/

46. Ge, L., Sadeghirad, B., Ball, G. D., da Costa, B. R., Hitchcock, C. L., Svendrovski, A., Kiflen, R., Quadri, K., Kwon, H. Y., Karamouzian, M., Adams-Webber, T., Ahmed, W., Damanhoury, S., Zeraatkar, D., Nikolakopoulou, A., Tsuyuki, R. T., Tian, J., Yang, K., Guyatt, G. H., & Johnston, B. C. (2020). Comparison of dietary macronutrient patterns of 14 popular named dietary programmes for weight and cardiovascular risk factor reduction in adults: Systematic review and network meta-analysis of Randomised Trials. BMJ, m696. https://doi.org/10.1136/bmj.m696

47. Daneschvar, H. L., Aronson, M. D., & Smetana, G. W. (2016). FDA-approved anti-obesity drugs in the United States. The American Journal of Medicine, 129(8). https://doi.org/10.1016/j.amjmed.2016.02.009

48. Hvizdos, K. M., & Markham, A. (1999). Orlistat. Drugs, 58(4), 743–760. https://doi.org/10.2165/00003495-199958040-00015

49. McNeely, W., & Benfield, P. (1998). Orlistat. Drugs, 56(2), 241–249. https://doi.org/10.2165/00003495-199856020-00007

50. Smith, S. R., Stenlof, K. S., Greenway, F. L., McHutchison, J., Schwartz, S. M., Dev, V. B., Berk, E. S., & Kapikian, R. (2011). Orlistat 60 mg reduces visceral adipose tissue: A 24-week randomized, placebo-controlled, Multicenter Trial. Obesity, 19(9), 1796–1803. https://doi.org/10.1038/oby.2011.143

51. Heisler, L. K., Jobst, E. E., Sutton, G. M., Zhou, L., Borok, E., Thornton-Jones, Z., Liu, H. Y., Zigman, J. M., Balthasar, N., Kishi, T., Lee, C. E., Aschkenasi, C. J., Zhang, C.-Y., Yu, J., Boss, O., Mountjoy, K. G., Clifton, P. G., Lowell, B. B., Friedman, J. M., … Cowley, M. A. (2006). Serotonin reciprocally regulates melanocortin neurons to modulate food intake. Neuron, 51(2), 239–249. https://doi.org/10.1016/j.neuron.2006.06.004

52. Apovian, C. M., Aronne, L. J., Bessesen, D. H., McDonnell, M. E., Murad, M. H., Pagotto, U., Ryan, D. H., & Still, C. D. (2015). Pharmacological management of obesity an endocrine society clinical practice guideline. Reproductive Endocrinology, (23), 59. https://doi.org/10.18370/2309-4117.2015.23.59-63

53. Rothman, R. B., & Baumann, M. H. (2000). Neurochemical mechanisms of Phentermine and fenfluramine: Therapeutic and adverse effects. Drug Development Research, 51(2), 52–65. https://doi.org/10.1002/1098-2299(200010)51:2<52::aid-ddr2>3.0.co;2-h

54. Duncan, M. J., Vandelanotte, C., Rosenkranz, R. R., Caperchione, C. M., Ding, H., Ellison, M., George, E. S., Hooker, C., Karunanithi, M., Kolt, G. S., Maeder, A., Noakes, M., Tague, R., Taylor, P., Viljoen, P., & Mummery, W. K. (2012). Effectiveness of a website and mobile phone based physical activity and nutrition intervention for middle-aged males: Trial protocol and baseline findings

of the MANUP study. BMC Public Health, 12(1). https://doi.org/10.1186/1471-2458-12-656

55. Pesta, D. H., & Samuel, V. T. (2014). A high-protein diet for reducing body fat: Mechanisms and possible caveats. Nutrition & Metabolism, 11(1), 53. https://doi.org/10.1186/1743-7075-11-53

56. Paddon-Jones, D., Westman, E., Mattes, R. D., Wolfe, R. R., Astrup, A., & Westerterp-Plantenga, M. (2008). Protein, weight management, and satiety. The American Journal of Clinical Nutrition, 87(5). https://doi.org/10.1093/ajcn/87.5.1558s

57. Oliveira, C. L., Boulé, N. G., Sharma, A. M., Elliott, S. A., Siervo, M., Ghosh, S., Berg, A., & Prado, C. M. (2020). A high-protein total diet replacement increases energy expenditure and leads to negative fat balance in healthy, normal-weight adults. The American Journal of Clinical Nutrition, 113(2), 476–487. https://doi.org/10.1093/ajcn/nqaa283

