Effect of Regular Dietary Consumption of Beans or Peas on Body Weight, Body Composition, and Blood Pressure in Men and Women with Mild Hypercholesterolemia

by

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Abstract

Pulse consumption has been associated with beneficial effects on heart health. In this randomized controlled trial, 51 participants with mild hypercholesterolemia were randomly assigned to consume study food items containing ¾ cup beans, peas, or rice (control) per day, 5 days per week for 6 weeks as part of their normal diet. Dietary intake, body weight, waist circumference, hip circumference, blood pressure, perceived satiety following study food intake, gastrointestinal (GI) symptoms, and adherence to the dietary protocol were evaluated. The study foods were well tolerated. The overall self-reported compliance rate was 98.3%. GI symptoms in response to pulse consumption returned to baseline levels by the end of the trial. Consumption of beans, but not peas led to higher absolute fibre intake (g/d) and higher fibre density of the diet (g/1000 kcal). However, the dietary intervention did not induce significant changes in the intake of total energy, potassium, magnesium, sodium, or percentage energy intake from macronutrients. Consumption of beans or peas did not affect body weight, body composition, or blood pressure. Perceived satiety also did not differ among the diet groups. Further research is needed to examine the effect of consuming different pulse varieties on other risk factors associated with heart health and the minimal effective doses of pulse intake.

Preface

This thesis is an original work by Yuzhu Liang. No part of this thesis has been previously published. The research conducted in this thesis is part of a multi-centre randomized controlled trial led by the University of Alberta and the University of Manitoba. Study recipes were developed by Dr. Michel Aliani, professor at the University of Manitoba. Janis Baarda, research assistant at the University of Alberta, assisted with participant recruitment, participant visits and study food preparation. Jessica Thompson, knowledge translation coordinator at the University of Alberta assisted with participant visits and study food preparation. Jenny Brown and Naomi Porciuncula, undergraduate students at the University of Alberta refined the tracking document for study food consumption, and helped with study food preparation. The research project, of which this thesis is a part, received research ethics approval from the University of Alberta Research Ethics Board and the University of Manitoba Research ethics board, project name “Substantiating a Health Claim for Pulses (beans and peas) and Cholesterol Lowering”, No. Pro00030390, on October 16, 2014.

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List of Abbreviations

AI	Adequate intake
ANOVA	Analysis of variance
BCE	Before the common era
BMI	Body mass index
BP	Blood pressure
CCHS	Canadian Community Health Survey
CCK	Cholecystokinin
CHD	Coronary heart disease
CVD	Cardiovascular disease
DASH	Dietary approaches to stop hypertension
DBP	Diastolic blood pressure
EDTA	Ethylenediaminetetraacetic acid
FAO	Food and Agriculture Organization of the United Nations
GI	Gastrointestinal
GLP-1	Glucagon-like peptide 1
HbA1c	Hemoglobin A1c

HC	Hip circumference
HDL-C	High-density lipoprotein cholesterol
LDL-C	Low-density lipoprotein cholesterol
MDP	Mediterranean dietary pattern
MUFA	Monounsaturated fatty acids
NHANES	National Health and Examination Survey
PST	Plasma separation tubes
PUFA	Polyunsaturated fatty acids
PYY	Peptide YY
RCT	Randomized controlled trial
SAS	Statistical Analysis Software
SBP	Systolic blood pressure
SCFA	Short chain fatty acids
SEM	Standard error of the mean
SST	Serum separating tubes
TC	Total cholesterol
VAS	Visual analog scales
WC	Waist circumference

Chapter 1. Introduction

Hypercholesterolemia is a major risk factor for cardiovascular disease (CVD), which is the leading cause of death worldwide and responsible for 25% of total deaths in Canada (1, 2). Data from the 2009 – 2011 Canadian Health Measures Survey demonstrated that approximately one quarter of the Canadian population aged 6 to 79 had elevated low-density lipoprotein cholesterol (LDL-C) concentrations (3). Clinically, it has been estimated that a 1% reduction in serum LDL-C through either drug or dietary interventions is associated with a 1% decrease in coronary heart disease (CHD) risk (4).

For individuals with hypercholesterolemia at risk for developing CHD, diet and lifestyle modification is commonly recognized as the first step of intervention before any drug treatment takes place (5). Anderson et al (6) suggested that approximately 75% of the population with hypercholesterolemia will benefit through implementation of appropriate dietary strategies alone. Two main proposed dietary approaches for cholesterol-lowering include decreasing intake of saturated fat and cholesterol, and increasing intake of cholesterol-reducing foods (7). It is well known that multiple dietary components contribute to the risk of developing CVD and related risk factors (8). While targeting the overall dietary pattern may maximize beneficial effects to heart health, it is equally important to identify functional food ingredients that lower CVD risk (8). Incorporating such ingredients into a normal diet may be a simple and sustainable strategy to promote heart health.

Pulses such as dry beans, dry peas, chickpeas and lentils are dried seeds of the leguminous crops harvested solely for their grains (9). Pulses have been credited as part of a heart-healthy diet because they are a rich source of fibre, protein, B vitamins and minerals such as potassium and magnesium while containing a minimal amount of saturated fat and sodium (10, 11). Epidemiological evidence has associated higher pulse intake with reduced incidence of CVD and CHD (12). Pulse fibre has often been recognized as the nutrient component primarily responsible for lipid-lowering (13). In particular, soluble fibre is able to bind to bile salts, prevent their reabsorption, and increase liver uptake of circulating cholesterol (14). Although not fully understood, short chain fatty acids (SCFA) produced by bacterial fermentation of fibre in the colon have been suggested to inhibit hepatic cholesterol synthesis (15).

In addition to hypercholesterolemia, excess body weight, abdominal fat accumulation, and elevated blood pressure (BP) are important risk factors for CVD. A reduction of each measurement has been associated with lower cardiovascular mortality (16-18). Fibre and protein have been reported to produce greater satiating effects than other nutrients (19, 20); therefore, pulses as a source of both fibre and protein have been suggested to suppress energy intake, and enhance weight loss over the longer term. Pulses also contain a significant amount of potassium and magnesium, and both nutrients have been demonstrated to confer BP-lowering effects (21, 22). Data from the National Health and Examination Survey (NHANES) 1999 – 2002 demonstrate that bean consumers had lower body weight, smaller waist circumference (WC), and lower systolic BP compared to non-consumers (23). The effect of pulse supplementation on body weight and WC remains controversial according to results from controlled feeding trials, but most trials to date, especially those with intentional energy restriction have reported beneficial effects of pulse-based interventions relative to controls (24, 25). It remains unclear, however, whether the long-term weight reduction upon pulse consumption is mediated by acute satiety and food intake suppression. In agreement with the NHANES data, pulse-based feeding trials in general have shown greater BP-lowering effect in response to the pulse-rich diet relative to the control diet (26).

Although most evidence points to beneficial effects of pulse consumption on CVD risk factors including lipid profile, body weight, WC and BP, the minimal effective amount of pulse intake still remains to be determined. This information is useful for making recommendations regarding pulse intake that are practical and feasible for the Canadian population given the habitual pulse consumption is quite low (median weekly intake ~ 0.6 cup) (27). Therefore, studies incorporating smaller quantities of pulses into subjects' diet are needed to examine the effectiveness. Also, most clinical trials have employed either beans or mixed varieties of pulses as active ingredients of the intervention diets; yet, the effectiveness of different pulse varieties on CVD-related risk factors has not been compared. Documenting the extent to which different types of pulses may exert varying effects may provide consumers with guidance or assurances about the metabolic effects of their food choices. Together, this information will advance our current understanding on the relationship between pulse consumption and their effects on CVD prevention.

This thesis is part of a multi-centre randomized controlled trial (RCT). The primary objective of the greater study is to examine the effectiveness of consuming beans versus peas versus rice (control) at the level of ¾ cup per day, 5 days per week for 6 weeks on plasma LDL-C concentrations in individuals with mild hypercholesterolemia. Since the clinical trial is currently within the recruitment phase, this thesis is a preliminary report detailing the secondary outcomes of the study, among participants enrolled at the Edmonton site between May 2013 and March 2014. More specifically, we examined the effects of consuming beans versus peas versus rice with the aforementioned dose, frequency and duration on body weight, body composition and BP as well as key nutrients associated with changes of these physical measurements in individuals with mild hypercholesterolemia. We also evaluated feasibility of consuming the study pulses through determining gastrointestinal (GI) symptoms during the study and the compliance rate. Specific objectives were:

(1) To compare changes in total energy consumption and dietary intake of macronutrients (carbohydrate, fibre, protein, fat) and key micronutrients (potassium, magnesium, sodium) over time across the diet groups;

(2) To examine changes in body weight, WC, hip circumference (HC), BP, perceived satiety following study food consumption, and GI symptoms over time across the diet groups; and

(3) To determine participant adherence to prepared study food items in the randomized controlled feeding trial.

It was hypothesized that:

(1) Dietary incorporation of beans or peas would increase participants' intakes of fibre, protein, potassium and magnesium compared with dietary incorporation of rice;

(2) Dietary incorporation of beans or peas would reduce body weight, WC, systolic and diastolic BP compared with dietary incorporation of rice;

(3) Consumption of study foods containing beans or peas would lead to greater satiety as compared with consumption of study foods containing rice; and

(4) Consumption of study foods containing beans or peas would increase participants' perceived GI symptoms, and the symptoms would decrease over time; consumption of study foods containing rice would not alter participants' perceived GI symptoms during the intervention as compared to before the intervention.

Chapter 2. Literature Review

2.1 Pulses

2.1.1 Definition

Pulses are members of the legume family with one to twelve seeds enclosed in a pod. The word "pulse" comes from the Latin word "puls" meaning thick soup or potage (28). According to the Food and Agriculture Organization of the United Nations (FAO), pulses are limited to leguminous crops harvested exclusively for dry grains (9). As a consequence, those legumes harvested green such as fresh beans and fresh peas, and those grown primarily for oil extraction such as soybeans and peanuts are excluded from the definition. Although greater than 80 different pulse species are consumed by humans (29), the FAO only recognizes 11 primary pulses (9). Among these, seven varieties are widely grown, with dry beans, dry peas and chickpeas accounting for over 60% of global pulse production (30).

2.1.2 A brief history

Legumes are among the earliest food crops cultivated by humans (31). Evidence suggests that pulses, including peas and lentils, were first domesticated between 8000 and 7000 BCE (32). Pulse varieties originated in diverse regions of the world with suitable climatic conditions. Remains of kidney beans have been found in the Peruvian Andes and dated at about 6000 BCE (32). It is now widely accepted that common beans (*Phaseolus vulgaris*) originated in Mexico, Guatemala, and the high Andes (33). They were introduced to Europe in the 16th century and were soon spread throughout Europe and the rest of the world (31). Unlike common beans, wild species of peas were originated in areas with cooler temperatures including the Levant, eastern Turkey, Syria and northern Iraq dating back as far as 8000 BCE (32). By 4000 BCE, domesticated peas (*Pisum sativum*) reached Western Europe, and soon spread into Egypt, Caucasus, Eastern Europe, and reached India by about 2000 BCE. However, peas were not introduced to America until the 16th century (34).

2.1.3 Production and consumption patterns

Today, the world's leading producers of pulses include Canada, India, China, Myanmar and Brazil with half of global pulse output from these countries (35). In 2010, total world pulse production doubled

the amount in 1980 (33). The same trend was seen in Canada with a more than five-fold increase over the past two decades (36). Globally, beans, chickpeas and peas are the most important pulse varieties in terms of harvested area and production (35). Pea is mainly produced in Canada, Russia and China, chickpea in India, and bean producing countries are widely distributed around the world (35). Not only is Canada among world's top producers of beans and peas, but it is the largest exporter of peas and lentils (36).

In many developing countries, pulses represent an important dietary constituent, and are considered complementary to cereal grains, roots, and tubers that have low protein content (37). In areas such as South America, Africa and India, annual pulse consumption is up to 40 kg/capita. By contrast, consumption in the Western societies remains quite low. West Europeans consume less than 3.9 kg/capita per year (38). On average, adults in Canada and the United States consume no more than one cup of pulses per week (27, 39). The amount is even lower in Australia, with only 9.8 g of legume and pulse products consumed on a daily basis (< ½ cup per week) according to the National Nutrition Survey: Nutrient Intakes and Physical Measurements, Australia (40). High pulse production and concomitant low consumption in Canada suggests consumption of pulse-containing products among the Canadian population could be expanded.

2.1.4 Nutritional and health benefits of pulses

Pulses are low-energy, nutrient-dense foods. They contain 2 – 3 times the amount of protein as compared with cereal grains while having a low percentage energy from fat (41). They are also a rich source of complex carbohydrate, B vitamins, minerals, and contain a number of bioactive phytochemicals including phenolic compounds, phytosterols, phytic acid and saponins. Data from the 1999 – 2002 NHANES suggest that compared with adults who did not consume pulses, those who consumed only ½ cup of pulses per day had significantly higher intakes of fibre, protein, folate, zinc, iron, and magnesium, and lower intakes of saturated fat and total fat (39). There is evidence from both epidemiological studies and clinical trials demonstrating a protective effect of regular pulse consumption against cardiovascular disease, weight gain and elevated BP, which is attributed to nutritional profile of pulses (14, 23). Detailed discussion regarding health implications of dietary pulses is provided in a later section.

2.1.5 Recommendations

Pulse consumption has been promoted by dietary guidelines for health in general as well as prevention of CVD-related risk factors. The 2010 Dietary Guidelines for Americans highlights beans and peas as foods to increase that contribute to healthful eating patterns and improve intake of nutrients well below recommendations (42). These Guidelines recommend intake of 1.5 – 2.5 cups cooked pulses per week based on daily calorie intake ranging from 1800 to 2800 kcal. In the Canada's Food Guide, pulses belong to the food group of meat and alternatives with ¾ cup of cooked pulses considered 1 serving (43). Although a targeted number of servings is not specified, one of the key messages from the Food Guide is to consume meat alternatives such as beans, lentils and tofu often. In addition, the American Heart Association recommends consumption of dry beans and dry peas as part of a healthy diet that protects against high blood cholesterol, high BP, and excess body weight (44). Similarly, individuals with elevated BP are encouraged to follow the Dietary Approaches to Stop Hypertension (DASH) eating plan, which recommends regular consumption of dietary pulses as "sources of energy, magnesium, protein, and fibre" (45).

2.2 Pulse consumption, body weight and body composition

2.2.1 Epidemiological evidence

Owing to their nutritional composition characterized by low energy density, high fibre and protein content, pulses have been suggested as a functional ingredient for improving energy intake regulation and weight management (46). Consuming meals low in energy density and high in fibre may prolong eating time, promote postprandial satiety and delay return of hunger (47, 48). Also, diets high in protein may facilitate weight loss by producing a greater thermic effect than those lower in protein (49). To date, the relationship between consumption of pulses as an individual ingredient, body weight and body composition remains largely unexplored in epidemiological settings. Of the few publications available, data from the 1999 – 2002 NHANES suggest adults who consumed baked beans or other varieties of beans on the day of their 24-hour dietary recall had lower body weight and WC than those who did not (23). A more recent case-control study in Iran demonstrated the prevalence of metabolic syndrome was significantly higher among individuals in the lowest quartile of legume consumption defined as 1 serving

per week or less compared with those in the highest quartile defined as 3 servings per week or greater (50).

The potential benefits of consuming pulses on body weight and body composition have been evaluated in studies where pulses were incorporated into a participants' regular dietary pattern. For example, much attention has been paid to the protective effect of the traditional Mediterranean diet rich in pulses in addition to vegetables, fruits, cereals, nuts and olive oil against overweight and obesity. Findings from an earlier cross-sectional survey suggest high adherence to the Mediterranean dietary pattern (MDP) was inversely associated with prevalence of obesity among adult men and women living in Girona, Spain (51). Over a follow-up period of between 2 to 10 years, beneficial effects of the MDP against obesity, weight gain and abdominal obesity were detected in several prospective cohort studies (52-54), but not others (55, 56). Nonetheless, when legumes or pulses were evaluated separately from other dietary components, the effect on body weight and body composition became small and non-significant (53-55). Overall, findings from current observational studies (52-56) provide mixed evidence regarding the protective role of pulse consumption in weight management. Clearly, longitudinal prospective cohort studies specifically examining the effects of pulses on development of chronic diseases would be helpful to better identify potential relationships between these factors. On the other hand, observational studies are only useful for making associations between dietary variables and health outcomes as the analyses are often confounded by other lifestyle factors. It is possible that pulse consumption is simply an indicator of a healthy lifestyle in general. Thus, whether pulse consumption alone is predictive of weight change remains unclear. Dietary intervention trials using pulses as the active ingredients are necessary to address this question.

2.2.2 Clinical trials with intended energy restriction

To test if pulse consumption exerts additional benefits on weight management compared with energy restriction alone, several clinical trials have incorporated pulses into energy-restricted diets of overweight and obese individuals. Abete and colleagues (24) compared the weight loss effect of four hypocaloric diets in 35 obese males during an 8-week intervention period. Volunteers were randomly assigned to one of the dietary treatments: a control diet without legumes or fatty fish, a high protein diet

where proteins were predominantly derived from meat, eggs, and skimmed dairy products, a fatty fish diet where fatty fish as the main source of protein was consumed 3 days per week, and a legume diet where pulses as the main source of protein were consumed 4 days per week. At the end of the intervention, volunteers in all diet groups experienced significant weight loss and reduction in WC. Additionally, the legume diet produced a significantly greater percentage of weight loss compared with the control diet, but not the high protein or the fatty fish diet. Thus, findings of this study support the hypothesis that pulses, when incorporated into an energy-restricted diet, may facilitate weight loss. The type and quantity of pulses used in the study was not specified, however.

Following this publication, the same group of investigators conducted another 8-week RCT to examine the efficacy of two hypocaloric diets with or without pulses in obese men and women (25). Both diets were designed to produce a 30% reduction in participants' energy intake. In addition, those in the pulse group consumed 160 to 235 g cooked lentils, chickpeas, beans and peas daily depending on the baseline energy intake of each individual. As expected, calorie restriction resulted in significant reduction in body weight, WC, and percentage body fat in both groups. Moreover, similar to the previous trial, the pulse group achieved greater weight loss relative to the control group. However, because information regarding total energy intake of each diet group during the intervention was not reported, the mechanism by which pulse consumption facilitated weight loss was unclear. It is also important to note that this study and the one described above did not observe beneficial effects of pulse consumption on WC relative to consumption of the control diet. Since abdominal obesity has been strongly associated with CHD risk (57)(57), the effect of pulse consumption on WC needs to be examined in future studies. Nonetheless, results from the above clinical trials (24, 25) consistently showed that consumption of pulses within an energy-restricted diet was able to enhance weight loss in obese individuals at least in short-term dietary interventions (8 weeks).

With respect to long-term weight management, prevention of weight regain following weight loss remains a major challenge (58). In this sense, identifying functional ingredients that promote maintenance of healthy body weight and body composition is of importance (59). To date, few clinical trials have been undertaken to examine if pulse consumption contributes to weight control following energy restriction.

During an 18-month RCT by Venn et al (60), reduced energy intake among overweight and obese subjects was achieved through nutritional and lifestyle education strategies for the first 6 months. Participants in the intervention group also increased their consumption of mixed pulses (2 servings or 180 g per day, cooked) and whole grain products as instructed. During the 12-month weight maintenance phase, participants were asked and reinforced to continue the same dietary practice through monthly contact. Although participants in the intervention group had significantly higher pulse consumption throughout the study based on their diet records, weight loss was not different between groups at 6 months. Higher pulse consumption also failed to prevent weight regain between 6 and 18 months when compared with the control group. Interestingly, by the end of the trial, the intervention group experienced greater decrease in WC than the control group.

Taken together, there is evidence from clinical trials supporting the added benefits of pulses on weight loss and maintenance when consumed in the context of energy-restricted diets. One possible explanation to the beneficial effects of pulse-containing diets is that pulse consumption is associated with greater satiety, which may in turn contribute to reduced hunger or cravings and better adherence to the dietary protocol (61). However, sustainability of the weight loss effect and the potential benefits on body composition in response to regulation pulse intake requires additional investigation.

2.2.3 Clinical trials without intended energy restriction

In addition to the above studies where pulses were consumed as part of a hypocaloric diet, a number of clinical trials where pulses were incorporated into a habitual diet also reported body weight and body composition in response to the dietary intervention as a secondary outcome (59, 62-67). In most cases, trials ranging from 8 to 16 weeks did not detect changes in body weight or body composition (62-66), which is likely attributable to an absence of energy imbalance in the intervention groups. Another possible explanation is that the trials were not sufficiently powered to detect changes in body weight or body composition in response to the intervention. Comparison of these trials is difficult because of a wide range of body mass index (BMI) and heterogeneity of health status among participants at study entries. Still, results of these studies suggest energy restriction plays a key role in modifying body weight and

body composition. On the other hand, increasing pulse consumption alone may be insufficient to produce independent effects on weight control.

Data from two recent publications, however, have shown promising evidence supporting the beneficial effects on body weight and body composition in response to pulse supplementation. Mollard et al (59) demonstrated incorporating ¾ cup mixed pulses daily into the habitual diet for 8 weeks reduced WC among overweight and obese adults. Similarly, Jenkins et al (67) reported following a 12-week dietary intervention, type 2 diabetic patients who consumed 1 cup of pulses daily had decreased body weight and WC. In both studies, the observed anthropometric changes were accompanied by a reduction in daily energy intake of 200 – 400 kcal on average, although no instruction on energy restriction was given. Consequently, it is likely that pulse consumption plays a role in food intake suppression, which in turn acts as the driving force that reduced body weight and WC.

2.3 Pulse consumption and satiety

The cornerstone for weight reduction is ultimately achieving negative energy balance, either through decreased energy intake, or increased energy expenditure. Although exact mechanisms responsible for maintaining energy balance remain largely uncertain, appetitive sensations that influence food intake and rejection have been viewed as a bridge that couple energy intake with expenditure (68). Therefore, to understand the effect of pulse consumption on appetite control and energy balance, the following sections provide a brief overview of current knowledge on satiety assessment, pulse components associated with appetite regulation, as well as human trials examining the acute effect of pulse intake on satiety.

2.3.1 Definition and assessment of satiety

Satiety, also known as “post-ingestive or inter-meal satiety” is a component of appetitive sensations that refers to “the suppression of further intake after eating has ended” (69). It is distinct from satiation, the process that leads to eating cessation or “intra-meal satiety” (69).

Satiety in human subjects is inherently difficult to measure as it is influenced by both physiological and cognitive factors (69). Common approaches to assessing satiety include questionnaires, food intake,

and biomarkers (68). The two main questionnaire-based methods are categorical scales and visual analog scales (VASs). With VASs, specific appetitive sensations are rated by drawing a mark on a straight line with extreme statements of subjective feelings anchored on opposite ends (69). A series of scales such as hunger, satisfaction, fullness, desire to eat, etc. are often used collectively due to the fact that appetite is multidimensional (68). For example, a question asking about hunger may yield quite different answers from a question asking about the desire to eat (68). However, one drawback is that these subtle differences may be difficult to capture among untrained subjects (68). Furthermore, perceived appetitive sensations such as hunger, fullness, etc. vary considerably among different individuals and under different situations. For this reason, VASs are best used in within-subject, repeated measure experimental designs (70, 71). Most often, the same questions are administered before and at intervals after consumption of study foods for several hours until the next meal to monitor reported satiety (72).

In addition to questionnaires, food intake serves as another index of appetite. Under standard conditions, short-term studies have reported participants' *ad libitum* food intake following consumption of the study food items in conjunction to subjective ratings of appetite in response to study food consumption to describe the satiating effect of study foods (73, 74). However, under free-living conditions, the correlation between appetite and actual food intake may dissipate because a number of factors such as availability of food, social constraint, and emotional stress can obscure the relationship (68).

Compared with questionnaires and food intake, biomarkers of appetite are less influenced by cognitive and environmental factors (68), and may therefore be useful for quantifying appetite and satiety along with subjective tools. Cholecystokinin (CCK) and glucagon-like peptide 1 (GLP-1) are released into the blood in response to nutrient intake, and both hormones are reflective of short-term satiation (70). Ghrelin and peptide YY (PYY), on the other hand, are candidate hormones for inter-meal satiety. Plasma ghrelin concentrations decrease following meal consumption and return to pre-meal concentrations before initiation of the next meal (70). In contrast, PYY is released following carbohydrate-, protein-, and fat-rich meals to suppress appetite (70). Additionally, leptin may serve as a long-term biomarker of satiety when subjects are not in energy balance, although it is not sensitive to acute changes of appetite (70).

2.3.2 Pulse components and appetite regulation

Components of pulses have been examined with respect to their ability to promote satiety, suppress appetite and food intake via different mechanisms. When consumed with a meal, pulse fibre has been suggested to stimulate and prolong secretion of CCK by inducing gastric distension and delaying gastric emptying (75). The presence of both soluble and insoluble fibres in pulses can effectively increase viscosity and bulk, which leads to a sensation of gastric fullness (76). Foods with high fibre content require greater effort and time of mastication, which also contributes to decreased rate of ingestion and enhanced satiety (19). In addition, pulses are a good source of protein, and intake of protein has been shown to produce greater hunger-suppressing effect compared with carbohydrate and fat given the same amount of calories (20). For example, when male subjects were fed a high carbohydrate, a high fat, and a high protein diet isocaloric for three days on three occasions, the high protein diet was more satiating than the other two diets according to self-reported hunger and satiety (77). In rats, minor components of pulses including lectins and trypsin inhibitor have also been shown to independently stimulate CCK release, and thereby contribute to the feeling of satiation (78, 79). In support of this, Bourdon et al (80) demonstrated that in healthy males, the postprandial increases in plasma CCK concentration was almost twice as high in response to a bean flake-containing meal relative to a pulse-free control meal with matched energy content and macronutrient distribution. Moreover, SCFA from colonic fermentation of pulse fibre and resistant starch have been shown to up-regulate secretion of GLP-1 and PYY, which act as satiety signals to terminate feeding and enhance satiety (76, 81). Importantly, evidence suggests this SCFA-mediated hormone regulation may be prolonged. In healthy individuals, when brown beans were consumed instead of white wheat bread for an evening meal, a higher serum concentration of PYY and a lower concentration of ghrelin was observed after a standard breakfast 11 hours later (82). Colonic fermentation following brown bean consumption was confirmed by elevated levels of plasma SCFA and breath H_2 excretion.

2.3.3 Acute effect of pulse consumption on satiety

To test the acute effect of different pulse varieties on satiety and food intake, Mollard et al (73, 74) conducted two studies. In both cases, *ad libitum* consumption of pizza was preceded by ingestion of pulse-containing or pulse-free, high carbohydrate treatment meals 4 hours prior. In the first study,

participants consumed isocaloric treatment meals with fixed energy and volume (73). It was found that lentil and yellow pea, but not chickpea reduced participants' appetite rating before the pizza meal and resulted in less pizza consumption compared with the pulse-free treatment meal. In the second study, participants consumed treatment meals matched in energy density until "comfortably full" (74). In this case, lentil consumption exhibited the greatest satiating effect as evidenced by lower cumulative energy intake from the lentil-containing treatment meal and pizza compared with other pulse varieties and the pulse-free meal. Interestingly, self-reported appetite did not differ among groups either before or after the pizza meal. Thus, results of the above studies demonstrate in the short term and under standardized conditions, a meal rich in pulses may enhance satiety and suppress energy intake compared to a meal rich in carbohydrate such as white bread and pasta, although the capacity to regulate appetite and energy intake appears dependent upon pulse type.

As satiety is a short-term parameter, direct assessment of satiety over an extended period of time is difficult (76). In uncontrolled settings, individuals' appetite as well as food intake is likely influenced by other environmental and psychological factors that counterbalance physiological signals (76). Although measurement of satiety under laboratory conditions may provide the highest degree of sensitivity, accuracy, and precision, external validity of the results is questionable (69, 72). In other words, participants' lower appetite in response to pulse-containing foods relative to control foods reported in the short-term, controlled studies may not necessarily translate into reduced food intake and weight loss in the long run.

Currently, two randomized controlled trials with unintentional weight loss observed a reduction in participants' energy intake and concurrent weight loss when pulse containing foods were incorporated into habitual diets (59, 67). Among diabetic subjects, a daily consumption of 1 cup pulses (cooked weight) for 12 weeks led to a reduction in daily energy intake by ~200 kcal (67). Similarly, in overweight and obese adults, a daily consumption of ¾ cup pulses for 8 weeks led to lower daily energy intake by ~380 kcal (59). However, the role of satiety in both studies was not specified. As a result, whether or not the observed weight loss was mediated by short-term satiety following pulse consumption requires additional investigation.

2.4 Pulse consumption and blood pressure

Elevated BP is among the most prevalent risk factors of CVD (16) and has been identified as the most common feature of metabolic syndrome in European countries (83, 84). The risk of developing CVD gradually increases with elevated BP levels starting from 115/75 mm Hg, suggesting those with hypertension (systolic BP ≥ 140 mmHg, diastolic BP ≥ 90 mmHg) and those with prehypertension (systolic BP between 120 and 139 mmHg or diastolic BP between 80 and 89 mmHg) will all benefit from BP reduction (16). Both genetic and environmental factors such as diet, physical activity, and stress contribute to elevated BP. Along this line, dietary patterns emphasizing vegetables, fruits, whole grains, nuts and legumes, and limiting intake of red meat and high-fat dairy products, such as are recommended in the DASH eating plan and the Mediterranean diet are recommended as effective means for prevention and treatment of hypertension. Pulses share many nutritional characteristics with these diets, being rich in fibre, plant protein, potassium, magnesium, and antioxidants, and very low in sodium, saturated fat and cholesterol. Indeed, when the DASH diet was enriched with plant protein from beans and other sources, the BP-lowering effect was significantly improved (85). The following sections provide a summary of current research regarding the effect of pulse consumption on BP from epidemiological and clinical perspectives.

2.4.1 Epidemiological evidence

Epidemiological evidence concerning the relationship between dietary pulse consumption and BP is scarce. Results from the 1999 – 2002 NHANES demonstrate that adults who consumed baked beans had lower systolic BP than those who did not based on the 24-hour recall (23). When all bean types were taken into account, the risk of elevated systolic BP was reduced by 47% among bean consumers 20 to 40 years old. These results were consistent with those of a case-control study of middle-aged Iranian adults which reported that individuals with metabolic syndrome had lower legume consumption than their age- and gender-matched healthy counterparts (50). Moreover, systolic BP was inversely associated with legume intake among all study subjects after adjustment for physical activity, education level, BMI, and other lifestyle factors. While these observations point towards a beneficial effect of pulse consumption on BP, the retrospective design of both studies does not allow for clarification as to whether BP changes were preceded by dietary intake. Currently, available data from prospective cohorts support that adopting

diets rich in plant sources such as the DASH eating plan is associated with a reduced risk of hypertension development and a lower BP increase over an extended period (86-88). However, only one study to date has addressed the specific role of legumes on BP control (89), and none have specifically analyzed pulses as a separate food category. The lack of information highlights the need to further explore long-term and independent effect of regular pulse consumption on BP levels.

2.4.2 Clinical trials

Compared with the small number of epidemiological reports available in the literature, data from clinical trials on this topic is relatively abundant. A recent systematic review and meta-analysis by Jayalath et al (26) aggregated results from 8 controlled feeding trials using pulses as the major intervention ingredients and concluded substituting pulses isocalorically for other food items significantly reduced systolic BP by 2.25 mmHg and mean arterial BP by 0.75 mmHg, but had non-significant effect on diastolic BP. These clinical trials, with a median follow-up period of 10 weeks, involved participants with or without hypertension, and incorporated on average 1⅔ servings (~ 162 g) of cooked pulses daily into the intervention diet. Notably, only 2 out of 8 trials assessed BP as the primary outcome. Thus, the power to detect BP changes is likely limited in most cases. Although as many as 6 trials employed mixed pulse varieties, only 1 conducted in healthy males compared the effectiveness of individual varieties (chickpeas vs. lentils vs. green peas) on BP modulation, but was insufficiently powered to detect differences in BP. Therefore, additional human trials, especially those with hypertensive subjects are needed to address if beneficial effects on BP is dependent on pulse type.

In summary, current evidence supporting BP-lowering effect of dietary pulses is available from controlled feeding trials and observational studies mainly with cross-sectional and case-control designs. Since study populations have involved both hypertensive and normotensive individuals, incorporating pulses into a healthy diet is likely to facilitate BP lowering and heart disease prevention among the general public. On the other hand, to extend our understanding of the connection between pulse intake and BP, long-term and independent effect of pulse consumption, as well as specific effect of different pulse varieties should be addressed in future studies.

2.4.3 BP-lowering effect of pulse components

The BP-lowering effect of several pulse components has been documented in the literature. Recently published systematic reviews and meta-analyses of RCTs support the beneficial effect of higher protein intake in general on BP (90, 91). With respect to pulse protein in particular, it has been shown that substitution of white bread with lupin flour-enriched bread resulted in significantly higher protein intake and lower systolic and diastolic BP in overweight and obese individuals (92). Likewise, daily consumption of 1 cup of cooked pulses increased percentage energy intake from total and plant protein, and decreased systolic and diastolic BP in diabetic patients (67). Of importance is that incorporation of pulses into the diet also led to concomitant increase in fibre intake (67, 92), which by itself, has been shown to elicit BP-lowering effect (93). In addition, minerals that are found in abundance in pulses, including potassium and magnesium, have been demonstrated to reduce BP in clinical trials (21, 22). Therefore, an additive effect of individual nutrients may be important for BP regulation and could contribute to the BP responses to pulse consumption.

2.5 Pulse consumption and GI symptoms

2.5.1 Components responsible for GI symptoms

The raffinose family of oligosaccharides including raffinose, stachyose and verbascose are soluble carbohydrates and are contained in pulses (94). The approximate concentration ranges from 2.6 to 6.6% in beans and 5.1 to 8.7% in peas on a dry weight basis (95). Due to the lack of α-galactosidase in human, this class of compounds are not digested or absorbed in the upper intestinal tract, and are highly fermentable by colon microflora (94-96). While pulse oligosaccharides may act as prebiotic agents by stimulating beneficial bifidobacteria, byproducts of fermentation including H_2 and CO_2 are primarily responsible for flatulence and GI discomfort (97). For individuals with low habitual dietary fibre intake, increased flatulence may also be a short-term outcome of increasing fibre consumption from pulses, and the symptom is believed to improve as regular pulse consumption continues (97).

2.5.2 Consumers' perception of GI symptoms

GI symptoms such as flatulence, bloating, increased stool frequency and diarrhea are common complaints in response to increased pulse consumption in subjects participating in clinical trials that increase pulse intake above normally consumed levels (59, 62, 98). Among the general public, the belief

that pulse consumption causes flatulence has become a major challenge for promoting adherence to recommended dietary legumes by health professionals (99). Only two reports in the literature have quantitatively evaluated GI symptoms associated with pulse consumption in clinical trials (97, 100). Winham and Hutchins (97) summarized results from three feeding studies and reported daily consumption of ½ cup cooked navy or pinto beans increased flatulence in less than 50% of study participants during the first week of dietary intervention, and the symptom dissipated in most participants by the second or third week of bean consumption. Even smaller proportions of participants experienced increased bloating frequency in response to navy bean (0 – 21%) and pinto bean (0 – 40%) consumption for the duration of the intervention. Similarly, Veenstra et al (100) reported daily intake of 100 g spray-dried powders of chickpeas, lentils, or peas did not significantly alter occurrence of flatulence or abdominal discomfort in healthy males. A small proportion of participants (10% or less) reported increased bloating and cramping of modest severity in response to the treatments. Collectively, these findings demonstrate GI symptoms associated with pulse consumption are likely well-tolerated by healthy adults. Flatulence, bloating and other GI symptoms tend to normalize over time with regular pulse consumption, and therefore, should not become a major concern when incorporating pulses into a normal diet.

2.6 Compliance in diet intervention trials

2.6.1 Measurement of compliance

Diet intervention trials that aim to establish relationships between intake and health outcomes require accurate and reliable measurement of participant compliance to the dietary protocol (101). Approaches to evaluating dietary compliance can be broadly categorized as self-report and objective measures. Twenty-four-hour recall, food record, and food frequency questionnaire represent the principle tools for self-report (101). In cases where study foods are provided, comparing foods distributed and foods unfinished is another way to determine compliance. In turn, objective measures mainly involve assessing changes of chemical compounds in biological samples (e.g. blood and urine) corresponding to study food consumption. Both approaches have strengths and limitations. Self-reported intake data rely entirely on participant provided information, and are prone to estimation bias. Objective measures are free of self-reported errors, but often, they are not reflective of long-term food intake and could be

expensive and invasive (102). Ideally, the best strategy to assess compliance would be to use self-reported information in conjunction with objective measures to increase the accuracy of measurement (101, 102). For instance, urinary concentrations of isoflavone correlate well with circulating levels. Isoflavone excretion in overnight urine samples has been compared with estimated intakes measured using 24-hour recall and soy intake logs to confirm participants' adherence to a soy-based diet (103). In another RCT, hydroxytyrosol concentrations in urine and α-linoleic acid concentrations in plasma, corresponding to intake of olive oil and mixed nuts, were measured before and during the intervention and compared against self-reported intake values from questionnaires (104). One barrier to applying objective measures is that validated biomarkers are currently unavailable for many food items including pulses. In such cases, self-report becomes the single most critical means for compliance assessment. Diet logs that keep close track of study food intake has been the most widely used tool for monitoring compliance (59, 63, 92, 105). Seven-day food record has also been used assuming the records are representative of study food intake during a period of intervention (67). Development of food-item specific biomarkers is therefore in need to allow for objective assessment of compliance that complements self-reported data.

2.6.2 Factors associated with participant compliance

Although participant compliance is a frequently reported variable in diet interventions, only a limited number of studies have explored factors related to compliance in detail. Inclusion of a run-in period prior to randomization has been recommended to enhance compliance during the subsequent intervention. Depending on study design and purpose, a run-in period may involve provision of study foods to test the feasibility of consumption (103), or provision of a control diet to identify participants unable to adhere to the protocol (106), but the common purpose is to exclude individuals who have difficulty adhering to the diet regimen. In addition, a wide variety of food choices is thought to promote compliance (103), whereas a lack of variety has been recognized as a contributor to deviations (106). Other reported factors associated with compliance include attention from research staff (106), preference of study foods (106), availability of study foods (107), and skills to prepare study foods (107). With regard to demographic characteristics of participants, only one study reported African American participants were less likely to be adherent to the DASH diet compared with Whites, addressing a need for culturally

sensitive strategies to increase compliance (108). Other studies, however, did not observe significant associations between groups of different sex, ages, ethnicities, education, income, or marital status and compliance rate (106, 109). Because of variations in study design and protocol (e.g. short-term versus long-term intervention, partial versus total replacement of habitual diet by study foods), it is difficult to reach general consensus as to what factors best predict compliance rate in a given study.

Chapter 3. Methods

3.1 Study design

This clinical trial followed a multi-centre, unblinded, randomized controlled design. Adult men and women with mild hypercholesterolemia were randomly assigned to consume study food items containing beans, peas, or rice 5 days per week for 6 weeks as part of their regular diet. Upon confirmation of eligibility by telephone and in-person screening, participants attended study visits at baseline, week 3 and week 6 of the intervention period. The protocol of this RCT was approved by the ethics boards at the University of Alberta and the University of Manitoba. The trial is registered at ClinicalTrials.gov (ClinicalTrials.gov identifier: NCT01661543).

3.2 Participants

The goal of the overall study is to recruit 150 participants from Edmonton and Winnipeg (75 per site). This thesis reports on some of the characteristics of the first 51 participants recruited into the Edmonton study centre. In Edmonton, recruitment was done through newspaper advertisements, posters, campus newsletters and volunteer websites. An example of the recruitment poster is shown in Appendix A. Participants were screened and enrolled on an ongoing basis beginning in May, 2013. Inclusion criteria were: 1) Male, or non-pregnant, non-lactating female, aged 20 to 75 years; 2) Fasting serum LDL-C ≥ 3.00 mmol/L and ≤ 5.00 mmol/L; 3) Fasting serum triglycerides ≤ 4.00 mmol/L; 4) Stable body weight (± 5%) for the past 3 months and BMI of 20 – 40 kg/m^2; 5) Must have been on a stable regime for the past 3 months if taking medications or if taking vitamin and mineral/dietary/herbal supplements; 6) Able to read, write and communicate orally in English; 7) Willing to comply with the protocol requirements, including a stable level of physical activity and no other pulse-containing foods consumed during the study; 8) Willing to provide informed consent.

In addition, participants were excluded based on the following criteria: 1) Regular high pulse consumption (>2 servings per week, 1 serving is defined as 0.6 cup for the purpose of the particular document); 2) Use of medications to lower blood lipids or to lower blood glucose; 3) Use of non-prescription products designed to lower blood lipids (e.g. margarine or yogurt with added plant sterols) within the past 3 months; 4) Medical history of liver disease, renal insufficiency, inflammatory bowel

disease or other GI disorders influencing GI motility or nutrient absorption; 5) Any acute medical or surgical condition(s) within the past 3 months precluding study participation; 6) Conditions or medications which are likely to increase the risk to the participants or study personnel, or to reduce the ability of the participant to comply with the protocol, or affect the results; 7) History of GI reactions or allergies to beans, peas or rice-based foods, or to one or more ingredients in the study foods which significantly limits the number of study foods that can be consumed; 8) Currently participating in or having participated in a food intervention study within the last 3 months; 9) Individuals who consume a vegan diet (consume only plant-based sources of protein).

3.3 Study foods and treatment protocol

Study food items in the form of soups and casseroles were developed at the University of Manitoba. They were prepared at both study centres by trained personnel and were provided to participants as ready-to-eat food items. Study pulses including black beans, pinto beans, navy beans, Great Northern beans, green peas, and yellow peas were kindly provided by the Alberta Pulse Growers. The main steps of preparing the study pulses involved soaking in water at 4 °C for 12 – 16 hours, followed by boiling (35 – 55 minutes for beans, and 120 minutes for peas). Rice, which was used in control foods, was cooked using a conventional rice cooker. The background ingredients of each food item were identical across the three study arms. Once cooked, each formulation was divided into individual servings, which were then combined with ¾ cup (~120 g) cooked beans, peas, or rice as final products. Food portions were frozen at -20 °C in freezer-safe storage bags before distributed to participants. A complete list of recipe names and ingredients is shown in Appendix B.