58. Ravn, A.-M., Ture Gregersen, N., Christensen, R., Graasbøl Rasmussen, L., Hels, O., Belza, A., Raben, A., Meinert Larsen, T., Toubro, S., & Astrup, A. (2013). Thermic effect of a meal and appetite in adults: An individual participant data meta-analysis of meal-test trials. Food & Nutrition Research, 57(1), 19676. https://doi.org/10.3402/fnr.v57i0.19676

59. Davidenko, O., Darcel, N., Fromentin, G., & Tomé, D. (2013). Control of protein and energy intake - brain mechanisms. European Journal of Clinical Nutrition, 67(5), 455–461. https://doi.org/10.1038/ejcn.2013.73

60. Belza, A., Ritz, C., Sørensen, M. Q., Holst, J. J., Rehfeld, J. F., & Astrup, A. (2013). Contribution of gastroenteropancreatic appetite hormones to protein-induced satiety. The American Journal of Clinical Nutrition, 97(5), 980–989. https://doi.org/10.3945/ajcn.112.047563

61. Perez-Tilve, D., Nogueiras, R., Mallo, F., Benoit, S. C., & Tschoep, M. (2006). Gut Hormones Ghrelin, PYY, and GLP-1 in the regulation of energy, balance, and metabolism. Endocrine, 29(1), 61–72. https://doi.org/10.1385/endo:29:1:61

62. Drummen, M., Tischmann, L., Gatta-Cherifi, B., Adam, T., & Westerterp-Plantenga, M. (2018). Dietary protein and energy balance in relation to obesity and co-morbidities. Frontiers in Endocrinology, 9. https://doi.org/10.3389/fendo.2018.00443

63. METTLER, S. A. M. U. E. L., MITCHELL, N. I. G. E. L., & TIPTON, K. E. V. I. N. D. (2010). Increased protein intake reduces lean body mass loss during weight loss in athletes. Medicine & Science in Sports & Exercise, 42(2), 326–337. https://doi.org/10.1249/mss.0b013e3181b2ef8e

64. Griffin, H. J., Cheng, H. L., O'Connor, H. T., Rooney, K. B., Petocz, P., & Steinbeck, K. S. (2013). Higher protein diet for weight management in young overweight women: A 12-month randomized controlled trial. Diabetes, Obesity and Metabolism, 15(6), 572–575. https://doi.org/10.1111/dom.12056

65. Wycherley, T. P., Moran, L. J., Clifton, P. M., Noakes, M., & Brinkworth, G. D. (2012). Effects of energy-restricted high-protein, low-fat compared with standard-protein, low-fat diets: A meta-analysis of randomized controlled trials. The American Journal of Clinical Nutrition, 96(6), 1281–1298. https://doi.org/10.3945/ajcn.112.044321

66. Pal, S., Radavelli-Bagatini, S., Hagger, M., & Ellis, V. (2014). Comparative effects of whey and casein proteins on satiety in overweight and obese individuals: A randomized controlled trial. European Journal of Clinical Nutrition, 68(9), 980–986. https://doi.org/10.1038/ejcn.2014.84

67. Veldhorst, M. A. B., Nieuwenhuizen, A. G., Hochstenbach-Waelen, A., van Vught, A. J. A. H., Westerterp, K. R., Engelen, M. P. K. J., Brummer, R.-J. M., Deutz, N. E. P., & Westerterp-Plantenga, M. S. (2009). Dose-dependent satiating effect of whey relative to casein or soy. Physiology & Behavior, 96(4-5), 675–682. https://doi.org/10.1016/j.physbeh.2009.01.004

68. Antonio, J., Ellerbroek, A., & Carson, C. (2018). The effects of a high-protein diet on bone mineral density in exercise-trained women: A 1-year investigation. Journal of Functional Morphology and Kinesiology, 3(4), 62. https://doi.org/10.3390/jfmk3040062

69. Hernández-Alonso, P., Salas-Salvadó, J., Ruiz-Canela, M., Corella, D., Estruch, R., Fitó, M., Arós, F., Gómez-Gracia, E., Fiol, M., Lapetra, J., Basora, J., Serra-

Majem, L., Muñoz, M. Á., Buil-Cosiales, P., Saiz, C., & Bulló, M. (2016). High dietary protein intake is associated with an increased body weight and total death risk. Clinical Nutrition, 35(2), 496–506. https://doi.org/10.1016/j.clnu.2015.03.016

70. Slavin, J. (2013). Fiber and prebiotics: Mechanisms and health benefits. Nutrients, 5(4), 1417–1435. https://doi.org/10.3390/nu5041417

71. Slavin, J., & Green, H. (2007). Dietary fibre and satiety. Nutrition Bulletin, 32(s1), 32–42. https://doi.org/10.1111/j.1467-3010.2007.00603.x

72. Jonnalagadda, S. S., Harnack, L., Hai Liu, R., McKeown, N., Seal, C., Liu, S., & Fahey, G. C. (2011). Putting the whole grain puzzle together: Health benefits associated with whole grains—summary of American Society for Nutrition 2010 Satellite symposium. The Journal of Nutrition, 141(5). https://doi.org/10.3945/jn.110.132944