During the intervention, participants were instructed to take out one package of study food at a time from the freezer, defrost it at refrigerated temperature, and heat it up before consuming. The food item could be consumed anytime during the day, and participants were requested to eat all contents of the package. The addition of other ingredients, specifically seasonings, into the study foods was permitted to meet personal preference. Participants were asked to avoid consuming additional pulses while maintaining their habitual diet and physical activity level during the intervention period. A list of common pulse-containing foods was provided for their reference (Appendix C).

3.4 Study procedure

3.4.1 Telephone pre-screening and screening visit

Individuals interested in participating contacted study personnel via telephone or email. Potential participants completed a telephone pre-screening interview where a summary of the study information was provided, and the aforementioned eligibility criteria with the exception of fasting LDL-C concentration, triglyceride concentration, and BMI were discussed. Individuals who passed the telephone pre-screening were invited to attend a screening session to further confirm eligibility.

At the beginning of the screening visit, participants provided written informed consent before any measurements were taken. Demographic information such as age, sex, ethnicity, education, occupation, and income was collected using a questionnaire. Participants' medical history, current use of medications and/or supplements, and baseline habitual consumption of pulses, as assessed by a shortened food frequency questionnaire, was confirmed and evaluated to ensure eligibility. In addition, participants were asked to report their family history of chronic diseases, physical activity level, smoking, alcohol use, and meal pattern. To assess serum lipid concentrations (total cholesterol, LDL-C, HDL-C, and triglyceride), a 5 mL blood sample was drawn after a 12-hour fast (no food or beverages except for water) by a phlebotomist. A detailed protocol of blood sample analysis is found in Appendix D. Height and weight were measured by study personnel to calculate BMI. Height was measured using a digital stadiometer and recorded to the nearest 0.1 cm (QuickMedical Heightronic Digital Stadiometer, Issaquah, WA, USA). Height obtained at the screening visit was used for the duration of the study period. Body weight was measured using a digital scale (752KL, Health-o-meter Professional, Bridgeview, IL, USA) with participants' shoes removed, and was recorded to the nearest 0.1 kg. All anthropometric measurements were made twice, and the mean values were calculated and entered into the database. At the end of the visit, participants received a three-day food record, a diet history questionnaire, and a GI symptoms questionnaire to complete at home prior to the baseline visit.

Once the serum lipid concentration results became available, study personnel notified all screened individuals regarding their eligibility via telephone. For those who were eligible and still interested in participating, a baseline study visit was scheduled and they were asked to complete the

additional questionnaires. Those who were ineligible and those who were no longer interested in participating were thanked for their time, and asked to discard the additional questionnaires.

3.4.2 Baseline and follow-up study visits

Participants who were enrolled in the study completed three visits: baseline, week 3, and week 6 of the intervention period. At the baseline visit, participants were assigned to one of the three diet groups according to the study randomization schedule; a block randomization schedule was generated at the University of Manitoba and participants were blocked into groups of 15 people. The 3 diet groups were not matched for any parameters. In all three visits, a fasting blood sample (about 40 mL) was collected for determination of the serum lipid profile, glucose, insulin, hemoglobin A1c (HbA1c), polyphenol concentrations and biomarkers of vascular function, inflammation, B-vitamin status, and related metabolites. A urine sample was obtained for analysis of polyphenol concentrations and metabolomic profile. Samples were divided into 500 µg or 1.5 mL microfuge tubes and stored at -80 °C for future analysis.

BP and anthropometrics including body weight, waist and hip circumference were measured by trained study personnel. WC was measured at the smallest horizontal circumference between the lower costal ribs and the iliac crest. HC was measured at the level of maximum extension of the buttocks. At baseline and week 3 visits, participants were supplied with study foods for the following 3 weeks. They were reminded about the treatment protocol and were given instructions on how to prepare study foods. To assess compliance, participants received a tracking document to record their consumption of study foods including recipe name, any food items that were missed or consumed partially, and other additional comments on a daily basis. Throughout the study, participants also completed three-day food record, GI questionnaire, satiety questionnaire and study food questionnaire at time points listed in **Figure 3-1**. Study personnel reviewed questionnaires with participants to ensure completeness and clarity. A copy of the information letter and consent form, and a list of study questionnaires relevant to the thesis are found in Appendices E – K.

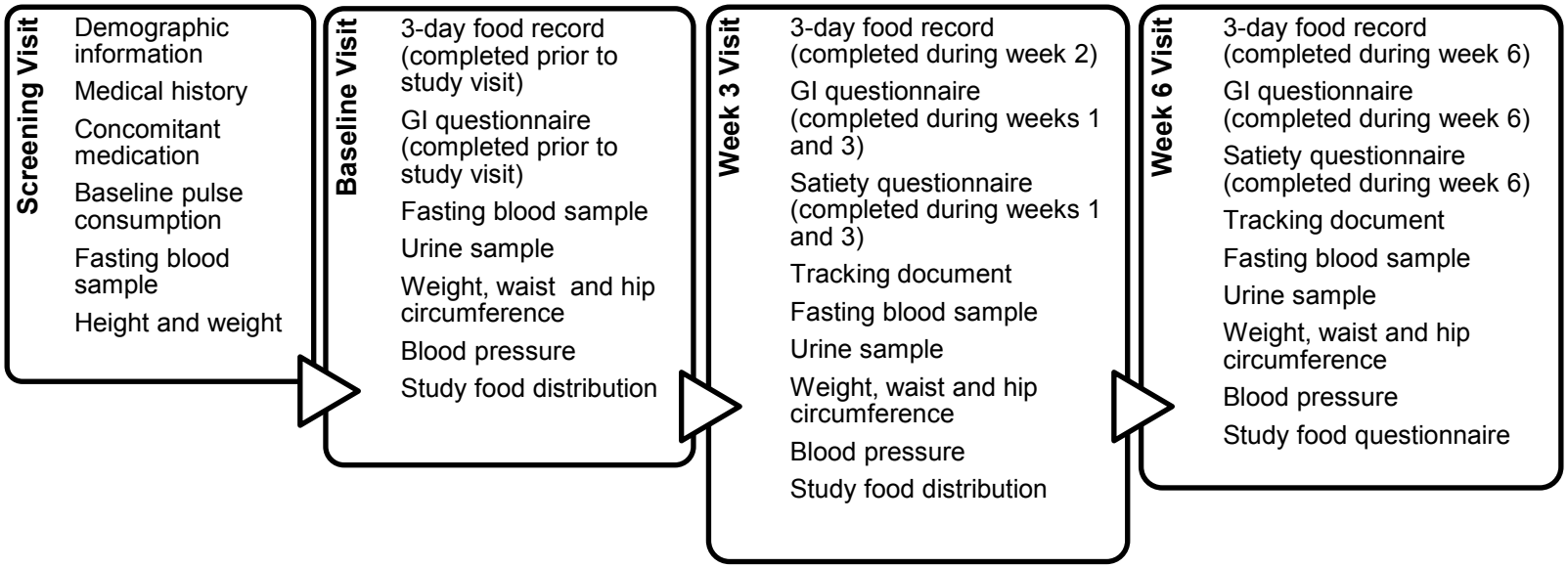


Figure 3- 1. Time points for collection of participant information, biological samples and physical measurements.

3.5 Protocol details

3.5.1 BP

BP was measured after participants were seated quietly for 5 minutes with an automated sphygmomanometer (ADC 9000BPS ADview 9000 Modular Diagnostic Station with BP and SpO_2, Tiger Medical, Irvington, NJ, USA). Two measurements were taken, separated by 1 minute. If the readings were different by 10 mmHg or greater for systolic or diastolic BP, a third measurement was taken, and the mean of the closest 2 values was calculated and recorded.

3.5.2 Diet assessment

Participants completed three-day food records (2 weekdays and 1 weekend day) prior to the intervention and during weeks 2 and 6 of the intervention period as has been previously described (110). All dietary data were entered into the Food Processor software (version 10.12.0; ESHA Research, Salem, OR, USA) for analysis of nutrient intake. Food items were primarily selected from the Canadian Nutrient File database, and then the United States Department of Agriculture National Nutrient Database.

3.5.3 Satiety assessment

Satiety was evaluated during weeks 1, 3 and 6 of the intervention period. Specifically, participants were asked to record the name of the study food item consumed and the time of consumption. In addition, they were asked to rate their feeling of hunger, satisfaction, fullness, and prospective food consumption on a VAS, 30 minutes after consuming the study food item. The VASs were 100 mm lines with words anchored at each end describing opposite extremes of each appetitive sensation. Hunger was assessed by asking “How hungry do you feel?” “I am not hungry at all” (0 mm) versus “I have never been more hungry” (100 mm); satisfaction was assessed by asking “How satisfied do you feel?” “I am completely empty” (0 mm) versus “I cannot eat another bite” (100 mm); fullness was assessed by asking “How full do you feel?” “Not full at all’ (0 mm) versus “totally full” (100 mm); prospective food consumption was assessed by asking “How much more do you think you can eat?” “Nothing at all” (0 mm) versus “a lot” (100 mm). In addition, an overall satiety score was calculated as [(100 - hunger) + (100 - prospective food consumption) + satisfaction + fullness] / 4. Reproducibility and validity of this method is described elsewhere (111).

3.5.4 GI symptoms

Participants completed a GI questionnaire (adapted from Winham and Hutchins 2011) (97) prior to the intervention, and during weeks 1, 3 and 6 of the intervention period. Participants were asked to report changes in flatulence frequency, stool frequency, stool consistency, feeling of bloating and daily activities due to GI symptoms during the past week. If any changes occurred, the amount of change was rated on a 5-point scale with “1” indicating little change, and “5” indicating a lot of change.

3.6 Statistical analysis

Statistical analyses were conducted among the first 51 participants enrolled at the Edmonton study site. All available data were included into the analysis including those participants who did and did not complete the trial. Distributions of individual variables of interest were examined for normality using residual plots. Participants’ prospective food intake demonstrated skewed distribution, and was square root transformed before analysis.

Across the diet groups, participants’ baseline demographic characteristics, physical measurements, dietary intake as well as compliance rate were compared using one-way analysis of variance (ANOVA) with Tukey's HSD test for pairwise comparisons. To evaluate the effect of group, time and group x time interaction on outcome variables of interest including physical measurements, dietary intake, and satiety, repeated measures mixed model ANOVA (PROC MIXED) was applied. Compound symmetry was chosen as the covariance structure because it has the smallest Akaike Information Criteria for most outcome variables examined (112). Where a significant group x time effect was seen, post-hoc pairwise comparison with Tukey-Kramer adjustment was applied. For categorical data, McNemar’s test was used for within-subject comparisons, while Chi-square test or Fisher’s exact test was used for between-subject comparisons. Within individual diet groups, percentage of participants meeting the adequate intake (AI) level of fibre during weeks 2 and 6 of the intervention was compared with baseline using McNemar’s test. At individual time points (baseline, week 2 and week 6), percentage of participants meeting the AI levels of fibre was compared across the diet groups using Chi-square test.

In addition, to determine the effect of time on perceived GI symptoms, the occurrence of increased GI symptoms (flatulence frequency, stool frequency, bloating) and occurrence of any changes in normal daily activities as a result of GI symptoms was compared between baseline and week 1, between baseline and week 3, and between baseline and week 6 using McNemar’s test within individual

diet groups. At each time point, the above parameters were compared across the diet groups using Fisher's exact test to determine the effect of diet. The amount of changes in each GI symptom was not evaluated in the current study because for certain GI symptoms at a given time point, an extremely small number of participants experienced changes and proceeded to respond to the questions regarding severity.

All statistical analyses were conducted using SAS (version 9.3; SAS Institute Inc., Cary, NC, USA). Results are presented as mean ± standard error of the mean (SEM) unless otherwise noted, and $p \leq 0.05$ was considered significant.

Chapter 4. Results

4.1 Participant characteristics

Of the 220 participants screened for eligibility between May 7, 2013 and February 13, 2014, fifty-one were eligible and randomized to one of the three study treatment groups (**Figure 4-1**). The main reasons for exclusion were high pulse consumption (n = 40), LDL-C concentrations were lower (n = 24) or higher (n = 10) than the targeted range, use of glucose- or lipid-lowering medications (n = 17), and liver or GI disorders (n = 15), among others. By the end of the 6-week intervention, 88.2% (n = 15), 82.4% (n = 14), and 94.1% (n = 16) participants in the rice group, bean group, and pea group respectively completed the study. Two participants in the rice group dropped out due to dissatisfaction with the study foods. Two and one participant in the bean group and pea group dropped out due to health issues unrelated to the study. One participant in the bean group dropped out due to abdominal pains probably associated with the study foods.

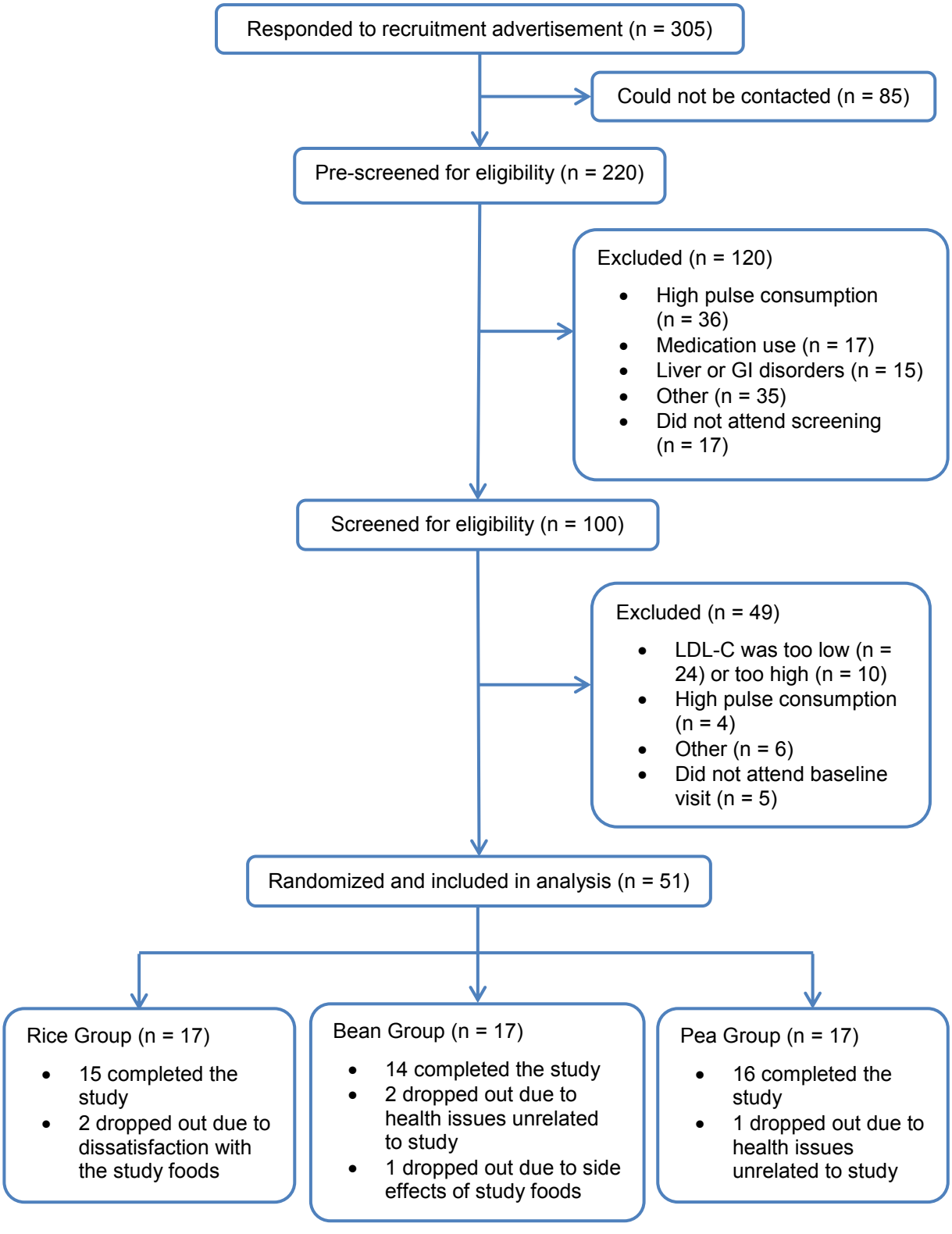


Figure 4- 1. Flow chart of the first 51 participants enrolled at the Edmonton study site.

Baseline demographic characteristics and physical measurements of study participants are shown in **Table 4-1**. The majority of participants were Caucasian (78.4%), female (68.6%) and had an age in the 50s or 60s (64.7%). Mean BMI fell within the overweight category, while mean WC indicated both males and females did not have substantially increased risk of metabolic complications according to the World Health Organization cut-off points. At baseline, there were no significant differences in age, weight, BMI, WC, HC, systolic BP or diastolic BP across the diet groups ($p > 0.05$). Seven participants were taking BP-lowering medications, and were distributed evenly among the diet groups (n = 2 in the rice group, n = 3 in the bean group, and n = 2 in the pea group).

Table 4- 1. Baseline characteristics of the first 51 study participants enrolled at the Edmonton study site[1]

Variable	Rice (n = 17)	Bean (n = 17)	Pea (n = 17)	p-value
Age (years)	48.2 ± 3.6	53.5 ± 3.0	53.5 ± 2.9	0.40
Sex (Male/Female)	4/13	6/11	6/11	—
Body weight (kg)	71.9 ± 2.3 M: 79.3 ± 2.8 F: 69.7 ± 2.7	81.1 ± 4.0 M: 84.9 ± 6.4 F: 79.1 ± 5.2	82.4 ± 4.4 M: 96.8 ± 8.2 F: 74.6 ± 3.5	0.10 M: 0.24 F: 0.23
Height (cm)	M: 181.2 ± 2.0 F: 162.5 ± 1.7	M: 181.2 ± 3.0 F: 165.0 ± 2.2	M: 182.2 ± 2.5 F: 164.0 ± 2.0	M: 0.95 F: 0.66
BMI (kg/m^2)	26.0 ± 1.1 M: 24.2 ± 1.0 F: 26.6 ± 1.4	27.8 ± 1.2 M: 25.7 ± 1.1 F: 28.9 ± 1.6	28.1 ± 1.0 M: 29.1 ± 2.3 F: 27.6 ± 0.9	0.35 M: 0.18 F: 0.47
Waist circumference (cm)	86.3 ± 3.5 M: 84.3 ± 1.7 F: 87.0 ± 4.5	89.6 ± 2.7 M: 90.2 ± 4.3 F: 89.3 ± 3.5	92.2 ± 3.2 M: 101.0 ± 6.4 F: 87.5 ± 2.9	0.42 M: 0.11 F: 0.91
Hip circumference (cm)	102.6 ± 2.0 M: 100.4 ± 2.3 F: 103.3 ± 2.5	105.8 ± 2.3 M: 103.5 ± 4.0 F: 107.0 ± 2.9	108.3 ± 2.3 M: 107.1 ± 3.2 F: 109.0 ± 3.2	0.19 M: 0.46 F: 0.35
Waist/Hip ratio	0.84 ± 0.02 M: 0.84 ± 0.02 F: 0.84 ± 0.03	0.85 ± 0.02 M: 0.87 ± 0.02 F: 0.83 ± 0.02	0.85 ± 0.02 M: 0.94 ± 0.03 F: 0.81 ± 0.02	0.85 M: 0.08 F: 0.61
Systolic blood pressure (mmHg)	121 ± 4	129 ± 3	129 ± 3	0.15
Diastolic blood pressure (mmHg)	74 ± 2	78 ± 3	79 ± 2	0.28

[1] Values are mean ± standard error of the mean.
Abbreviation: BMI, body mass index.

4.2 Compliance

According to the self-reported tracking document, the overall compliance rate was 98.3% (range: 83.3% - 100.0%) among those who completed the study (n = 45; **Figure 4-2**). There were no differences in compliance rate across the diet groups ($p > 0.05$), and all but two participants consumed more than 90% of the study foods provided.

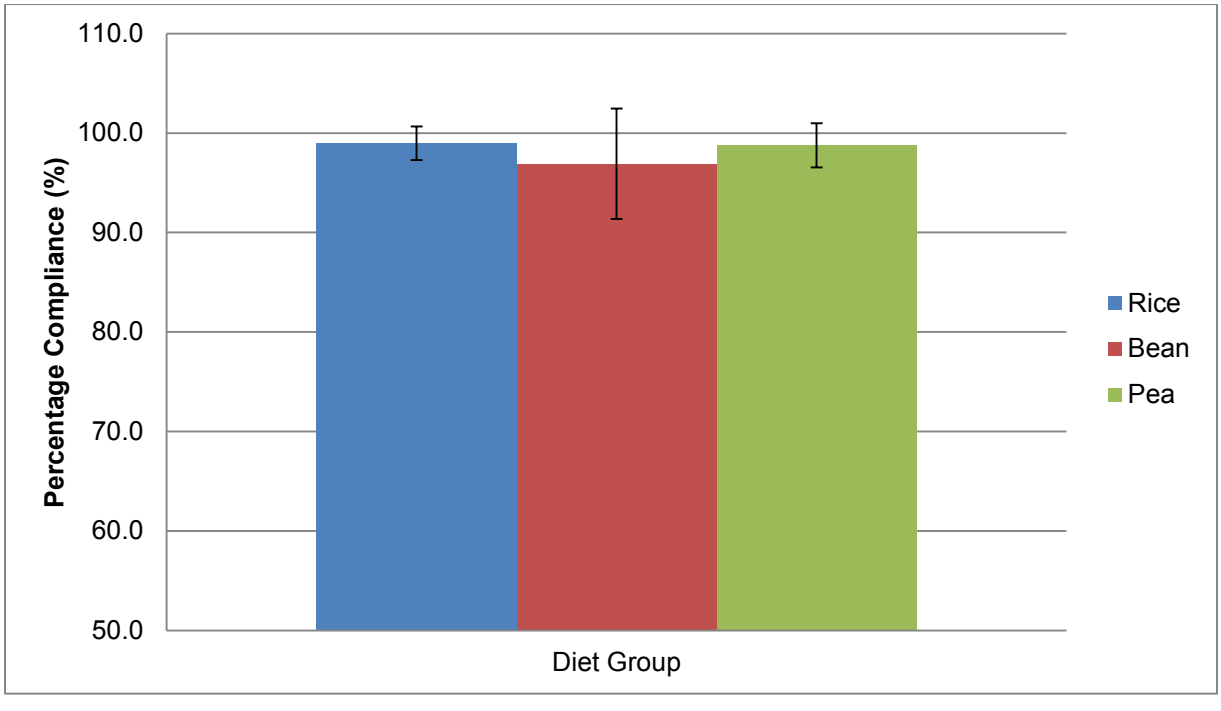


Figure 4- 2. Participant compliance rates calculated from information for the first 51 participants from the Edmonton site who completed the study (n = 45). Data shown are mean ± standard deviation.

4.3 Dietary intake

Table 4-2 provides a summary of dietary intake of study participants at baseline. There were no significant differences in the absolute intake of carbohydrate (g/d), fibre (g/d), protein (g/d), polyunsaturated fatty acids (PUFA) (g/d), potassium (mg/d), or magnesium (mg/d) across the diet groups. Mean habitual pulse consumption was low in all three groups. However, although randomized, participants in the rice group had significantly lower intake of total energy ($p = 0.05$), total fat ($p = 0.02$) and monounsaturated fatty acids (MUFA, $p = 0.03$) than those in the pea group. Intake of sodium was lower in the rice group than the bean group ($p = 0.03$). Also, intake of protein ($p = 0.04$), saturated fat ($p = 0.02$) and cholesterol ($p = 0.01$) was lower in the rice group than the other two groups. Nonetheless, % energy intake from protein ($p = 0.54$), total fat ($p = 0.31$), saturated fat ($p = 0.08$) and MUFA ($p = 0.49$) was not different across the groups.

Table 4- 2. Baseline dietary energy, nutrient and pulse intake of the first 51 study participants enrolled at the Edmonton study site[1,2]

Characteristic	Rice (n = 17)	Bean (n = 17)	Pea (n = 17)	p-value
Energy (kcal/d)	1710 ± 88[a]	1940 ± 108[ab]	2113 ± 137[b]	0.05
Carbohydrate (g/d)	218 ± 15	215 ± 15	234 ± 22	0.72
Fibre (g/d)	21 ± 2	22 ± 2	23 ± 2	0.81
Protein (g/d)	77 ± 4[a]	95 ± 7[b]	97 ± 6[b]	0.04
Fat (g/d)	61 ± 4[a]	74 ± 5[ab]	82 ± 6[b]	0.02
Saturated fat (g/d)	19 ± 2[a]	27 ± 2[b]	27 ± 3[b]	0.02
Cholesterol (mg/d)	218 ± 27[a]	331 ± 27[b]	314 ± 25[b]	0.009
MUFA (g/d)	22 ± 1[a]	27 ± 2[ab]	31 ± 3[b]	0.03
PUFA (g/d)	13 ± 7	12 ± 5	15 ± 5	0.46
Sodium (mg/d)	2152 ± 191[a]	3098 ± 308[b]	2867 ± 243[ab]	0.03
Potassium (mg/d)	2775 ± 157	3145 ± 161	3231 ± 179	0.13
Magnesium (mg/d)	311 ± 22	343 ± 26	348 ± 23	0.49
Pulses (cup/week)	0.41 ± 0.08	0.39 ± 0.10	0.39 ± 0.10	0.98
Carbohydrate (% kcal)	51 ± 2	44 ± 2	44 ± 3	0.06
Fibre density (g/1000 kcal)	12 ± 1	11 ± 1	11 ± 1	0.65
Protein(% kcal)	18 ± 1	20 ± 1	19 ± 1	0.54
Fat (% kcal)	32 ± 2	34 ± 1	35 ± 1	0.31
Saturated fat (% kcal)	10 ± 1[a]	12 ± 1[b]	11 ± 1[ab]	0.08
MUFA (% kcal)	12 ± 1	12 ± 1	13 ± 1	0.49
PUFA (% kcal)	7 ± 1	6 ± 0	6 ± 0	0.25

[1] Values are mean ± standard error mean.
[2] Values within a row with different superscript letters are significantly different ($p \leq 0.05$).
Abbreviations: MUFA: Monounsaturated fatty acids; PUFA: Polyunsaturated fatty acids.

As shown in **Table 4-3**, there was an effect of group on daily intake of energy, protein, fat, saturated fat, MUFA, sodium, potassium and % energy from saturated fat. The rice group had significantly lower absolute intake of sodium, potassium and lower % energy from saturated fat than the bean group, lower absolute intake of energy, fat, and MUFA than the pea group, and lower absolute intake of protein and saturated fat than the bean group and the pea group. The group effect on protein, fat, MUFA, sodium and potassium intake can be explained by differences in energy intake as % energy from the macronutrients as well as sodium and potassium intake per 1000 kcal did not differ among the diet groups.

In addition, absolute daily intake of carbohydrate, PUFA, as well as % energy intake from carbohydrate, fat, and PUFA was influenced by time. Baseline intake of carbohydrate was lower compared with the intake during week 2 ($p = 0.04$). In contrast, baseline intake of PUFA was higher than the intake during weeks 2 and 6 ($p = 0.03$, $p = 0.02$). Percentage energy intake from carbohydrate increased from baseline to weeks 2 and 6 ($p = 0.002$), whereas % energy intake from total fat and PUFA dropped from baseline to weeks 2 and 6 of the intervention ($p < 0.05$).

A significant effect of group x time interaction was found on absolute intake of fibre ($p = 0.01$; **Figure 4-3a**). Average daily fibre intake in the bean group increased from 22 g/d (SEM = 2) at baseline to 30 g/d (SEM = 2) at week 2, and dropped slightly to 28 g/d (SEM = 2) at week 6, whereas the intake remained relatively unchanged in the rice group and the pea group over the course of the study. Post-hoc analysis indicates fibre intake in the bean group was significantly greater during week 2 relative to baseline ($p = 0.002$) as well as the intake of the rice group at all time points ($p < 0.05$). Fibre density of participants' diet was also influenced by group x time interaction ($p = 0.006$; **Figure 4-3b**). In response to the first two weeks of diet intervention, there was an increase in fibre density in the bean group and the pea group in comparison to the rice group, although the increase in the pea group did not reach statistical significance. Over the remaining 4-week study period, fibre density stayed relatively stable within individual diet groups. When study food items were excluded from the analysis, fibre density of the background diet during the intervention did not differ from that reported at baseline within diet groups, suggesting participants did not alter their habitual fibre intake as a result of being part of the study (**Table 4-4**). In comparison with the AI level of dietary fibre defined as 14 g/1000 kcal, mean fibre density of the bean group stayed above the AI for the duration of the intervention. The percentage of participants

meeting the recommendation increased from 17.6% at baseline to 68.8% during week 2 ($p = 0.01$), and to 50.0% during week 6 ($p = 0.05$) in the bean group.

Finally, according to the self-reported tracking document, there was a 9-fold increase in weekly pulse consumption in the bean group ($p < 0.0001$) and the pea group ($p < 0.0001$) during the intervention relative to baseline. By contrast, participants in the rice group did not consume pulses as instructed (**Table 4-3**).

Table 4- 3. Energy, nutrient and pulse intake at baseline, week 2 and week 6 of the study of the first 51 study participants enrolled at the Edmonton study site [1,2]

Characteristic	Rice			Bean			Pea			p-value	
	Baseline (n = 17)	Week 2 (n = 15)	Week 6 (n = 15)	Baseline (n = 17)	Week 2 (n = 16)	Week 6 (n = 14)	Baseline (n = 17)	Week 2 (n = 17)	Week 6 (n = 16)		
Energy (kcal/d)	1710 ± 88[a]	1715 ± 109[a]	1674 ± 88[a]	1940 ± 108[ab]	2044 ± 109[ab]	2005 ± 129[ab]	2113 ± 137[b]	2148 ± 134[b]	1925 ± 120[b]	Group Time Group x Time	0.02 0.21 0.41
Carbohydrate (g/d)	218 ± 15[a]	231 ± 17[b]	222 ± 14[ab]	215 ± 15[a]	243 ± 14[b]	242 ± 14[ab]	234 ± 22[a]	255 ± 18[b]	232 ± 17[ab]	Group Time Group x Time	0.54 0.05 0.37
Fibre (g/d)	21 ± 2[ab]	20 ± 2[a]	21 ± 3[a]	22 ± 2[a]	30 ± 2[b]	28 ± 2[ab]	23 ± 2[ab]	27 ± 2[ab]	26 ± 2[ab]	Group Time Group x Time	0.03 0.01 0.01
Fibre density (g/1000 kcal)	12 ± 1[ab]	11 ± 1[ab]	12 ± 1[ab]	11±1[a]	15±1[b]	15±1[b]	11±1[ab]	13±1[ab]	14 ± 1[ab]	Group Time Group x Time	0.31 0.001 0.01
Protein (g/d)	77 ± 4[a]	71 ± 3[a]	79 ± 4[a]	95 ± 7[b]	97 ± 6[b]	95 ± 7[b]	97 ± 6[b]	99 ± 8[b]	94 ± 7[b]	Group Time Group x Time	0.01 0.76 0.48
Fat (g/d)	61 ± 4[a]	57 ± 6[a]	53 ± 6[a]	74 ± 5[ab]	71 ± 6[ab]	73 ± 8[ab]	82 ± 6[b]	78 ± 7[b]	67 ± 6[b]	Group Time Group x Time	0.02 0.06 0.55
Saturated fat (g/d)	19 ± 2[a]	18 ± 2[a]	17 ± 2[a]	27 ± 2[b]	25 ± 3[b]	25 ± 3[b]	27 ± 3[b]	27 ± 3[b]	25 ± 3[b]	Group Time Group x Time	0.01 0.45 0.95
Cholesterol (mg/d)	218 ± 27	229 ± 30	272 ± 38	331 ± 27	300 ± 34	258 ± 23	314 ± 25	279 ± 35	280 ± 35	Group Time Group x Time	0.14 0.43 0.14

MUFA (g/d)	22 ± 1[a]	21 ± 3[a]	19 ± 2[a]	27 ± 2[ab]	26 ± 2[ab]	27 ± 3[ab]	31 ± 3[b]	28 ± 3[b]	25 ± 2[b]	Group 0.03 Time 0.17 Group x Time 0.64
PUFA (g/d)	13 ± 2[a]	11 ± 2[b]	10 ± 1[b]	12 ± 1[a]	11 ± 1[b]	13 ± 2[b]	15 ± 1[a]	13 ± 1[b]	10 ± 1[b]	Group 0.76 Time 0.01 Group x Time 0.11
Sodium (mg/d)	2152 ± 191[a]	2167 ± 138[a]	2525 ± 282[a]	3098 ± 308[b]	2854 ± 199[b]	3122 ± 298[b]	2867 ± 243[ab]	3161 ± 362[ab]	2447 ± 231[ab]	Group 0.03* Time 0.98 Group x Time 0.08
Potassium (mg/d)	2775 ± 157[a]	2721 ± 173[a]	2838 ± 164[a]	3145 ± 161[b]	3514 ± 197[b]	3476 ± 193[b]	3231 ±179[ab]	3401 ± 171[ab]	3307 ± 162[ab]	Group 0.005* Time 0.25 Group x Time 0.27
Magnesium (mg/d)	311 ± 22	295 ± 24	306 ± 27	343 ± 26	376 ± 27	371 ± 31	348 ± 23	340 ± 21	350 ± 22	Group 0.10 Time 0.76 Group x Time 0.39
Carbohydrate (% kcal)	51 ± 2[a]	54 ± 2[b]	53 ± 2[b]	44 ± 2[a]	48 ± 2[b]	49 ± 2[b]	44 ± 3[a]	48 ± 2[b]	49 ± 2[b]	Group 0.05 Time 0.001 Group x Time 0.84
Protein (% kcal)	18 ± 1	17 ± 1	20 ± 1	20 ± 1	19 ± 1	19 ± 1	19 ± 1	19 ± 1	20 ± 1	Group 0.67 Time 0.08 Group x Time 0.59
Fat (% kcal)	32 ± 2[a]	29 ± 2[b]	28 ± 2[b]	34 ± 1[a]	31 ± 2[b]	32 ± 2[b]	35 ± 1[a]	32 ± 1[b]	31 ± 2[b]	Group 0.25 Time 0.004 Group x Time 0.84
Saturated fat (% kcal)	10 ± 1[a]	9 ± 1[a]	9 ± 1[a]	12 ± 1[b]	11 ± 1[b]	11 ± 1[b]	11 ± 1[ab]	11 ± 1[ab]	11 ± 1[ab]	Group 0.03 Time 0.33 Group x Time 0.69
MUFA (%kcal)	12 ± 1	11 ± 1	10 ± 1	12 ± 1	12 ± 1	12 ± 1	13 ± 1	11 ± 1	11 ± 1	Group 0.36 Time 0.07 Group x Time 0.83

PUFA (% kcal)	7 ± 1[a]	6 ± 1[b]	5 ± 1[b]	6 ± 0[a]	5 ± 0[b]	6 ± 1[b]	6 ± 0[a]	5 ± 0[b]	5 ± 0[b]	Group Time Group x Time	0.41 0.002 0.19
Pulses (cup/week)[3]	0.4 ± 0.4[a]		0.0[b]	0.4 ± 0.4[a]		3.6 ± 0.2[c]	0.4 ± 0.4[a]		3.7 ± 0.1[c]	Group Time Group x Time	<0.0001 <0.0001 <0.0001

[1]Values are mean ± standard error of the mean.

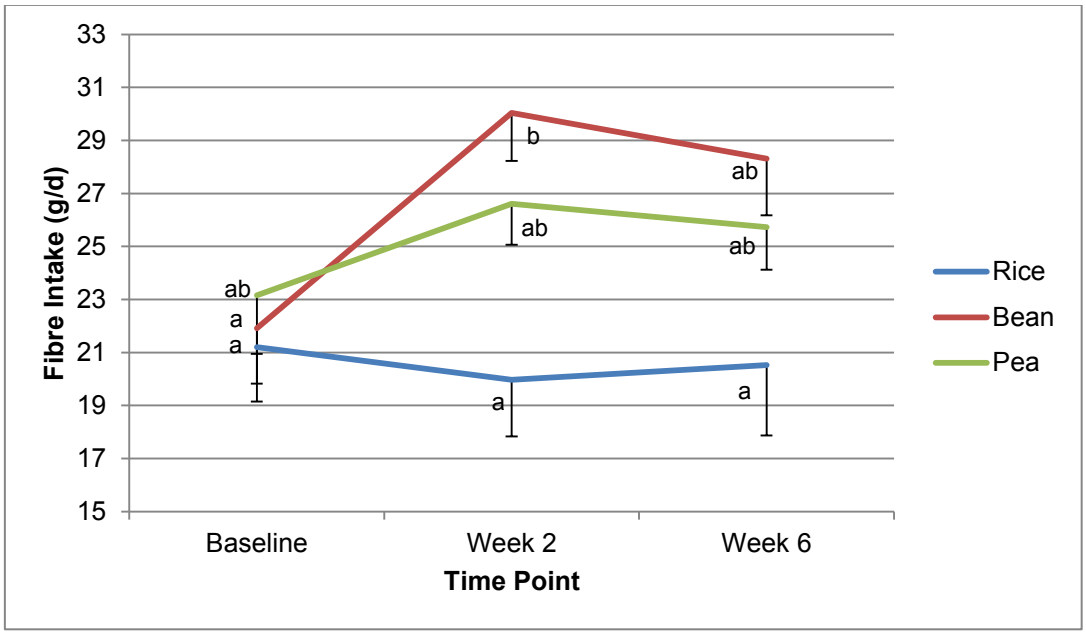
[2] Values within a row with different superscript letters are significantly different ($p \leq 0.05$).
There was a significant main effect of diet group on intake of total energy, fibre, fat, saturated fat, monounsaturated fat, sodium and potassium. There was a significant main effect of time on intake of carbohydrate, fibre, polyunsaturated fat, fibre density of the diet, % energy from carbohydrate, % energy from fat and % from polyunsaturated fat.

[3] Weekly pulse consumption at baseline was assessed using a shortened food frequency questionnaire administered at the screening visit; weekly pulse consumption during the 6-week intervention was calculated according to a self-reported tracking document completed on a daily basis.

*Effect of diet group was no longer significant after adjusting for total energy intake (mg/1000 kcal) for sodium ($p = 0.29$) and potassium ($p = 0.65$).

Abbreviations: MUFA, Monounsaturated fatty acids; PUFA, Polyunsaturated fatty acids.

(a)



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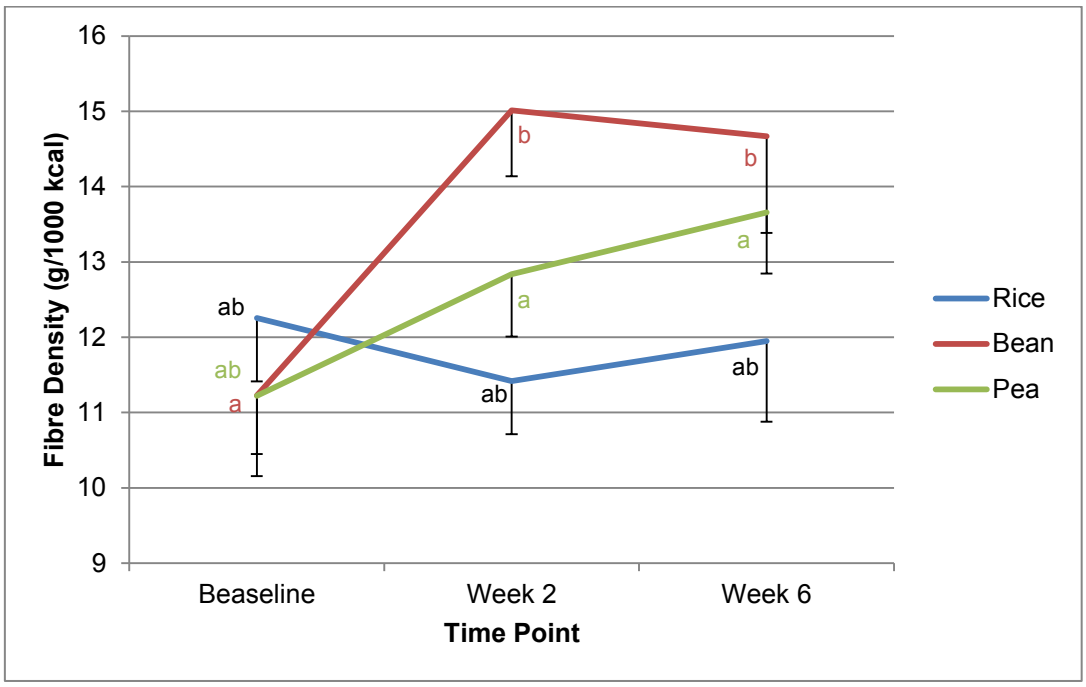


Figure 4- 3. Changes in participants' fibre intake (a) and fibre density of the diet (b) in the rice group (n = 17), bean group (n = 17), and pea group (n = 17) over the 6-week study period. Values are presented as mean and standard error mean. Data points with different letters are significantly different. There was a significant effect of group x time interaction on absolute fibre intake (p = 0.01) and fibre density of the diet (p = 0.01) according to repeated measures mixed model ANOVA.

Table 4- 4. Fibre density of participants' diet at baseline and their background diet, excluding study food items, during the intervention[1]

Diet group	Fibre density (g/1000 kcal)			p-value
	Baseline	Week 2	Week 6	
Rice	12 ± 1	11 ± 1	12 ± 1	0.58
Bean	11 ± 1	11 ± 1	11 ± 1	0.96
Pea	11 ± 1	10 ± 1	11 ± 1	0.72

[1] Differences across time points were compared using one-way repeated measure ANOVA.