73. Aoe, S., Ikenaga, T., Noguchi, H., Kohashi, C., Kakumoto, K., & Kohda, N. (2014). Effect of cooked white rice with high β-glucan barley on appetite and energy intake in healthy Japanese subjects: A randomized controlled trial. Plant Foods for Human Nutrition, 69(4), 325–330. https://doi.org/10.1007/s11130-014-0437-6

74. Samra, R. A., & Anderson, G. H. (2007). Insoluble cereal fiber reduces appetite and short-term food intake and glycemic response to food consumed 75 min later by Healthy Men. The American Journal of Clinical Nutrition, 86(4), 972–979. https://doi.org/10.1093/ajcn/86.4.972

75. Du, H., van der A, D. L., Boshuizen, H. C., Forouhi, N. G., Wareham, N. J., Halkjær, J., Tjønneland, A., Overvad, K., Jakobsen, M. U., Boeing, H., Buijsse, B., Masala, G., Palli, D., Sørensen, T. I. A., Saris, W. H. M., & Feskens, E. J. M. (2009). Dietary fiber and subsequent changes in body weight and waist circumference in European men and women. The American Journal of Clinical Nutrition, 91(2), 329–336. https://doi.org/10.3945/ajcn.2009.28191

76. Abutair, A. S., Naser, I. A., & Hamed, A. T. (2016). Soluble fibers from psyllium improve glycemic response and body weight among diabetes type 2 patients (randomized control trial). Nutrition Journal, 15(1). https://doi.org/10.1186/s12937-016-0207-4

77. Chew, K. Y., & Brownlee, I. A. (2018). The impact of supplementation with dietary fibers on weight loss: A systematic review of Randomised Controlled Trials. Bioactive Carbohydrates and Dietary Fibre, 14, 9–19. https://doi.org/10.1016/j.bcdf.2017.07.010

78. Jovanovski, E., Mazhar, N., Komishon, A., Khayyat, R., Li, D., Blanco Mejia, S., Khan, T., L Jenkins, A., Smircic-Duvnjak, L., L Sievenpiper, J., & Vuksan, V. (2020). Can dietary viscous fiber affect body weight independently of an energy-restrictive diet? A systematic review and meta-analysis of randomized controlled trials. The American Journal of Clinical Nutrition, 111(2), 471–485. https://doi.org/10.1093/ajcn/nqz292

79. Williams, C. L., & Bollella, M. (1995). Is a high-fiber diet safe for children? Pediatrics, 96(5), 1014–1019. https://doi.org/10.1542/peds.96.5.1014

80. Davidson, M. H., & Maki, K. C. (1999). Effects of dietary inulin on serum lipids. The Journal of Nutrition, 129(7). https://doi.org/10.1093/jn/129.7.1474s

81. Panoff, L. (2020, March 16). Are Protein Bars Good for you? Healthline. Retrieved April 11, 2022, from https://www.healthline.com/nutrition/are-protein-bars-good-for-you

82. Chow, J. M., Choe, Y. S., Noss, M. J., Robinson, K. J., Dugle, J. E., Acosta, S. H., & Garleb, K. A. (2007). Effect of a viscous fiber-containing nutrition bar on satiety of patients with type 2 diabetes. Diabetes Research and Clinical Practice, 76(3), 335–340. https://doi.org/10.1016/j.diabres.2006.09.013

83. Trier, C. M., & Johnston, C. S. (2012). Ingestion of nutrition bars high in protein or carbohydrate does not impact 24-H Energy Intakes in healthy young adults. Appetite, 59(3), 778–781. https://doi.org/10.1016/j.appet.2012.08.012

84. Astbury, N. M., Taylor, M. A., French, S. J., & Macdonald, I. A. (2014). Snacks containing whey protein and polydextrose induce a sustained reduction in daily energy intake over 2 WK under Free-living conditions. The American Journal of Clinical Nutrition, 99(5), 1131–1140. https://doi.org/10.3945/ajcn.113.075978

85. Godin, G., & Shephard, R. J. (1985). Leisure Time Exercise Questionnaire. PsycTESTS Dataset. https://doi.org/10.1037/t31334-000

86. Zaharudin, N., Tullin, M., Pekmez, C. T., Sloth, J. J., Rasmussen, R. R., & Dragsted, L. O. (2021). Effects of brown seaweeds on postprandial glucose, insulin and appetite in humans – a randomized, 3-way, blinded, cross-over meal study. Clinical Nutrition, 40(3), 830–838. https://doi.org/10.1016/j.clnu.2020.08.027

87. Myfitnesspal. MyFitnessPal. (n.d.). Retrieved April 11, 2022, from https://www.myfitnesspal.com/.

88. McKiernan, F., Hollis, J. H., & Mattes, R. D. (2008). Short-term dietary compensation in free-living adults. Physiology & Behavior, 93(4-5), 975–983. https://doi.org/10.1016/j.physbeh.2007.12.014

89. Creasy, S. A., Rynders, C. A., Bergouignan, A., Kealey, E. H., & Bessesen, D. H. (2018). Free-living responses in Energy Balance to short-term overfeeding in adults differing in propensity for obesity. Obesity, 26(4), 696–702. https://doi.org/10.1002/oby.22121

90. Whybrow, S., Mayer, C., Kirk, T. R., Mazlan, N., & Stubbs, R. J. (2007). Effects of two weeks' mandatory snack consumption on energy intake and Energy Balance*. Obesity, 15(3), 673–685. https://doi.org/10.1038/oby.2007.567

91. Ptomey, L. T., Montgomery, R. N., Gorczyca, A. M., Szabo-Reed, A. N., Sullivan, D. K., Hastert, M., Foster, R. N. S., Washburn, R. A., & Donnelly, J. E. (2022). The impact of exercise and cumulative physical activity on energy intake and diet quality in adults enrolled in the Midwest Exercise Trial for the Prevention of weight regain. British Journal of Nutrition, 1–12. https://doi.org/10.1017/s0007114521005122

92. Barutcu, A., Briasco, E., Moon, J., Stensel, D. J., King, J. A., Witcomb, G. L., & James, L. J. (2021). Planned morning aerobic exercise in a fasted state increases energy intake in the preceding 24 h. European Journal of Nutrition, 60(6), 3387–3396. https://doi.org/10.1007/s00394-021-02501-7

93. Shephard, R. J. (2011). The effects of exercise-induced weight loss on appetite-related peptides and motivation to eat. Yearbook of Sports Medicine, 2011, 167–169. https://doi.org/10.1016/s0162-0908(10)79776-2

94. Willis, H. J., Thomas, W., Eldridge, A. L., Harkness, L., Green, H., & Slavin, J. L. (2010). Increasing doses of fiber do not influence short-term satiety or food intake and are inconsistently linked to gut hormone levels. Food & Nutrition Research, 54(1), 5135. https://doi.org/10.3402/fnr.v54i0.5135

95. Rolls, B. J., & Roe, L. S. (2002). Effect of the volume of liquid food infused intragastrically on satiety in women. Physiology & Behavior, 76(4-5), 623–631. https://doi.org/10.1016/s0031-9384(02)00801-6

96. Cutrufello, P. T., & Dixon, C. B. (2013). The effect of acute fluid consumption and hydration status on percent body fat and minimum wrestling weight. Journal of Strength and Conditioning Research, 27(7), 1950–1957. https://doi.org/10.1519/jsc.0b013e318277981c

APPENDIX A

IRB APPROVAL

APPROVAL: EXPEDITED REVIEW

Carol Johnston
CHS: Health Solutions, College of
602/496-2539
CAROL.JOHNSTON@asu.edu

Dear Carol Johnston:

On 12/28/2021 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Examination of the daily ingestion of high protein nutrition bars (with or without added fiber) for one week on 24-h energy intake and satiety in healthy young adults
Investigator:	Carol Johnston
IRB ID:	STUDY00015151
Category of review:	
Funding:	Name: Graduate College (GRAD)
Grant Title:	
Grant ID:	
Documents Reviewed:	• calendar, Category: Participant materials (specific directions for them); • consent, Category: Consent Form; • health history questionnaire, Category: Screening forms; • online screener, Category: Screening forms; • protocol, Category: IRB Protocol; • pure protein bar, Category: Drug Attachment; • quest protein bar, Category: Drug Attachment; • satiety measure, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • verbal script (ad), Category: Recruitment Materials;

The IRB approved the protocol from 12/28/2021 to 12/27/2022 inclusive. Three weeks before 12/27/2022 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 12/27/2022 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

REMINDER - All in-person interactions with human subjects require the completion of the ASU Daily Health Check by the ASU members prior to the interaction and the use of face coverings by researchers, research teams and research participants during the interaction. These requirements will minimize risk, protect health and support a safe research environment. These requirements apply both on- and off-campus.

The above change is effective as of July 29th 2021 until further notice and replaces all previously published guidance. Thank you for your continued commitment to ensuring a healthy and productive ASU community.

Sincerely,

IRB Administrator

cc:

Minghan Pang

APPENDIX B

INFORM OF CONSENT

Informed Consent

Nutrition Bars and Satiety

INTRODUCTION

The purposes of this form are (1) to provide you with information that may affect your decision as to whether or not to participate in this research study, and (2) to record your consent if you choose to be involved in this study.