4.4 Satiety

According to the satiety questionnaire, participants consumed study foods as lunch or an afternoon snack in over 70% of the occasions. There was no significant effect of diet group, time, or group x time interaction on ratings of satiety, fullness, prospective food intake, or overall satiety scores ($p > 0.05$; **Table 4-5**). Participants in the bean group had significantly higher hunger scores during week 6 than week 3 ($p = 0.006$).

Table 4- 5. Participants' perceived satiety upon consumption of study foods during weeks 1, 3 and 6 of the study among the first 51 study participants enrolled at the Edmonton study site[1,2]

Characteristic	Rice			Bean			Pea			p-value	
	Week 1 (n = 15)	Week 3 (n = 15)	Week 6 (n = 15)	Week 1 (n = 15)	Week 3 (n = 16)	Week 6 (n = 14)	Week 1 (n = 17)	Week 3 (n = 17)	Week 6 (n = 16)		
Hunger (mm)	24 ± 6^{ab}	24 ± 7^{ab}	27 ± 6^{ab}	22 ± 5^{ab}	13 ± 3^{a}	31 ± 7^{b}	12 ± 4^{ab}	22 ± 5^{ab}	16 ± 4^{ab}	Group Time Group x Time	0.42 0.06 0.004
Satisfaction (mm)	68 ± 6	70 ± 7	73 ± 6	74 ± 3	68 ± 6	75 ± 6	69 ± 6	69 ± 4	78 ± 4	Group Time Group x Time	0.94 0.32 0.78
Fullness (mm)	77 ± 7	73 ± 6	77 ± 6	76 ± 3	76 ± 4	74 ± 6	69 ± 7	69 ± 4	78 ± 4	Group Time Group x Time	0.66 0.39 0.47
Prospective food intake (mm)	25 ± 8	33 ± 8	18 ± 6	24 ± 5	16 ± 3	26 ± 7	26 ± 7	31 ± 7	20 ± 5	Group Time Group x Time	0.72 0.17 0.04
Satiety score (mm)	74 ± 6	72 ± 6	76 ± 5	76 ± 3	79 ± 3	73 ± 6	75 ± 5	72 ± 5	80 ± 4	Group Time Group x Time	0.90 0.50 0.28

[1] Values are mean ± standard error of the mean.
[2] Values within a row with different superscript letters are significantly different ($p \leq 0.05$).

4.5 Physical measurements

As shown in **Table 4-6**, a significant group x time effect was seen for body weight and BMI ($p = 0.03$). From baseline to week 6, changes in body weight followed different patterns among the diet groups (**Figure 4-4a**). When genders were analyzed separately, the group x time interaction remained significant in female participants ($p = 0.03$, **Figure 4-4b**). The pattern of weight changes in female participants of individual diet groups was consistent with that of overall study participants. However, post-hoc pairwise comparisons did not detect any significant differences in weight when both genders were analyzed together, or when female participants were analyzed alone. In addition, there was no significant effect of diet group, time, or group x time interaction on body weight in male participants (**Table 4-6, Figure 4-4c**).

Consistent with body weight, changes in BMI during the intervention differed among the diet groups in all study participants as well as female participants ($p = 0.03$ for group x time interaction, **Table 4-6, Figure 4-5a, Figure 4-5b**). Again, no significant differences between BMI values were found when post-hoc pairwise comparisons were performed. For male participants, no significant effect of diet group, time, or group x time interaction was found on BMI (**Table 4-6, Figure 4-5c**).

In addition, there was no significant effect of group, time or group x time interaction on other physical measurements including WC, HC, WC to HC ratio, systolic BP, and diastolic BP ($p > 0.05$). When participants taking BP-lowering medications were excluded from the analysis, the above effects remained non-significant.

Table 4- 6. Physical measurements of the first 51 participants enrolled at the Edmonton study site at baseline, week 3 and week 6 of the study[1]

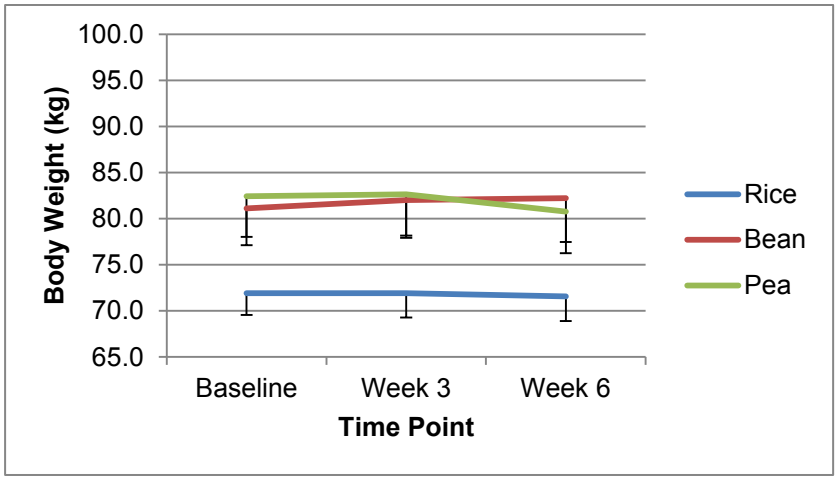
Variables	Rice			Bean			Pea			p-value
	Baseline (n = 17)	Week 2 (n = 15)	Week 6 (n = 15)	Baseline (n = 17)	Week 2 (n = 16)	Week 6 (n = 14)	Baseline (n = 17)	Week 2 (n = 17)	Week 6 (n = 16)	
Body weight (kg)	71.9±2.4	71.9±2.6	71.6±2.7	81.1±4.0	82.0±4.1	82.2±4.8	82.4±4.4	82.7±4.5	80.8±4.5	Group 0.10 Time 0.46 Group x Time 0.03
Body weight (female; kg)	69.7±2.7	69.1±3.1	68.8±3.2	79.1±5.2	80.4±5.6	80.8±6.3	74.6±3.5	74.7±3.6	74.4±3.7	Group 0.20 Time 0.49 Group x Time 0.03
Body weight (male; kg)	79.3±2.8	79.6±2.8	79.1±2.3	84.9±6.4	84.7±6.2	84.7±7.9	96.8±8.2	97.3±8.4	94.8±9.9	Group 0.24 Time 0.65 Group x Time 0.62
BMI (kg/m^2)	26.0±1.1	25.8±1.2	25.7±1.2	27.8±1.2	28.0±1.2	28.2±1.4	28.1±1.0	28.2±1.0	27.6±1.0	Group 0.33 Time 0.43 Group x Time 0.03
BMI (female; kg/m^2)	26.6±1.4	26.3±1.6	26.2±1.6	28.9±1.6	29.5±1.7	29.6±1.9	27.6±0.9	27.6±0.9	27.5±0.9	Group 0.42 Time 0.59 Group x Time 0.03
BMI (male; kg/m^2)	24.2±1.0	24.3±1.0	24.1±1.0	25.7±1.1	25.7±1.1	25.7±1.4	29.1±2.3	29.3±2.4	27.9±2.5	Group 0.17 Time 0.53 Group x Time 0.75
WC (female; cm)	87.0 ± 4.6	86.7 ± 4.9	86.5 ± 5.0	89.3 ± 3.5	88.4 ± 3.7	89.0 ± 3.6	87.5 ± 2.9	87.9 ± 2.7	87.4 ± 2.9	Group 0.94 Time 0.27 Group x Time 0.08
WC (male; cm)	84.3±1.7	86.0±2.7	81.8±1.3	90.2±4.3	93.6±3.3	91.4±6.3	101.0±6.4	101.0±6.1	97.4±6.4	Group 0.11 Time 0.23 Group x Time 0.61
HC (female; cm)	103.3±2.5	102.9±2.7	103.1±3.1	107.0±2.9	108.4±2.8	108.7±3.6	108.4±3.2	108.4±3.2	108.5±3.2	Group 0.45 Time 0.12 Group x Time 0.64

HC (male; cm)	100.4±2.3	101.9±1.7	98.1±2.2	103.5±4.1	103.8±3.2	103.1±5.1	107.1±3.2	108.1±4.1	105.3±3.8	Group 0.40 Time 0.15 Group x Time 0.87
Waist/Hip ratio	0.84±0.02	0.84±0.02	0.84±0.02	0.85±0.02	0.85±0.02	0.84±0.02	0.85±0.02	0.85±0.02	0.84±0.02	Group 0.89 Time 0.87 Group x Time 0.84
SBP (mmHg)	121±4	121±4	119±3	129±3	131±3	131±4	129±3	128±3	123±4	Group 0.16 Time 0.22 Group x Time 0.35
DBP (mmHg)	74±2	75±3	74±2	78±3	79±3	80±3	79±2	79±2	77±2	Group 0.16 Time 0.93 Group x Time 0.95

[1] Values are mean ± standard error if the mean.

Abbreviations: BMI, body mass index; WC, waist circumference; HC, hip circumference; SBP, systolic blood pressure; DBP, diastolic blood pressure.

(a)



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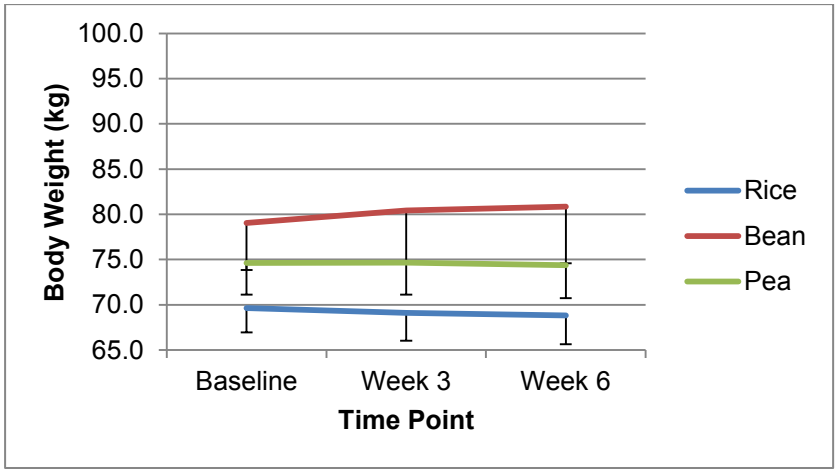

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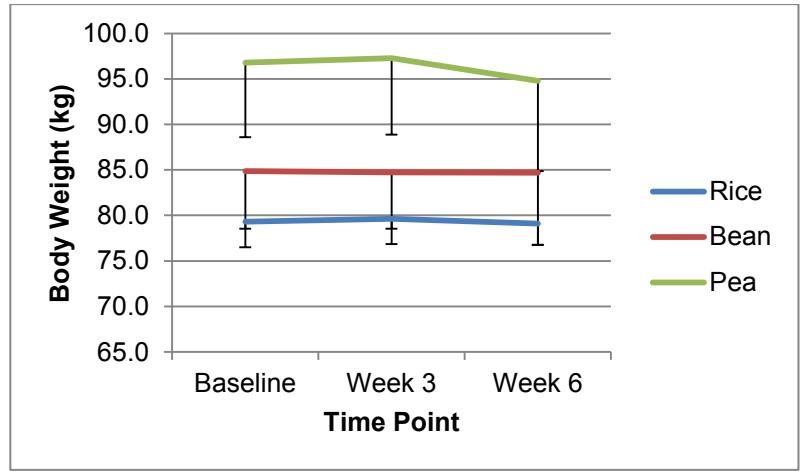
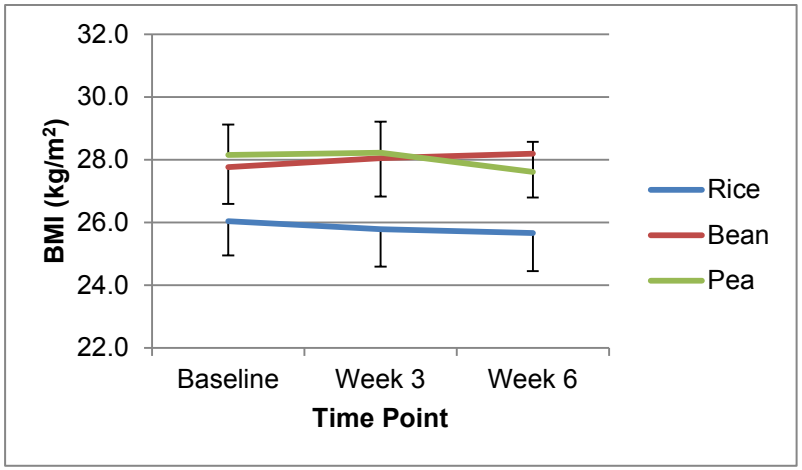
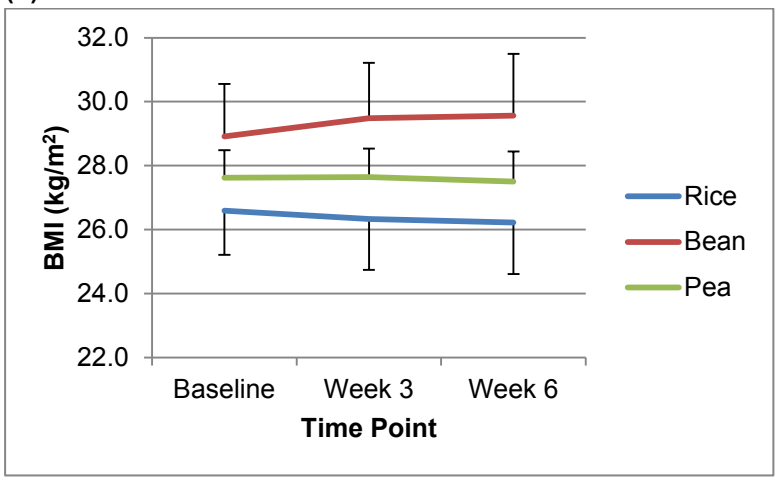


Figure 4- 4. Changes in body weight of all study participants (a), female participants (b), and male participants (c) in the rice group (n = 17, 13 females and 4 males), bean group (n = 17, 11 females and 6 males), and pea group (n = 17, 11 females and 6 males) over the 6-week study period. Values are presented as mean and standard error of the mean. There was a significant effect of group x time interaction on body weight of all study participants (p = 0.03) and female participants (p = 0.03) according to repeated measures mixed model ANOVA.

(a)



(b)



(c)

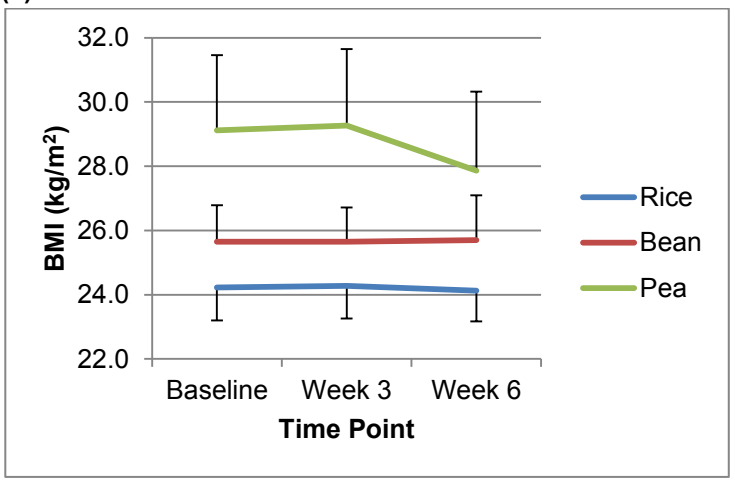


Figure 4- 5. Changes in body mass index (BMI) of all study participants (a), female participants (b), and male participants (c) in the rice group (n = 17, 13 females and 4 males), bean group (n = 17, 11 females and 6 males), and pea group (n = 17, 11 females and 6 males) over the 6-week study period. Values are presented as mean and standard error of the mean. There was a significant effect of group x time interaction on body weight of all study participants (p = 0.03) and female participants (p = 0.03) according to repeated measures mixed model ANOVA.

4.6 Occurrence of GI symptoms

Overall, increased flatulence was the most commonly reported GI symptom in response to pulse consumption. Prior to the study, the occurrence of flatulence was not different across the diet groups (**Figure 4-6**). During the first week of intervention, 73% participants in the bean group and 65% in the pea group experienced increased flatulence. The occurrence of flatulence was significantly higher compared with that reported in the rice group during week 1 ($p < 0.05$), and was also higher compared with baseline for both pulse groups ($p < 0.05$). During the third week of intervention, the proportion of participants with increased flatulence dropped to 44% for the bean group and 29% for the pea group. By the last week of the study, the numbers further dropped to 14% for the bean group and 19% for the pea group, and these were no longer different from baseline.

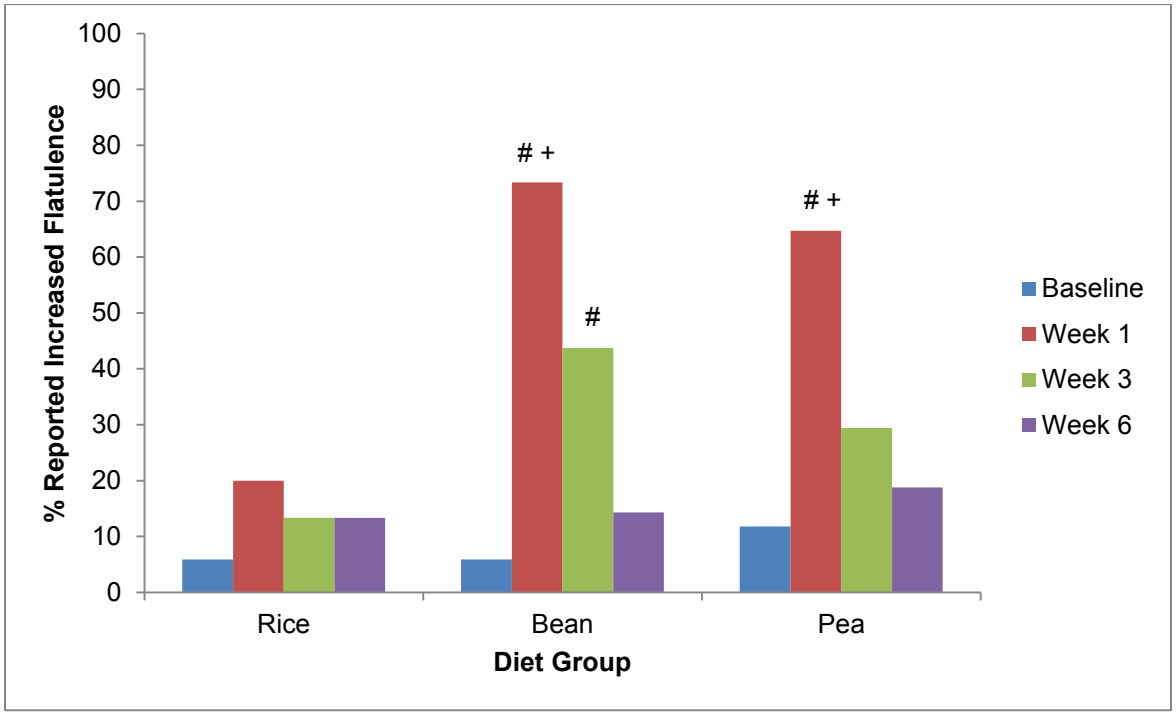


Figure 4- 6. Percentage of participants who reported increased flatulence during the week prior to each study visit for individual diet groups. "#" indicates significantly different from baseline of the corresponding diet group ($p < 0.05$); "+" indicates significantly different from rice group at the corresponding time point ($p < 0.05$).

A similar pattern of change was seen for occurrence of increased stool frequency (**Figure 4-7**). During week 1 of the intervention, a significantly higher percentage (40%) of participants in the bean group reported increased stool frequency compared with that of baseline ($p < 0.05$). The percentage decreased gradually and became non-significant from baseline during weeks 3 and 6 of the intervention. Participants in the rice group and the pea group had no changes in stool frequency during the intervention as compared with baseline. The occurrence of increased stool frequency did not differ across the diet groups at any time point.