RESEARCHERS

Dr. Carol Johnston (ASU Nutrition professor) and ASU nutrition graduate student, Minghan Pang, have requested your participation in a research study.

STUDY PURPOSE

The global energy bars market was valued at $645.0 million in 2020 and is estimated to reach $1,010.9 million by 2028. Convenience is the main reason for the increasing demand for energy bars. However, few studies have examined the health impact of energy bar consumption, particularly in regards to satiety. The commercial nutrition bar provides energy and essential nutrients such as protein and fiber. There is substantial evidence that protein and fiber have the potential to promote satiety. Although many studies found that protein and fiber promote satiety in the short term, only a few studies examined the effects of long-term satiety in free-living individuals. Most of these studies utilized protein and fiber supplements in a liquid form. Based on our knowledge, only one study has investigated the long-term impact of the energy bar on appetite and energy intake in free-living individuals. However, the effect of commercial energy bars that combine high protein and high fiber on appetite and satiety remain unclear.

DESCRIPTION OF RESEARCH STUDY

You have indicated to us that you are a non-smoker/non-user of cannabis, 18-35 years of age, and generally healthy. You are not currently ill and do not have unresolved chronic conditions. You have no known food allergies, are not pregnant or dieting, and have not gained or lost >7 pounds in the past 6 months. This is a 4-week study: you will ingest a nutrition bar daily during weeks 2 and 4. Otherwise, you will continue to consume your usual diet and not alter your physical activities during the study. You will record your diet and physical activity on 3 days each week of the trial using MyFitnessPal, a free app which we will help you download onto your i-phone and show you how to use. You will also be asked to record your hunger level 1-2 times daily throughout the trial via an online text message.

This research entails three visits to the study site on the downtown ASU campus (approximately 30 minutes per visit). You will be asked to complete health and diet questionnaires during these visits, and we will measure your weight and waist circumference. You will receive a $20 gift card at the end of week 2 and a $30 gift card at the end of week 4.

RISKS

There is minimal risk for participation in this study. The nutrition bars are commercially available. It is possible you may feel full or bloated after consuming the bars, but this would be an transitory effect.

BENEFITS

This trial is examining possible health benefits of nutrition bar consumption, but there is no direct benefit for your participation in this study.

NEW INFORMATION

If the researchers find new information during the study that would reasonably change your decision about participating, then they will provide this information to you.

CONFIDENTIALITY

All information obtained in this study is strictly confidential unless disclosure is required by law. The results of this research study may be used in reports, presentations, and publications, but your name or identity will not be revealed. In order to maintain confidentiality of your records, the investigators will use subject codes on all data collected, maintain a master list separate and secure from all data collected, and limit access to all confidential information to the study investigators.

WITHDRAWAL PRIVILEGE
You may withdraw from the study at any time for any reason without penalty or prejudice toward you. Your decision will not affect you any manner. We ask that you notify us in a timely manner if you decide to withdraw from the study, and we will ask you the reason for withdrawing for our records.

COSTS AND PAYMENTS
You will receive a $20 gift card at the end of week 2 and a $30 gift card at the end of week 4. There are no payments required for this study. You will receive the nutrition bars at no-cost.

COMPENSATION FOR ILLNESS AND INJURY
If you agree to participate in the study, then your consent does not waive any of your legal rights. However, in the event of harm, injury, or illness arising from this study, neither Arizona State University nor the researchers are able to give you any money, insurance coverage, free medical care, or any compensation for such injury. Major injury is not likely but if necessary, a call to 911 will be placed.

VOLUNTARY CONSENT
Any questions you have concerning the research study or your participation in the study, before or after your consent, will be answered by Dr. Carol Johnston, 550 N. 3rd St., Phoenix, AZ 85004. [602-496-2539]

If you have questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Research Compliance Office, at 480-965 6788.

This form explains the nature, demands, benefits and any risk of the project. By signing this form you agree knowingly to assume any risks involved. Remember, your participation is voluntary. You may choose not to participate or to withdraw your consent and discontinue participation at any time without penalty or loss of benefit. In signing this consent form, you are not waiving any legal claims, rights, or remedies. A copy of this consent form will be given to you.

Your signature below indicates that you consent to participate in the above study.

____________________________ ____________________________ ____________

Subject's Signature Printed Name Date

Contact phone number Email

INVESTIGATOR'S STATEMENT
"I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participation in this research study, have answered any questions that have been raised, and have witnessed the above signature. These elements of Informed Consent conform to the Assurance given by Arizona State University to the Office for Human Research Protections to protect the rights of human subjects. I have provided the subject/participant a copy of this signed consent document."