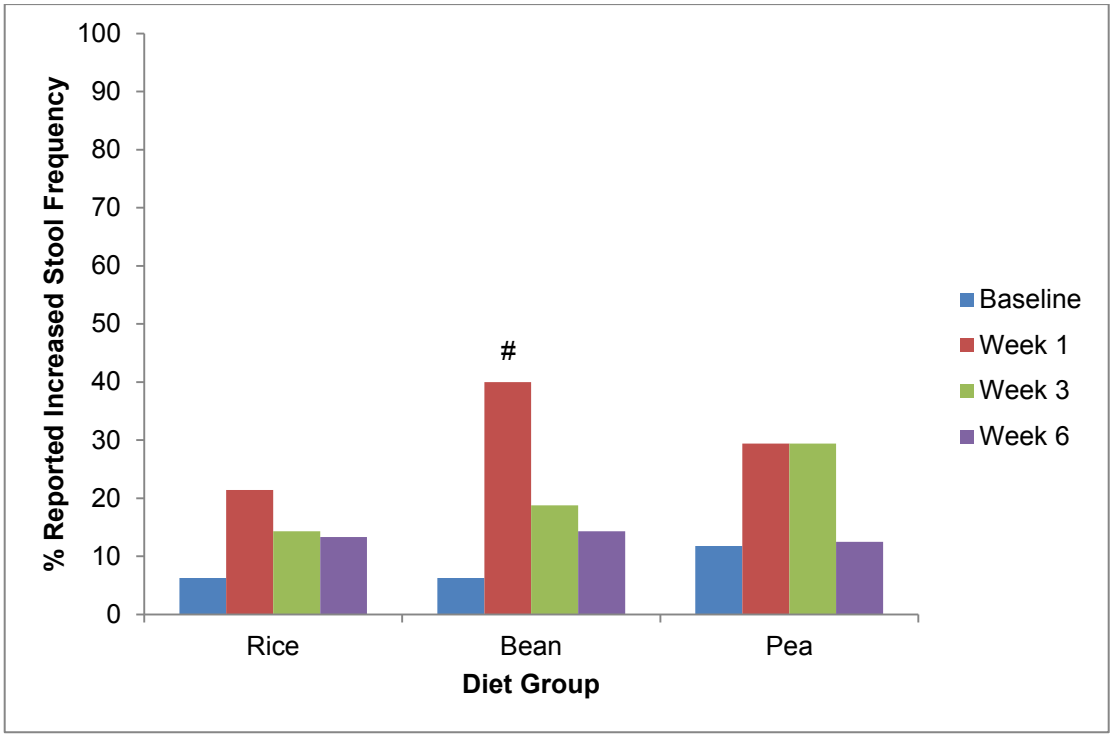


Figure 4- 7. Percentage of participants who reported increased stool frequency during the week prior to each study visit for individual diet groups. "#" indicates significantly different from baseline of the bean group ($p < 0.05$).

As shown in **Figure 4-8**, the occurrence of increased bloating during the intervention did not differ from baseline for any diet groups. Also, at each time point, the occurrence of bloating was not different across the diet groups.

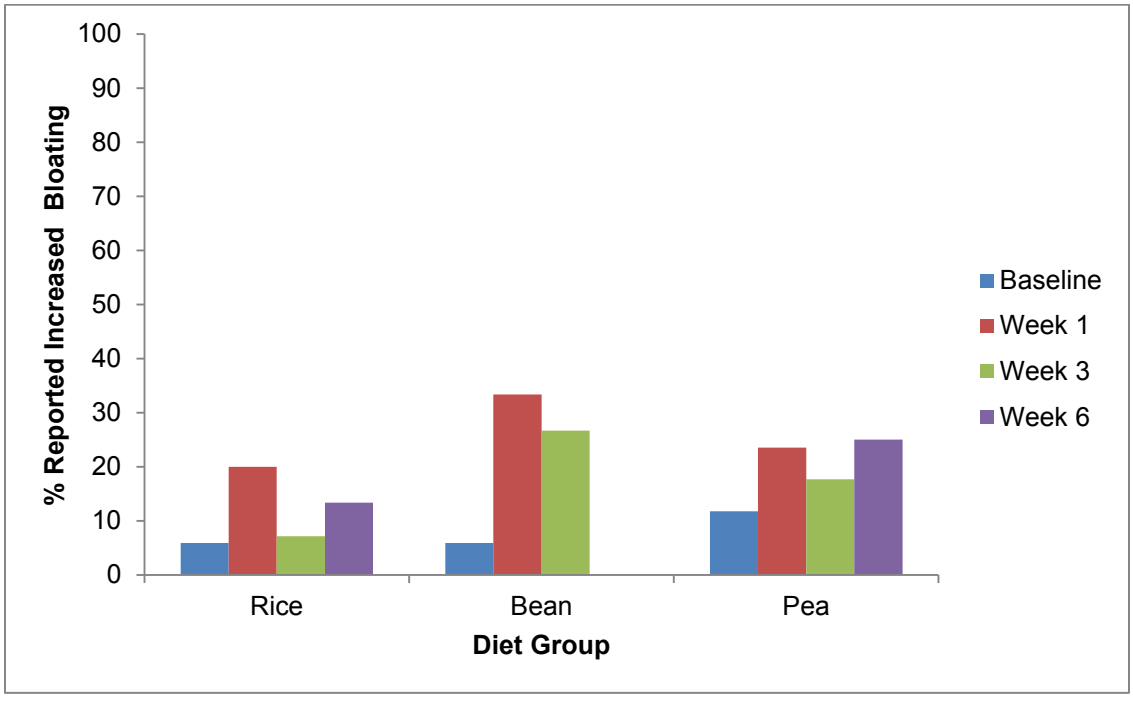


Figure 4- 8. Percentage of participants who reported increased bloating during the week prior to each study visit for individual diet groups. None of the participants in the bean group reported increased bloating during week 6.

In addition to specific GI symptoms, participants were asked whether their normal daily activities were affected by the symptoms. Compared with baseline, a higher percentage of participants in the bean group during week 1, and a higher percentage of participants in the pea group during week 3 reported their activities were affected ($p < 0.05$; **Figure 4-9**). However, only one participant in the bean group changed social activities due to the symptoms throughout the study. At individual time points, no difference was found with regard to the percentage of participants reporting that consumption of the study foods influenced their social activities among the diet groups.

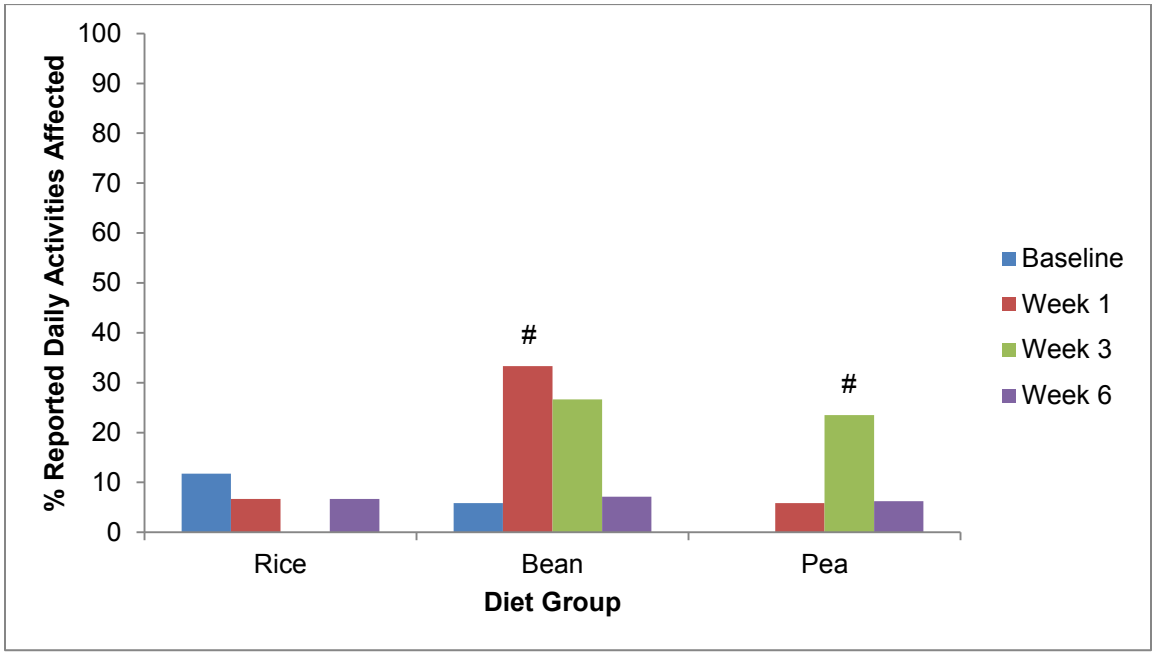


Figure 4- 9. Percentage of participants reporting that their daily activities were affected by GI symptoms during the week prior to each study visit for individual diet groups. "#" indicates significantly different from baseline of the corresponding diet group ($p < 0.05$). None of the participants in the rice group reported daily activities were affected during week 3. None of the participants in the pea group reported daily activities were affected at baseline.

Chapter 5. Discussion

5.1 Discussion

Preliminary results of the present RCT suggest incorporation of beans, but not peas as part of a habitual diet increased fibre intake of the study participants and fibre density of the diet. Although adherence rate to the study protocol was high, dietary supplementation of beans or peas did not lead to beneficial effects on body weight, body composition, or BP. Perceived satiety upon consumption of study foods also did not differ among the diet groups.

Pulses are a rich source of dietary fibre, providing approximately 7 g of fibre per ½ cup cooked serving on average (113). According to data from the 2004 Canadian Community Health Survey, Cycle 2.2 (CCHS), fibre intake increased most with pulse consumption among all nutrients analyzed (114). Relative to non-consumers, those who consumed only ½ cup of pulses per day had significantly higher fibre intake. Moreover, fibre intake of individuals in the highest quartile of pulse consumption (about 294 g or 2 cups per day) almost doubled fibre intake of non-consumers. Consistent with these observations, by incorporating ¾ cup per day of cooked beans, 5 days per week into the habitual diet in the present study, average fibre intake of the participants increased significantly from 22 to 30 g/d. Fibre density of participants' diet in the bean group also became higher in response to the intervention. Average fibre density of the diet was maintained above the AI level, defined as 14 g/1000 kcal, in contrast to 11 g/1000 kcal before the intervention. On an individual basis, the proportion of participants in the bean group meeting the AI level increased from 17.6% at baseline to 68.8% during week 2, and 50.0% during week 6. Of note, baseline fibre intake of the participants in the current study was slightly higher than the fibre intake of participants in the CCHS with a similar level of habitual pulse consumption (22 g/d fibre in the current study versus 18 g/d fibre in CCHS) (114). Therefore, the current findings demonstrate that regular bean consumption at the level of ¾ cup per day, 5 days per week, was an effective strategy for increasing fibre intake even in a population already having a high fibre intake.

Unlike the intervention with beans, incorporating the same amount of peas into participants' habitual diet in the present study did not significantly alter absolute fibre intake or fibre density. In part, the lack of significance was attributed to the lower fibre content in peas than beans by about 4 g per serving of the study food items on average. Also, the amount of pulses used in the current study (about ½ cup per

day on average) was lower than that used in other pulse-based feeding trials in the literature where an increase in fibre density was observed (67, 115). Perhaps for the same reason, although pulses contain high amounts of protein, potassium and magnesium, incorporation of the current amount of pulses as part of participants' normal diet did not significantly increase their daily intake of these nutrients compared with incorporation of rice.

The current results do not support beneficial effects of regular pulse consumption on body weight or body composition. These observations corroborate findings of most clinical trials where pulses or pulse-containing products were consumed as part of an *ad libitum* diet in a free-living setting (63, 64, 116-118). The lack of changes in anthropometric variables could be secondary to the relatively stable energy intake and macronutrient composition during the intervention. Contrary to our observations, Jenkins et al (67) recently reported lower body weight and smaller WC in diabetic subjects following a 12-week consumption of a pulse-rich diet. However, the amount of pulses supplemented in their study was 1 cup per day, which approximately doubled the amount in the current trial. The larger amount of pulses in their study may have produced a satiating effect as evidenced by a reduction of daily energy intake by ~200 kcal by the end of the intervention. Also, fibre density of the subjects' diet increased by 10 g/1000 kcal in their study, whereas it was increased by only 3 – 4 g/1000 kcal in the current study. Another review of clinical trials comparing weight loss effects of high- versus low-fibre diets under *ad libitum* energy intakes concluded that an additional daily intake of 14 g fibre was associated with a 10% decrease in energy intake and an average weight loss of 1.9 kg over a 3.8-month period (48). Accordingly, the increase in absolute daily fibre intake by 6 – 8 g in the bean group, and 3 – 4 g in the pea group was perhaps insufficient to exert beneficial effects on body weight or body composition. Furthermore, mean WC of male and female participants at baseline fell below the cut-off points of the World Health Organization indicating substantially increased risk of metabolic complications. Therefore, the lack of beneficial effects on WC might be attributed to population selection.

Interestingly, participants' body weight and BMI exhibited different patterns of changes among the diet groups over the 6-week intervention, primarily driven by female participants. This observation is not explained by energy intake as energy intake of all study participants as well as female participants remained stable over time within individual diet groups. It is possible that participants altered their levels

of physical activity, which in turn influenced total energy expenditure. Participants in our study were asked to maintain consistent levels of physical activity throughout the study. However, because physical activity was not closely monitored, exact mechanisms responsible for different patterns of body weight changes remain unknown.

According to results of the preliminary analysis, dietary supplementation of beans or peas did not result in lower systolic or diastolic BP among participants with mild hypercholesterolemia. Previously, it has been demonstrated that a daily intake of ¾ cup mixed pulses for 8 weeks significantly reduced systolic BP among overweight and obese subjects (59). Similarly, a daily consumption of 1 cup mixed pulses for 12 weeks was effective in reducing systolic and diastolic BP among diabetic subjects (67). In both studies, participants experienced concurrent reductions in body weight and WC, and both anthropometric changes have been independently associated with BP-lowering (119, 120). By contrast, when body weight and body composition remained unchanged, daily incorporation of 1.5 cups cooked pulses did not significantly alter BP levels among older adults (62). Therefore, it is possible that reductions in body weight and WC could enhance the BP-lowering effect of dietary pulse supplementation. In turn, the lack of changes in participants' anthropometric measurements in the current study may have minimized any BP-lowering effects of pulse intake.

Fibre, protein, potassium and magnesium are key nutrients in pulses with documented BP-lowering effects (22, 90, 93, 121). Partial substitution of lupin flour enriched bread for white bread in overweight and obese subjects effectively increased protein intake by 13.7 g/d, and fibre intake by 12.5 g/d, which led to a significant decrease in systolic BP by 3.0 mmHg (92). Although average fibre intake was increased upon pulse supplementation in the current study as well, the magnitude of 6 – 8 g/d in the bean group and 3 – 4 g/d in the pea group was much smaller than the reported increase in the above study. In addition, protein intake did not differ from baseline with the current intervention. Consequently, the lack of changes in BP could be attributed to the small increase in both nutrient components. In the current study, there was an increase in potassium intake by ~350 mg/d (9 mmol) in the bean group, ~120 mg/d (3 mmol) in the pea group, and an increase in magnesium by ~ 30 mg/d (1 mmol) in the bean group in response to pulse supplementation, although the increases were not statistically significant. According to meta-analyses examining BP-lowering effects of potassium (121) and magnesium (22)

supplementation, the current levels of increase of both minerals were too small to produce any beneficial effects on BP-lowering.

Finally, although participants in the pea group showed a reduction of systolic BP from 129 mmHg (SEM = 3) to 123 mmHg (SEM = 4), the reduction was not statistically significant. The small sample size of the preliminary analysis was likely underpowered to detect significant changes in BP in response to pulse supplementation.

Based on preliminary analysis of the satiety questionnaire, the three diet groups did not differ in ratings of hunger, satisfaction, fullness, prospective food intake, or the overall satiety score following study food consumption. These subjective measures of acute appetitive sensations are in line with the observation that total energy intake did not change significantly in any diet groups throughout the 6-week intervention. Under controlled laboratory settings, by using a crossover study design, consumption of pulses led to greater self-reported satiety and lower food intake at a later meal acutely as compared to other carbohydrate-rich foods such as white bread and pasta (73, 74, 122). Given the same results were not demonstrated in the current study, it is important to acknowledge several possible confounding factors regarding the current study design for short-term satiety measurements.

Firstly, the satiety rating scales have been recommended for use in within-subject repeated measures studies because individuals may differ in their response behaviour when subjectively rating appetitive sensations. In turn, the parallel design of the current study may have led to greater between-subject variations, making it less sensitive for distinguishing the satiating effects of different study foods. While randomization of participants to study groups may have controlled some of this effect, it was not thoroughly investigated (e.g. by having all participants rate satiety following consumption of a single food under controlled conditions). Secondly, unlike most laboratory studies that required fasting before consumption of the study foods (73, 74, 122), participants' pre-testing food intake or other lifestyle behaviours were not controlled for in the present study. It has been suggested that antecedent diet, energy balance, and physical activity are important confounders in appetite measurements (69). As a result, potential variations in these factors may have interfered with participants' ratings of satiety in the present study. Lastly, the satiety questionnaire was only completed at 30 minutes following consumption of the study food item. By contrast, the same questionnaire is commonly administered before and

repeated following study food consumption for several hours in laboratory studies. It has been reported that the satiety scales generally have better repeat-reliability when average scores over several hours are used rather than a score at a single time point (72). In addition, beans and peas possess lower glycemic index than white rice (76), and dry legumes in general is a class of foods with low glycemic index values (67). Compared with high glycemic index foods, low glycemic index foods have been reported to produce greater satiety 2 – 6 hours following consumption, but not within the first hour (76). Therefore, participants' perceived satiety at 30 minutes might not be representative of the results in the next few hours.

The current results show that following consumption of the bean-containing study foods, participants had significantly lower ratings of hunger during week 3 than week 6 of the intervention. Specific explanations for this observation are unclear as ratings of other appetitive sensations were not consistent with ratings of hunger. However, given the questionnaires were completed under free-living conditions, participants' ratings of hunger were likely influenced by a number of environmental and cognitive factors in addition to physiological signals. The fact that hunger was rated at only one time point following food intake may further increase the variation of ratings among different occasions. Therefore, the difference in hunger ratings between week 3 and week 6 might be attributed to factors other than physiological responses to study food consumption.

Despite the fact that assessment of satiety in laboratory settings provides greater sensitivity, accuracy, and precision, the experimental designs are often limited to measuring acute responses, and the results are difficult to be extrapolated to the free-living population. When pulses were incorporated into participants' habitual diet, most clinical trials ranging from 8 to 16 weeks did not report reduced energy intake (63, 64, 116, 117), which may serve as an indicator of appetite. In future studies, to better understand the role of short-term satiety in response to pulse consumption in long-term energy intake regulation, it may be helpful to examine acute satiety following pulse consumption and long-term energy balance within the same study, and integrate the findings from both phases. For examples, under controlled laboratory conditions, acute satiety following study food consumption may be evaluated with VAS, ghrelin concentrations, and prospective food intake. Under free-living settings, food intake before and during the trial may be used to reflect changes in participants' overall appetite. At the meantime, leptin concentrations and body weight can be measured to confirm the presence of energy imbalance.

Results of these preliminary analyses show that self-reported compliance rate was high, with participants consuming 98.3% of the study food items. The compliance rate in our study was comparable to a previously-reported compliance rate of 100.0% in a study where participants were asked to consume at least 104 g/d (about ⅔ cup) canned chickpeas as part of their normal diet (98), a rate of 89.5% in a study where participants were asked to consume 128 g/d (about ¾ cup) cooked mixed pulses as part of their diet (59), and was slightly higher than a rate of 74.0% in another study where participants were asked to incorporate 250 g/d (about 1.5 cups) cooked mixed pulses into their diet (62). It is possible and plausible that the lower amount of pulses required by this study protocol is more feasible for participants, and is associated with a higher compliance rate. Another factor that may have enhanced the compliance rate in the current study is that the pulses were provided to participants as part of ready-to-eat study food items. This approach may have effectively reduced participants' time, effort, and skills required for study food preparation. However, due to the lack of validated biomarkers for dietary pulse consumption, the self-reported compliance rate in the current study could not be confirmed by objective measurements of biological samples.

GI symptoms such as flatulence, bloating, increased stool frequency and diarrhea are common complaints in response to increased pulse consumption. In the current study, although a number of participants in the pulse groups reported increased flatulence and stool frequency during the first few weeks of the intervention, similar to observed by Winham and Hutchins (97), the occurrence of GI symptoms decreased over time, and returned to baseline levels by week 6 of the study. Moreover, only one participant in the bean group discontinued due to a GI-related adverse event. Therefore, together with the high compliance rate, the present results highlight regular consumption of pulses at the level of 1 serving (¾ cup) per day, 5 days per week is well tolerated, and thus represents a feasible strategy for increasing pulse consumption for most free-living individuals.

5.2 Strengths and limitations

The present RCT has several strengths. Compared with many other pulse-based feeding trials where a large quantity of pulses was incorporated into participants' habitual diet, the present study employed a smaller amount with a daily supplementation equivalent to one serving of meat alternatives (¾ cup) according to the Canada's Food Guide. The amount of pulses provided in the current trial was

perhaps more feasible for most free-living adults given the low level of habitual pulse intake among the general Canadian population. Moreover, the present RCT examined separately the effect of consuming beans versus peas on risk factors related to heart health, which allowed for comparison of biological functions among different pulse varieties. By contrast, pulse-based feeding trials in the past have primarily used beans or mixed pulse varieties as the active ingredients. In addition, providing participants with ready-to-eat study food items effectively minimized participants' time, effort, and skills required for study food preparation, and thus helped to increase the compliance rate.