Signature of Investigator Date

APPENDIX C

SAMPLE SIZE CALCULATION

	Author	Year	Satiety	±SD	N per group	Calculated n per group	Age Range	Health Status
1	Trier et al.	2013	1.1	1.16	15	20	28.4 ± 2.9	Healthy BMI 23.1 ± 0.9
2	Dina et al.	2018	2.4	4.9	30	68	22 ± 1.4	Healthy BMI 23.6 ± 1.6
3	Sharafi et al.	2018	1	3.9	50	241	30 ± 2	Overweight/obese BMI 29.6 ± 0.3
4	Zaharudin et al.	2021	1	1.8	20	53	28.8 ± 5.4	Healthy BMI 20.5-25.0
	Average		1.5	2.6	21.6	47	26.4 ± 3.2	

The study from Sharafi et al. was excluded from the sample calculation due to the participants' health status and calculated sample size.

APPENDIX D

FOOD PICTURE AND NUTRITION LABEL

Nutrition Facts

6 servings per container

Serving size 1 Bar (50g)

Amount per serving

Calories 180

	% Daily Value*
Total Fat 4.5g	6%
Saturated Fat 3.5g	18%
Trans Fat 0g	
Cholesterol 15mg	5%
Sodium 90mg	4%
Total Carbohydrate 17g	6%
Dietary Fiber 2g	7%
Total Sugars 3g	
Includes 2g Added Sugars	4%
Sugar Alcohol 4g	
Protein 21g	37%

Vitamin D 0mcg 0% • Calcium 100mg 8%

Iron 2.0mg 10% • Potassium 160mg 4%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Nutrition Facts

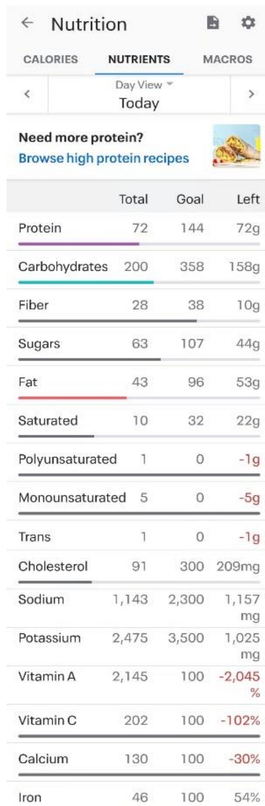
Serving size	1 bar (60g)
Amount per serving	
Calories	**180**
	% Daily Value*
Total Fat 7g	**9%**
Saturated Fat 2.5g	**13%**
Trans Fat 0g	
Cholesterol 5mg	**2%**
Sodium 220mg	**10%**
Total Carbohydrate 24g	**9%**
Dietary Fiber 14g	**50%**
Total Sugars <1g	
Includes 0g Added Sugars	**0%**
Erythritol 6g	
Protein 20g	**40%**
Vitamin D 0mcg	**0%**
Calcium 110mg	**8%**
Iron 1.6mg	**8%**
Potassium 180mg	**4%**

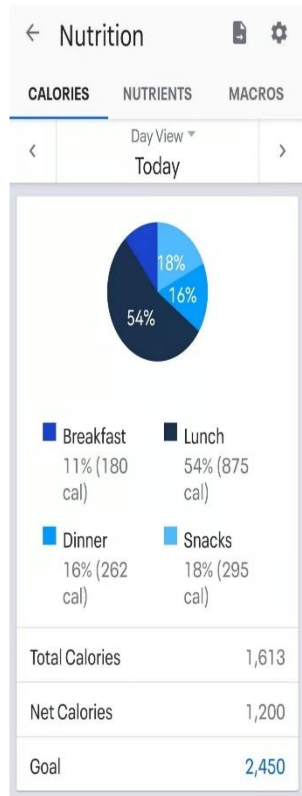
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