On the other hand, a number of limitations to the current study should also be noted. First of all, the greater study was powered based on plasma LDL-C concentrations; therefore, the preliminary analyses of secondary outcomes were likely underpowered to detect significant differences. Secondly, although participants were asked to maintain the same levels of physical activity for the duration of the study, their physical activity levels were not closely monitored over the 6-week intervention. As a consequence, whether physical activity levels acted as a confounding factor in the physical measurements is not clear. For example, it is not known if the differential changes among the three diet groups in body weight over the study period could be attributed to variations in physical activity levels. Thirdly, the current study design for measurement of satiety following study food intake was likely limited in comparing the differences among the diet groups, as well as comparing the differences over time within the same group. For one, between-subject variations in ratings of appetitive sensations might reduce the sensitivity of detecting differences in satiety as a result of study foods intake. Also, participants' ratings of satiety under free-living conditions were likely influenced by other environmental, social, and emotional factors, which might reduce the consistency between ratings at different occasions. Lastly, participants recruited for the current trial already had a fibre intake greater than the intake found in the average Canadians (123). It is possible that individuals interested in diet studies are more health concerned, and have better nutritional habit than the general population. Hence, the beneficial effect of dietary intervention on physical measurements might be decreased by selection of the population sample.

5.3 Conclusion and future directions

Preliminary results of the present RCT demonstrate regular consumption of beans or peas at the level of ¾ cup per day, 5 days per week as part of study food items was well tolerated by the participants.

Consumption of bean-containing study foods also led to higher fibre intake and increased fibre density of participants' diet; however, no beneficial effects on CVD-related risk factors including body weight, body composition, or BP were observed upon pulse supplementation in a sample of population with mild hypercholesterolemia.

Since the RCT is still within the recruitment phase, findings of the complete study will increase our understanding on the effect of regular pulse consumption on cholesterol-lowering and other risk factors of heart disease reported in the thesis. In future research, development and implementation of biomarkers specific to dietary pulses, along with self-reported compliance rate will permit more accurate estimations of participants' pulse intake during dietary interventions. In addition, to better define the minimal pulse intake beneficial for heart health, future clinical trials may employ dose-response study designs. Knowledge regarding the effectiveness of pulse varieties and doses on heart disease prevention and management will be important for supporting dietary recommendations and claims to improve the health status of Canadians.

Appendix A. Sample recruitment poster

UNIVERSITY OF ALBERTA
DEPARTMENT OF AGRICULTURAL, FOOD & NUTRITIONAL SCIENCE

Are your Cholesterol levels a little too high?

Volunteers Needed!

Are you:

- Between the ages of 20 and 75?
- From a family with a history of high cholesterol?
- Do you have higher cholesterol, but do not take any medication to lower it?
- Have you been a stable body weight for the past 3 months?
- Can you read and write in English?

What is the study about?

- This study will look at the cholesterol lowering effects of beans and peas.

What do I have to do?

- Those who are eligible will have the opportunity to participate in a ***6 week study***
- You will be provided with 5 prepared study food items PER WEEK to eat at home
- You will have to come to the University of Alberta campus for various tests and to pick up study food items
- Complete questionnaires at home

How Do I Benefit?

- You may see a lowering of cholesterol
- You will receive an honorarium on completion of the study

How do I get involved?

To be a part of this study, please contact Janis:
pulseRCT@ualberta.ca
780-492-4182

Janis
pulseRCT@ualberta.ca
780-492-4182

Appendix B. Study food information

a. Preparation of study beans, peas, and rice

Beans and Peas

Soaking

1. Weigh dried beans/peas according to table below
2. Wash under cold running water (1 min)
3. Place beans/peas in bowl in cold water equal to 3 times the weight of the beans/peas
4. Refrigerate for at least 12 hours

Cooking

1. Drain soaked beans/peas in strainer
2. Weigh
3. Wash under cold running water (1 min)
4. Place beans/peas in saucepan in cold water equal to 3 times the weight of the beans/peas
5. Place saucepan on high heat and bring to boil. Reduce heat to maintain cook water temperature at ~97 °C
6. Cook for time as noted below stirring every 9 min. Drain

Rice

Cooking

1. Place 330 g raw rice in cooker
2. Add 900 g water
3. Cook until cook light goes out. Check at 25 min and monitor thereafter
4. Turn off when water just gone

b. Background ingredients

Zucchini Casserole

Canola oil, onion, garlic, mushroom, zucchini, canned tomatoes, pasta, thyme, oregano, salt, cumin, water

Vegetable Soup

Canola oil, onion, garlic, carrot, corn, chicken powder, canned tomatoes, tomato sauce, thyme, summer savory, parsley, black pepper, cumin, water

Chicken Casserole

Canola oil, onion, garlic, chicken thigh, green pepper, red pepper, chicken powder, water, plain yogurt, mozzarella cheese, oregano, black pepper, cumin

Hamburger Soup

Onion, garlic, lean ground beef, canned tomatoes (Italian style), tomato sauce, mixed vegetables, dried onion soup, cumin, water

Tortellini Soup

Canola oil, onion, garlic, mushroom, green pepper, red pepper, zucchini, vegetable powder, Italian seasoning, cumin, water, cheese tortellini

Appendix C. List of pulse containing foods

Pulse Containing Foods

Beans, peas, lentils and chickpeas can appear in a variety of recipes, if you are eating out, or buying pre-made foods for home, be sure to read the ingredient list, or ask if the item you order has any beans/pulses in them!

Soups/Stews:

- Split pea soup
- Ham and pea soup
- Bean chili
- Chili with kidney beans
- Black bean soup
- Dahl
- Chickpea Curry
- Pork and beans
- Refried beans (Mexican style meals: quesadilla, rice and beans)
- Burrito
- Minestrone Soup
- Lentil Stew
- Gazpacho

Snacks

- Hummus
- Roasted chickpeas
- Bean and cheese dip
- Falafel
- Salsa

Salads

- Taco salad (may have black beans)
- Bean salad
- Couscous/quinoa salads

Other items:

- *Many vegetarian options will include beans, be sure to read ingredient lists!!
- Veggie burgers
- Huevos rancheros
- Samosa

Appendix D. Baseline fasting lipid profile, glucose, insulin and HbA1c levels of study participants

a. Laboratory methods for analysis of blood samples

At baseline, week 3, and week 6 study visits, blood samples were obtained after participants fasted for at least 12 hours (no food or beverages except for water) onsite by a trained phlebotomist using validated procedures and collection tubes (SST Gel for serum, Lithium Heparin PST Gel and EDTA for plasma). Plasma lipid profile (including TC, HDL-C and triglyceride concentrations), glucose and insulin concentrations were measured at the University of Alberta Hospital Laboratory. LDL-C concentrations were calculated using the Friedewald formula (124). HbA1c levels were tested at the DynaLIFE$_{DX}$ laboratory in Edmonton. In addition, whole blood, plasma and serum samples were divided onsite into 500 µL or 1.5 mL microfuge tubes and stored at -80 °C for future analysis of metabolomics, polyphenols, high-sensitivity C-reactive protein, vitamin B1 and folate.

TC, HDL-C, triglyceride, and glucose concentrations were determined using SYNCHRON LX Systems and reagents. Insulin concentrations were measured using the Roche Diagnostics Elecsys® 2010 System. The coefficient of variation values for the measurement of TC, HDL-C, triglyceride, glucose, and insulin are shown in **Table D-1**.

Table D- 1. Coefficient of variation for the measurement of glucose, total cholesterol, triglyceride, HDL-C, insulin and HbA1c

Test	Medical decision level	Coefficient of variation (%)
Glucose (mmol/L)	2.5 8.0 11.0	2.0 2.0 0.9
Cholesterol (mmol/L)	4.4 5.2	1.4 1.3
Triglyceride (mmol/L)	1.5 2.3	1.3 1.7
HDL-C (mmol/L)	0.9 1.0	2.2 2.0
Insulin (pmol/L)	10 350	9.0 3.0
HbA1c (%)	–	2.1

Abbreviation: HDL-C, high-density lipoprotein cholesterol; HbA1c, hemoglobin A1c.

b. Statistical analysis

Baseline differences across the diet groups were tested using one-way ANOVA. Statistical analyses were conducted using SAS (version 9.3; SAS Institute Inc., Cary, NC, USA).

c. Results

Table D-2 shows baseline fasting lipid profile, glucose, insulin, and HbA1c levels of the first 51 study participants enrolled at the Edmonton study site. According to the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (125), participants' mean total cholesterol concentration fell within the "borderline" (5.17 – 6.18 mmol/L) and "high" (> 6.21 mmol/L) categories. Mean LDL-C concentration was classified as "borderline high" (3.36 – 4.13 mmol/L). Mean HDL-C concentration was classified as "high" (≥ 1.56 mmol/L). According to the Canadian Diabetes Association Clinical Practice Guidelines Expert Committee (126), study participants did not have elevated fasting glucose concentrations (≥ 7.0 mmol/L) or elevated HbA1c levels (≥ 6.5%), which lead to the diagnosis of diabetes. In addition, there were no significant differences in any blood parameters across the diet groups at baseline ($p > 0.05$).

Table D- 2. Baseline fasting lipid profile, glucose, insulin and HbA1c levels of the first 51 study participants enrolled at the Edmonton study site[1]

Variable	Rice (n = 17)	Bean (n = 17)	Pea (n = 17)	p-value
TC (mmol/L)	6.14 ± 0.22	6.32 ± 0.18	5.85 ± 0.20	0.26
TG (mmol/L)	1.80 ± 0.21	1.66 ± 0.18	1.65 ± 0.20	0.82
HDL-C (mmol/L)	1.62 ± 0.16	1.57 ± 0.10	1.54 ± 0.11	0.93
LDL-C (mmol/L)	3.70 ± 0.19	4.00 ± 0.17	3.56 ± 0.13	0.16
HbA1c (%)	5.4 ± 0.1*	5.4 ± 0.1	5.4 ± 0.1	0.99
Glucose (mmol/L)	5.2 ± 0.1	5.1 ± 0.1	5.2 ± 0.1	0.56
Insulin (pmol/L)	76 ± 9	68 ± 9*	88 ± 14	0.73

[1] Values are presented as mean ± standard error of the mean.
* Values are available for 16 participants.
Abbreviations: TC, total cholesterol; TG, triglyceride; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; HbA1c, hemoglobin A1c.

Appendix E. Information letter and consent form

Information Sheet & Consent

Title: Substantiating a Health Claim for Pulses (Beans and Peas) and Cholesterol - Lowering

Investigators:

Investigator	Position, Dept	Phone Number	
Dr. Rhonda Bell	Professor, AFNS	780-492-7742	Rhonda.bell@ualberta.ca
Dr. Linda McCargar	Professor, AFNS	780-492-4987	Linda.mccargar@ales.ualberta.ca
Dr. Cathy Chan	Professor, AFNS	780-492-9939	cbchan@ualberta.ca
Dr. Spencer Proctor	Professor, AFNS	780-492-4672	Spencer.proctor@ales.ualberta.ca
Dr. Jocelyn Ozga	Professor, AFNS	780-492-2653	Jocelyn.ozga@ales.ualberta.ca
Dr. David Wishart	Professor, AFNS	780-492-0383	David.wishart@ualberta.ca
Dr. Peter Senior	Professor, MD	780-407-3636	petersenior@ualberta.ca
Ms. Janis Baarda	Research Assistant, AFNS	780-492-4182	pulseRCT@ualberta.ca

Background

Beans, peas, lentils and chickpeas (also known as "pulses") are healthy foods that contain twice the amount of protein as grains, are very high in fibre, key vitamins and minerals like folate and iron and are low in fat. This study will compare how regularly eating beans or peas may be good for heart health, especially blood lipids such as cholesterol and triglyceride levels.

Also, Canada is among the world's largest producers of pulses and is interested in promoting these items as part of a healthy diet. Currently people in Canada do not eat a lot of pulses, in part, because not many convenient food products contain pulses. Experts agree that we need specific studies, like this one, to compare the effects of different types of pulses such as navy beans, red beans yellow and green peas, on important indicators of health. We hope the results from this study will be used to show parts of the Canadian government the healthy effects of beans and peas. This information could stimulate the industries that grow and process these foods.

What is the study for?

The aim of this study is to look at how regularly eating pulses may improve risk factors for good heart health, especially blood lipids like cholesterol and triglyceride levels. People in this study will be asked to eat beans or peas or rice in amounts recommended in Canada's Food Guide.

What do participants do in this study?

- Eligible participants will be randomly assigned (similar to drawing a name from a hat) to a group and will be asked to consume either:

    - a) foods containing ¾ cup of cooked beans per serving for 5 days per week for six weeks, or
    - b) foods containing ¾ cup of cooked peas per serving for 5 days per week for six weeks, or;
    - c) foods containing ¾ cup of cooked rice per serving for 5 days per week for six weeks.
- The foods provided such as soups, side dishes, and entrees, should be eaten with the foods you normally eat. The study food will replace something else in your meal. You will receive a 3 week supply of the study food items at the baseline visit and again at the week three visit.
- You will be asked to not consume additional foods containing beans, lentils, chickpeas or dried peas, or make diet changes or changes to your physical activity during the study period.
- You will need to come to the University of Alberta Human Nutrition Research unit four times, and have one short telephone conversation with the study coordinator.

    - <u>Screening Visit (approximately 1.5 hours)</u>:
        - Ask you to fill out questionnaires about yourself (e.g age, education, occupation), and about your medical history, any medications you take, and your smoking habits
        - We will give you some questionnaires to take home. You will only be asked to fill them out if you are eligible for the study. We will call you in the next 10 days, after we get the results of your blood work, to confirm whether you should fill these out or not. One questionnaire asks about what you normally eat; it will take you ~1 hour to fill out.
        - One questionnaire is a 3-day food diary. We ask that you fill out everything you eat and drink for 2 weekdays and 1 weekend day on these forms. We will give you some training on how to do this before you leave this screening visit.
        - One asks about how your stomach/intestines feels after eating.
        - Measure your height, weight, waist and hip circumference.
        - If you are in a fasting state (no food or drink, besides water, for 12 hours before appointment) a blood sample will be collected (approximately 2 teaspoons). If you are not in a fasting state, you will be asked to come in for an additional appointment to collect a blood sample. This sample will determine if you are able to participate in the study.

When we know whether or not you are eligible for the study, we will contact you to confirm that you still want to participate, and schedule your next visit to the study center. You will be reminded to bring your questionnaires you were asked to fill out at home and to fast before your next appointment.

    - <u>Study Visit 1, Baseline (~1.5 hours)</u>:
        - We will review the questionnaires you completed.
        - We will measure your weight, blood pressure, waist and hip circumference, and collect a urine and fasting blood sample. The urine and

blood sample will be used to measure different chemicals in your body such as cholesterol, different hormones, and vitamins.
    - You will be asked to complete questionnaires about any changes in your medical history since you were last here.
    - You will be given enough food items so that you can eat one item every day for 5 days/week for about 3 weeks (you will pick up more meals at the 3 week visit). We will teach you how to prepare the food; usually this will mean defrosting the food item and heating it.
- Throughout the first 3 weeks, you will fill out questionnaires about the meals, your food intake, how your stomach/intestines feel after eating, and your feelings of hunger and fullness.
- Short Telephone Call, Week 2 (~15 min): We will talk to you on the phone about how easy or hard it has been for you to incorporate the study food items into your diet, and to confirm that you will be continuing in the study. This will make sure we can have your food items ready for you when you come to your next study visit. We can answer any questions you have about the study as well, you will be reminded to fast (no food or drink besides water for 12 hours) before the next appointment.
- Study Visit 2, Week 3 (~1 hour): We will measure your weight, blood pressure, waist and hip circumference, and collect urine and fasting blood sample. We will review the questionnaires you completed during the first 3 weeks of the project and will discuss your experiences so far with the meals, how you feel, and any changes you've made to your medications or lifestyle. You will be given the rest of the food items for the study.
- Study Visit 3, Final visit (~1 hour): We will measure your weight, blood pressure, waist and hip circumference and collect a urine and fasting blood sample. We will review the questionnaires you completed during the last 3 weeks of the project and will discuss your experiences with the meals, how you feel, and any changes you've made to your medications or lifestyle. We will ask you to fill out a few final questionnaires and give us any other feedback you wish, on the study.

What Do We Want to See?

We hope to see that intake of beans or peas will improve heart health and lower cholesterol and other blood lipids like triglycerides.

How Do I Benefit?

You may or may not benefit from participating in this study. You may see a lowering of cholesterol and improved heart health through the duration of the study. There is no cost associated with participating.

Are There Any Risks if I Participate?

There is a blood draw at the appointments. This is a routine procedure that will be used for obtaining samples. A needle will be inserted into a vein and blood will be withdrawn into tubes for laboratory tests. It is possible you may experience mild pain, fainting, bleeding, discoloration or bruising, and/or an infection at the place where the needle enters the vein to

draw blood. Bruising is very common and usually goes away after a few days. Infection is rare, as is dizziness or fainting during the procedure.

Some participants may experience gastrointestinal changes due to the dietary changes, such as bloating, flatulence (gas), or softer stools. The study doctor, Dr. Peter Senior, will monitor the results of your blood tests while you are participating in the study. If the results of your blood tests show anything out of the ordinary, the blood tests will be repeated (within ~ 5 working days). If the results remain the same, you will be withdrawn from the study and advised to consult your regular doctor.

If you experience any adverse reactions or notice any unusual signs or symptoms, you must contact the study doctor, Co-Investigator Dr. Peter Senior at 780-407-3636, immediately.

Do I have to participate?
No, taking part in this study is your choice. You may end your involvement with the study at any time without affecting your health care. You can withdraw from the study by contacting the Study Coordinator, Ms. Janis Baarda at 780-492-4182.

Will I be paid if I Participate?
You will be reimbursed for your parking or for the cost of your transportation for each study visit, up to a maximum of $10/visit. You will be provided with a maximum of $75 upon completion of the study (or partial payment if you withdraw from the study) to reimburse and thank you for your time. Reimbursement will be according to the number of completed visits as follows: $30 for Baseline Visit, $15 for Week 3 Visit, and $30 for Week 6 Visit.

Will My Records be Kept Private?
The consent forms and any questionnaire information you provide will be kept in locked filing cabinets or scanned and shredded in a locked confidential bin. Your privacy and your identity will be kept confidential. The study database will be stored on a computer drive protected by a password. All blood and urine samples will be stored in locked freezers in a secure research facility. These samples will be labelled with a study identification number and will not identify you by name or initials. Each participant will be issued a specific study identification code. All information contained in our summaries will be anonymous, and based on group data. Any report published as a result of this study will not identify you by name, address or any other personal information.

During research studies it is important that the data we get is accurate. For this reason your study information, including your name, may be looked at by people from the Health Research Ethics Board or University of Alberta. By signing the consent form you give permission for the collection and use of information for research purposes.

After the study is completed, your study information will be stored at the University of Alberta for 5 years. If you end your involvement during the study, the information that is obtained from you for study purposes up to that point, will not be destroyed unless you specifically request it. **If at any point during the study you decide you do not want researchers to keep your samples and data, you can ask the researchers to destroy it.**

What if I suffer a research-related injury?

If you become ill or injured as a result of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form you are not releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

Contact Information

If you have further questions related to this research, please contact: Dr. Rhonda Bell **780-492-7742**

If you have any concerns about any part of the study, please contact Health Research Ethics Board office, University of Alberta 780-492-9724.

UNIVERSITY OF ALBERTA

Consent

Title: Substantiating a Health Claim for Pulses (Beans and Peas) and Cholesterol - Lowering

Investigators:

Investigator	Position, Dept	Phone Number
Dr. Rhonda Bell	Professor, AFNS	780-492-7742
Dr. Linda McCargar	Professor, AFNS	780-492-4987
Dr. Cathy Chan	Professor, AFNS	780-492-9939
Dr. Spencer Proctor	Professor, AFNS	780-492-4672
Dr. Jocelyn Ozga	Professor, AFNS	780-492-2653
Dr. David Wishart	Professor, AFNS	780-492-0383
Dr. Peter Senior	Professor, MD	780-407-3636
Ms. Janis Baarda	Research Assistant, AFNS	780-492-4182

Please circle your answers:

Do you understand that you have been asked to be in a research study? YES NO

Have you read and received a copy of the attached Information Sheet? YES NO

Do you understand the benefits and risks involved in taking part in this research study? YES NO

Have you had an opportunity to ask questions discuss this study? YES NO

Do you understand that you can quit taking part in this study if you notify the researchers? YES NO

Has confidentiality been explained to you? YES NO

Do you understand who will be able to see your study information? YES NO

Do you agree to maintain your medication regime and physical activity, and not eat any additional bean or pea products? YES NO

Do you give us permission to use your data for the purpose specified? YES NO

I agree to take part in this study.

Name (please print) _____

Signature _____ **Date** _____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature _____ **Date** _____

Appendix F. Demographic questionnaire

Beans and Peas - Demographic Questionnaire Study ID: _____
Completed at Screening Visit Assessment Date: __/__/__

Instructions: Please tell us about yourself. To complete this section, please circle **one** response for each of the following questions, and fill in the blanks for the questions that require a response.

If you are not sure about an answer, your best guess is okay. You can add comments at the end. A few of the questions may sound as if they overlap, but they are asked for slightly different reasons.

Your answers are confidential. We use this information to compare groups of people in this study.

If you have any questions, please ask Ms Janis Baarda.