APPENDIX E

MYFITNESSPAL DATA AND EVALUATION

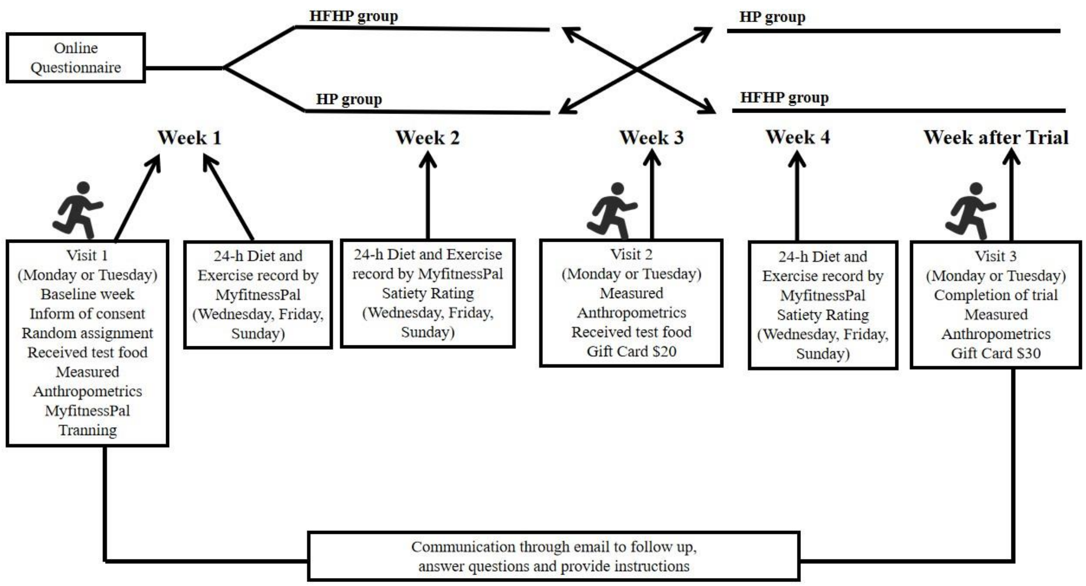

Diary
Today
Find A Nike® Store Ne:
Nike by Glendale
Calories Remaining
2,450 - 1,612 + 412 = 1,250
Goal Food Exercise Remaining
Breakfast 180
Double Chocolate 180
Quest, 1.0 Bar
ADD FOOD
Lunch 875
Rice 160
Jasmine Rice, 45.0 g raw weight
Carrots 52
1.0 cup, chopped
French Fries 250
French Fries (Plain), 0.5 cup
Cheese Burger 303
Homemade Cheese Burger, 1.0...
Apple Juice 110
Juice, 8.0 oz
ADD FOOD
Dinner 262
Carrots 52
1.0 cup, chopped
Chicken 100
Grilled chicken, 4.0 oz
Potato 110
Potato, 1.0 medium
ADD FOOD
Snacks 295
nut 190
nut, 1.0 cup
Banana 105
1.0 medium
This food is low in saturated fat.
ADD FOOD
Exercise 412
Running (jogging), 10.7 kph (5.... 412
30 minutes
Connect a step tracker
Automatically track steps and calories burned
ADD EXERCISE
Water
Water
2,000 ml
ADD WATER
Nutrition
Notes
Complete Diary
Home
Diary
Recipes
Plans
Me


Nutrition
CALORIES
NUTRIENTS
MACROS
Day View
Today
Need more protein?
Browse high protein recipes
Total Goal Left
Protein 72 144 72g
Carbohydrates 200 358 158g
Fiber 28 38 10g
Sugars 63 107 44g
Fat 43 96 53g
Saturated 10 32 22g
Polyunsaturated 1 0 -1g
Monounsaturated 5 0 -5g
Trans 1 0 -1g
Cholesterol 91 300 209mg
Sodium 1,143 2,300 1,157 mg
Potassium 2,475 3,500 1,025 mg
Vitamin A 2,145 100 -2,045 %
Vitamin C 202 100 -102%
Calcium 130 100 -30%
Iron 46 100 54%


Nutrition
CALORIES
NUTRIENTS
MACROS
Day View
Today
18%
16%
54%
Breakfast
11% (180 cal)
Lunch
54% (875 cal)
Dinner
16% (262 cal)
Snacks
18% (295 cal)
Total Calories 1,613
Net Calories 1,200
Goal 2,450

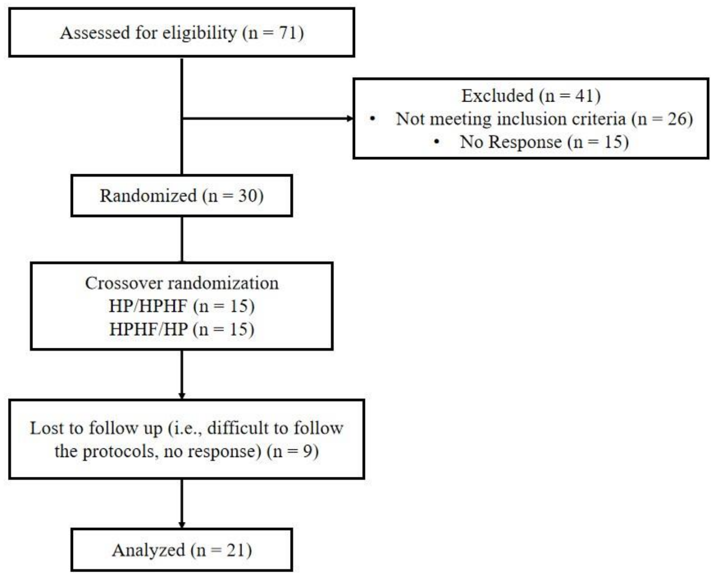
APPENDIX F

STUDY FLOW CHART


Online Questionnaire
HFHP group
HP group
HP group
HFHP group
Week 1
Week 2
Week 3
Week 4
Week after Trial
Visit 1 (Monday or Tuesday) Baseline week Inform of consent Random assignment Received test food Measured Anthropometrics MyfitnessPal Tranning
24-h Diet and Exercise record by MyfitnessPal (Wednesday, Friday, Sunday)
24-h Diet and Exercise record by MyfitnessPal Satiety Rating (Wednesday, Friday, Sunday)
Visit 2 (Monday or Tuesday) Measured Anthropometrics Received test food Gift Card $20
24-h Diet and Exercise record by MyfitnessPal Satiety Rating (Wednesday, Friday, Sunday)
Visit 3 (Monday or Tuesday) Completion of trial Measured Anthropometrics Gift Card $30
Communication through email to follow up, answer questions and provide instructions

APPENDIX G

STUDY FLOW DIAGRAM


Assessed for eligibility (n = 71)
Excluded (n = 41)
• Not meeting inclusion criteria (n = 26)
• No Response (n = 15)
Randomized (n = 30)
Crossover randomization
HP/HPHF (n = 15)
HPHF/HP (n = 15)
Lost to follow up (i.e., difficult to follow the protocols, no response) (n = 9)
Analyzed (n = 21)

APPENDIX H

HEALTH HISTORY QUESTIONNAIRE

HEALTH HISTORY QUESTIONNAIRE ID#__________________ Date: ___________

1. Gender: M F

2. Age: __________

3. Ethnicity: (please circle one) American Indian/Alaska Native Black or African-American
White or Caucasian Native Hawaiian/Other Pacific Islander
Hispanic or Latino Asian

4. Do you smoke or use cannabis? (please check)
__No, never
__Yes _# Cigarettes per day = ________
__ I used to, but I quit ____months/years (circle) ago
___ I use cannabis

5. Do you take any medications regularly? Yes No [*If yes, list type and frequency*]

Medication	Dosage	Frequency

6. Do you currently take supplements (vitamins, minerals, protein, herbs, etc.)? Yes No [*If yes, please list*]

Supplement	Dosage	Frequency

7. Have you been diagnosed with any acute or chronic condition (such as high blood pressure, heart disease or diabetes, but also intestinal problems such as IBS or Celiac)? Yes No [*If yes, please list*]

8. If female, are you pregnant or lactating? Yes No

9. Please circle the **number of times** you did the following exercises **for more than 15 minutes** last week.

Mild exercise (minimal effort):
Easy walking, golf, gardening, bowling, yoga, fishing, horseshoes, archery, etc.

Times per week: 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14+

Moderate exercise (not exhausting):
Fast walking, easy bicycling, tennis, easy swimming, badminton, dancing, volleyball, baseball, etc.

Times per week: 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14+

Strenuous exercise activities (heart beats rapidly):
Running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling, etc.

Times per week: 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14+

10. Do you plan to change your exercise level in the next 8 weeks? Yes No
If yes, explain:

____

11. Are you healthy and fit? Yes No
Comments:

____

12. How much alcohol do you drink? *State average number of drinks per week:* ____________

13. Do you have any food allergies? Yes No
If yes, explain:

____

14. Do you follow a special diet? Yes No
If yes, explain: ____

Do you plan to change your diet in the next 8 weeks? Yes No
If yes, explain:

____

15. Have you lost or gained more than 7 lbs in the last 6 months? Yes No
If yes, how much lost or gained? ____________ *How long ago?* ______________

16. Are you willing to consume a commercially available nutrition bar daily for two weeks?

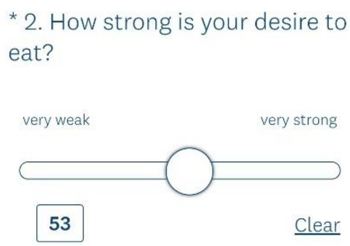
Yes No

17. Are you willing to come to the test site in downtown Phoenix (corner of Van Buren and 5th Streets) on three occasions during the study?

Yes No

APPENDIX I

SATIETY RATING


* 2. How strong is your desire to eat?

very weak | very strong

53

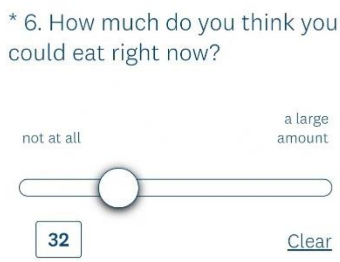
Clear


* 5. How satisfied do you feel?

completely empty | cannot eat another bite

22

Clear


* 6. How much do you think you could eat right now?

not at all | a large amount

32

Clear


* 3. How hungry do you feel?

not hungry at all | as hungry as I have ever felt

65

Clear


* 4. How full do you feel?

not full at all | totally full

59

Clear