Demographic Information

1. Your present age is _____ years.

2. Your present marital status:
   1 Single/Never Married
   2 Common-law/living with partner/living as married
   3 Divorced
   4 Separated
   5 Widowed

3. Are you presently?
   1 Employed
   2 Work from the home (stay at home parent, at home business)
   3 Unemployed
   4 Retired
   5 On Disability

4. Please describe your occupation. (If retired, please state your occupation before retirement):

   _____

5. What was the total income, **before taxes and deductions,** of all household members from all sources in the past 12 months?

1 Less than $20,000

2 $21,000 - $39,000

3 $40,000 - $69,999

4 $70,000 - $99,000

5 $100,000 or more

6. What is the highest level of education you have completed?

1 Less than high school diploma

2 Completed High School diploma

3 Completed trade, technical, or vocational school, or business/community college (e.g SAIT, NAIT, WTC)

4 Completed university undergraduate degree

5 Completed post – graduate degree

6 None

7 Other, specify: _____

7. How many dependent children or adults do you have in your household? _____

8. How many people including yourself live in your household? _____

Thank you for completing the Demographic Questionnaire.

Appendix G. Beans and peas study questionnaire

Beans and Peas - Study Questionnaire Study ID: _____
Completed Screening Visit Assessment Date: __/__/__

Section 1: Dietary Practice

Instructions: Please tell us about your normal eating habits. To complete this section, please circle **one** response for each of the following questions, and fill in the blanks that require a response.

1. What is the usual pattern of meals that you eat daily?

   1 None
   2 One meal per day
   3 Two meals per day
   4 Three meals per day
   5 More than three meals per day

Please tell us which meals (breakfast, lunch and dinner) you eat daily:

_____

_____

2. What is the usual pattern of snacks that you eat daily?

   1 No snacks
   2 One snack per day
   3 Two snacks per day
   4 Three snacks per day
   5 More than three snacks per day

Please tell us when you normally eat snacks (example: morning, mid-afternoon, evening, late night):

_____

_____

3. Do personal choices or religious or cultural practices influence what foods you can and cannot eat?

   1 Yes, always
   2 Occasionally
   3 No, never

Please tell us what these are, and how they determine what foods you eat:

_____

_____

4. Do you have any allergies or gastrointestinal reactions (examples: bloating, flatulence, upset stomach) to foods?

1 Yes 2 No

Please tell us what food allergies (or gastrointestinal reactions) you have: _____

_____

5. Do you have any gastrointestinal conditions (examples: irritable bowel syndrome (IBS), celiac disease)

1 Yes 2 No

Please tell us what conditions you have: _____

_____

6. Are there foods you dislike, or prefer not to eat?

1 Yes 2 No

Please tell us what foods you dislike: _____

_____

7. How often do you eat in restaurants?

1 Frequently, a few times or more per week

2 Regularly, once per week

3 Occasionally, once every few months

4 Seldom, a few times per year

5 Never

8. When you eat in restaurants, what are they typically like?

1 Cafés and Bistro

2 Family Style Dining (Boston Pizza, Red Robins)

3 Fine Dining

4 Hamburger Style Fast Food (McDonalds, Wendy's)

5 Sandwich Style Fast Food (Tim Horton's, Pita Pit, Subway)

9. Do you take any vitamin/mineral supplements? (ex: multi vitamins, vitamin C, multi- B complex, antacids for calcium, folate).

1 No…….. (please continue to question 10)

2 Yes……. (continue below)

If yes, please list which supplements you take including name, brand, frequency and dose.

Product	Brand Name	Frequency	Amount (size/dose)
Example: One a Day Essential	*Bayer*	*3x per week*	*1 pill – 100mg*

10. Do you take any natural health products (ex: Ginger root, Echinacea, Rose Hip)?

1 No…….. (please continue to question 11)

2 Yes……. (please continue below)

If yes, please list which products you take including name, brand, frequency and dose.

Product	Brand Name	Frequency	Amount (size/dose)
Example: St. Johns Wort	*Johnson & Johnson*	*3x per week*	*1 pill – 1000mg*

NOTE: ***If you consume any of the products listed in questions 9 and 10, please continue to take them during the study. Please do not stop or change what you are taking during the study.***

11. Do you take any dietary digestive aids?

1 No…….. (please continue to question 12)

2 Yes……. (please continue below)

If yes, please list which products you take including name, brand, frequency and dose.

Product	Brand Name	Frequency	Amount (size/dose)
Flaxseed (ground or whole)			
Dried Fruit. Example: prunes			
High Fibre Cereals – more than 5g fibre per serving. Example: Bran Buds, All Bran			
Digestive Aids. Example: Metamucil			
Others:			

NOTE: If you consume any of the products listed in question 11, please continue to take them during the study. Please do not stop or change what you are taking during the study.

12. Do you take any Soy products?
    1 No…….. (please continue to question 13)
    2 Yes…….(please continue below)

If yes, please list which products you take including name, brand, frequency and dose.

Product	Brand Name	Frequency	Amount (size/dose)
Soy supplements			
Products that contain soy beans			

13. Do you take any omega -3 supplements?
    1 No…….. (please continue to question 14)
    2 Yes…….(please continue below)

If yes, please list which products you take including name, brand, frequency and dose.

Product	Brand Name	Frequency	Amount (size/dose)
Fish oil capsules			
Flaxseed oil			

NOTE: If you consume any of the products listed in questions 12 and 13, please continue to take them during the study. Please do not stop or change what you are taking during the study.

Section 2: Frequency of Food Intake

Instructions: Please indicate how often you consume the following foods by marking the category that is closest to what you normally eat in a month.

Please note that items #15 - #19, (example: dried peas, dried beans, lentils, and chickpeas) may be mixed in dishes of foods that you consume (example: chili, split pea soup, hummus, stews, pork and beans, refried beans, black bean soup, dahl, burrito etc.).

Categories range from "NOT AT ALL" to "4 OR MORE TIMES PER DAY". Please do not skip any items:

	Not at All	Rarely	1-3 times per Month	1-2 times per Week	3-5 times per Week	Once per Day	2-3 times per Day	4 or more times per Day
14. Dried peas	( )	( )	( )	( )	( )	( )	( )	( )

Dried peas may include split, green, or yellow peas.
Dried peas do NOT include fresh, frozen or canned green peas, or pea pods.

What would typical foods and serving sizes be? _____

_____

15. Dried beans ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( )

Dried beans may include navy beans, red kidney beans, black beans, pinto beans, etc.
Dried beans DO NOT include fresh, frozen or canned yellow or green beans.

What would typical foods and serving sizes be? _____

_____

16. Lentils ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( )

What would typical foods and serving sizes be? _____

_____

17. Chickpeas ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( )

What would typical foods and serving sizes be? _____

_____

Additional bean, pea, chickpea, and lentil containing food items can NOT be consumed during the study (see list of pulse containing foods for examples). Consuming these foods and products may conflict with study results.

	Not at All	Rarely	1-3 times per Month	1-2 times per Week	3-5 times per Week	Once per Day	2-3 times per Day	4 or more times per Day
18. Rice	( )	( )	( )	( )	( )	( )	( )	( )

What would typical foods and serving sizes be? _____

_____

19. Phytosterols ( ) ( ) ( ) ( ) ( ) ( ) ( ) ( )

(Special Margarines, yogurts etc containing plant sterols. Examples: Becel pro.activ, Danacol, Astro biobest with Plant Sterols)

What would typical foods and serving sizes be? _____

_____

NOTE: If you consume any of the products with phytosterols listed in question 19, please do NOT take them during the study.

Section 3: Physical activity

20. During a typical **7-day period** (one week), how many times on the average do you do the following kinds of exercise for **more than 15 minutes** during your free time (write on each line the appropriate number).

Times/Week

a) Strenuous Exercise (Heart Beats Rapidly) _____
(Examples: running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling.)

b) Moderate Exercise (Not Exhausting) _____
(Examples: fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing.)

c) Mild Exercise (Minimal Effort) _____
(Examples: easy walking, yoga, archery, fishing from river bank, bowling, horseshoes, snowmobiling.)

Section 4: Feasibility for Participation in the Study

Instructions: The following questions will help us determine whether this study is right for you. Please provide one response (**Yes** or **No**) to each of the following questions.

21. Do you have a freezer in your home to store frozen food items that we will provide to you?

1 Yes 2 No

22. Do you have enough space (approximately 1 foot x 1 foot x 1 foot or 30cm x 30 cm x 30cm) in your freezer to store enough food items to cover a 2 to 3 week period?

1 Yes 2 No

23. Do you have a microwave available for use in your home?

1 Yes 2 No

24. Will you be required to travel or be away for an extended period of time while participating in the study?

1 Yes 2 No

25. Do you agree that you will **not** consume dried peas, beans, lentils or chickpeas in addition to the food items that you will be provided?

1 Yes 2 No

26. Do you agree that you will consume your usual diet, and vitamin/mineral supplements or natural health products (if you consume these), for the duration of the study?

1 Yes 2 No

27. If you take any medications, do you think that you might need to make any changes to your current medication(s) while participating in the study?

1 Yes 2 No

If yes, please provide more information about the types of changes and why:

_____

_____

28. Do you agree to maintain the same level of exercise throughout the duration of the study?

1 Yes 2 No

29. Please enter today's date: ____day ____month _____year

If you have any comments, please write them below:

_____

Thank you so much for your time!

We know all our participants have busy lives, and we are grateful that you have made time in your schedule to help us with this important research.

Appendix H. Three-day dietary intake record
(only day 1 is shown as an example)

THREE-DAY DIETARY INTAKE RECORD

Week to be completed:_____

Study ID:_____

Phone Number: _____

Record Dates: _____ _____ _____ _____ _____ _____

(Day) (Month) (Day) (Month) (Day) (Month)

University of Alberta
Department of Agricultural, Food and Nutritional Science

INSTRUCTIONS FOR RECORDING DAILY FOOD INTAKE

Please record your food intake for **2 week days and one weekend day.**
It is important to record ALL foods and beverages – whether it is a full course meal at home or a quick can of pop at school/work.

The Three-Day Dietary Intake Record has a separate section for every day Each day is broken up into 6 eating times:

1. Morning meal	2. Midmorning snack	3. Midday meal
4. Afternoon snack	5. Evening meal	6. Evening snack

It is a good idea to carry your Dietary Intake Record book with you and record your entries as soon after eating as possible. Please include the following information on your food record:

1. **FOOD AND BEVERAGE ITEMS** Column: Enter all foods and beverages consumed at the meal or snack time. Please record the specific type of food (for example: *WHOLE WHEAT* bread, *FROSTED FLAKES* cereal). In the same column, record all toppings or items added at the time of eating (for example: sugar, syrup, jam, butter, mayonnaise, gravy, milk, salt, etc.). For combination foods, please include detailed information on each item. For example: If you had a tuna sandwich, you would list the following foods and include detailed information for each of them: white bread, mayonnaise, celery, solid white tuna, salt.

2. **DESCRIPTION OF ITEM** Column: For every food or beverage item listed, include the following (if applicable):
   - **Brand**: *MIRACLE WHIP* mayonnaise, *PIZZA HUT DEEP DISH* pizza, *OREO* cookie, *ACTIVITA* yogurt.
   - **Type of flavour**: *BLUEBERRY* muffins, *STRAWBERRY* yogurt
   - **Method of cooking**: *FRIED, BAKED, BBQ'D, HOMEMADE*
   - **All other relevant information included on food label**: *LOW FAT,* ranch fat free salad dressing, *28% M.F. (MILK FAT*) cheddar cheese, *LEAN* Ground Beef ,

   For fruits and vegetables specify the varieties if possible e.g. "Granny smith" apple and other information's such as frozen, canned sweetened/unsweetened, sliced etc.

3. **AMOUNT** Column**:** Specify number and units of measure of food or beverage item and the amount of any topping or items added.. E.g. 2 cups, 1 Teaspoon. Use appropriate units of measures necessary e.g. "cup", "grams", "piece", "ounce", "number", size of fruit (small, medium, large), "teaspoon", or "tablespoon. Use measuring cups and spoons whenever possible.

Homemade foods - attach the recipe to the additional information sheet and mention the portion you had eaten E.g. $1/5^{th}$ of a batch of stew, and how many servings the recipe yields.
Restaurants: Include as much information as possible. Make sure you include the name of the restaurant, name of the dish and the options that you have chosen.
Please attach the food labels of processed foods if possible and do ensure that you have entered "label attached"

Fill in the blanks on the bottom of each record. Please list any vitamin or mineral supplements and/or herbal products taken, including quantities and detailed label information along with the Drug Identification number (DIN). Indicate the time of your meal or snack and where it was eaten (for example: at home, at a restaurant). If you did not eat a meal or snack, please place a check mark (✓) in the space provided on the bottom of the page, so that we do not think you forgot to record it.

In the evening do a check over your day to ensure you haven't missed anything.
Dietary record should reflect the way you usually eat. Please do not change your normal eating habits for the 3 days you are recording your food intake. Your honesty is crucial to the success of this research study.

Sample Meal

FOOD AND BEVERAGE ITEMS	DESCRIPTION OF ITEM	AMOUNT
Enter all foods and beverages consumed. For combination foods, please include detailed information on each item.	Include a detailed description of each food and drink item consumed including: - Brand name - Flavour - Method of cooking - All other relevant information on food/drink label	Enter number of units and units of measure: for example: cup, grams, ounce, piece, teaspoon, tablespoon
Spaghetti with tomato/meat sauce:		
Pasta	Whole wheat Spaghetti, cooked	2 Cup
Tomato sauce	Hunt's canned sauce, roasted garlic flavour	1 Cup
Meat balls	Made with extra lean ground beef	5 Number (1 oz/ball)
Parmesan cheese, grated	Kraft, 30% Milk Fat (M.F.)	1 Tablespoon
Garlic Bread:		
Italian Bread	Toasted	3 Piece (large slice)
Garlic Butter		3 Teaspoon
Caesar salad:		
Lettuce	Romaine	1 Cup
Croutons	Safeway brand, garlic flavor	2 Tablespoon
Bacon bits	Simulated flavour, No Name Brand	2 Tablespoon
Caesar salad dressing	Kraft, Fat free	2 Tablespoon
Milk	1%	1 Cup
Tiramisu	Sarah Lee	1 Slice
Coffee	Brewed, Black	1 Cup

Vitamin/Mineral Supplements or Herbal Products taken:_____

_____

Fill in blanks: Time of meal/snack: 6:00 pm **Location meal/snack was consumed:** at home

Please CHECK (✓) if you did not eat or drink at this meal or snack time:_____

Sample Meal

FOOD AND BEVERAGE ITEMS	DESCRIPTION OF ITEM	AMOUNT
Enter all foods and beverages consumed. For combination foods, please include detailed information on each item.	Include a detailed description of each food and drink item consumed including: - Brand name - Flavour - Method of cooking - All other relevant information on food/drink label	Enter number of units and units of measure: for example: cup, grams, ounce, piece, teaspoon, tablespoon
Strawberry - Kiwi Juice	Sunrype 100% fruit juice	½ Cup (125 ml)
Bacon	Maple leaf regular	1 piece
Whole wheat bread:	Toasted, homemade (recipe attached)	2 Piece (small slice)
Margarine	Becel, polyunsaturated salt reduced spread	3 teaspoon
Peanut butter	Compliments, 100% natural crunchy	2 teaspoon (10 ml)
Jam	Blueberry haven, blueberry, no sugar	3 teaspoon
Granola bar	Nature valley, sweet and salty, gluten free, Almond (Label attached)	1 Bar
Apple	Granny smith	1 medium size

Vitamin/Mineral Supplements or Herbal Products taken:_____

_____

Fill in blanks: Time of meal/snack: 6:00 pm **Location meal/snack was consumed:** at home

Please CHECK (✓) if you did not eat or drink at this meal or snack time:_____

Day 1 – Morning Meal

FOOD AND BEVERAGE ITEMS	DESCRIPTION OF ITEM	AMOUNT
Enter all foods and beverages consumed. For combination foods, please include detailed information on each item.	Include a detailed description of each food and drink item consumed including: - Brand name - Flavour - Method of cooking - All other relevant information on food/drink label	Enter number of units and units of measure: for example: cup, grams, ounce, piece, teaspoon, tablespoon

Vitamin/Mineral Supplements or Herbal Products taken:

_____

_____

Fill in blanks: Time of meal/snack:_____ Location meal/snack was consumed:_____
Please CHECK (✓) if you did not eat or drink at this meal or snack time:_____

Day 1 - Mid-Morning Snack

FOOD AND BEVERAGE ITEMS	DESCRIPTION OF ITEM	AMOUNT
Enter all foods and beverages consumed. For combination foods, please include detailed information on each item.	Include a detailed description of each food and drink item consumed including: - Brand name - Flavour - Method of cooking - All other relevant information on food/drink label	Enter number of units and units of measure: for example: cup, grams, ounce, piece, teaspoon, tablespoon

Vitamin/Mineral Supplements or Herbal Products taken:_____

_____

Fill in blanks: Time of meal/snack:_____ **Location meal/snack was consumed:**_____

Please CHECK (✓) if you did not eat or drink at this meal or snack time:_____

Day 1 - Midday Meal

FOOD AND BEVERAGE ITEMS	DESCRIPTION OF ITEM	AMOUNT
Enter all foods and beverages consumed. For combination foods, please include detailed information on each item.	Include a detailed description of each food and drink item consumed including: - Brand name - Flavour - Method of cooking - All other relevant information on food/drink label	Enter number of units and units of measure: for example: cup, grams, ounce, piece, teaspoon, tablespoon

Vitamin/Mineral Supplements or Herbal Products taken:_____

_____

Fill in blanks: Time of meal/snack:_____ **Location meal/snack was consumed:**_____

Please CHECK (✓) if you did not eat or drink at this meal or snack time:_____

Day 1 - Afternoon Snack

FOOD AND BEVERAGE ITEMS	DESCRIPTION OF ITEM	AMOUNT
Enter all foods and beverages consumed. For combination foods, please include detailed information on each item.	Include a detailed description of each food and drink item consumed including: - Brand name - Flavour - Method of cooking - All other relevant information on food/drink label	Enter number of units of units and measure: for example: cup, grams, ounce, piece, teaspoon, tablespoon

Vitamin/Mineral Supplements or Herbal Products taken:_____

_____

Fill in blanks: Time of meal/snack:_____ **Location meal/snack was consumed:**_____

Please CHECK (✓) if you did not eat or drink at this meal or snack time:_____

Day 1 - Evening Meal

FOOD AND BEVERAGE ITEMS	DESCRIPTION OF ITEM	AMOUNT
Enter all foods and beverages consumed. For combination foods, please include detailed information on each item.	Include a detailed description of each food and drink item consumed including: - Brand name - Flavour - Method of cooking - All other relevant information on food/drink label	Enter number of units of units and measure: for example: cup, grams, ounce, piece, teaspoon, tablespoon

Vitamin/Mineral Supplements or Herbal Products taken:_____

_____

Fill in blanks: Time of meal/snack:_____ **Location meal/snack was consumed:**_____

Please CHECK (✓) if you did not eat or drink at this meal or snack time:_____

Day 1 - Evening Snack

FOOD AND BEVERAGE ITEMS	DESCRIPTION OF ITEM	AMOUNT
Enter all foods and beverages consumed. For combination foods, please include detailed information on each item.	Include a detailed description of each food and drink item consumed including: - Brand name - Flavour - Method of cooking - All other relevant information on food/drink label	Enter number of units and units of measure: for example: cup, grams, ounce, piece, teaspoon, tablespoon

Vitamin/Mineral Supplements or Herbal Products taken:_____

_____

Fill in blanks: Time of meal/snack:_____ **Location meal/snack was consumed:**_____

Please CHECK (✓) if you did not eat or drink at this meal or snack time:_____

ADDITIONAL INFORMATION

(For example: recipes or food/drink label information)

Appendix I. Tracking document

(only weeks 1 – 3 are shown as an example)

Beans and Peas – Tracking Document Study ID: _____
Completed weeks 1-3 Study Week : _____

Week 1:

Instructions – For each study food item you eat, please add a short comment about the food, such as how it tasted, whether you enjoyed it, or any other comments you think are important for us to know. On the days where a study food was not consumed, mark an X over that day of the week. You must consume **5** study foods per week. *Study Coordinator to fill in dates.*

Day 1 DATE	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
Study Food Name	Study Food Name	Study Food Name	Study Food Name	Study Food Name	Study Food Name	Study Food Name
How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**
Comments:	Comments:	Comments:	Comments:	Comments:	Comments:	Comments:

Remember! Please eat one serving of each study food item per day for 5 days of the week. The study foods should be eaten as a part of your regular diet (i.e. Replace something in your meal with the study food item). Do not eat more than one study food item per day. Drink fluids when you eat the study foods and consume fluids each day.

This week remember to fill out each of the following questionnaires: □ GI Questionnaire □ Satiety Questionnaire

Week 2:

Instructions – For each study food item you eat, please add a short comment about the food, such as how it tasted, whether you enjoyed it, or any other comments you think are important for us to know. On the days where a study food was not consumed, mark an X over that day of the week. You must consume **5** study foods per week. *Study Coordinator to fill in dates.*

Day 1 DATE	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
Study Food Name	Study Food Name	Study Food Name	Study Food Name	Study Food Name	Study Food Name	Study Food Name
How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**
Comments:	Comments:	Comments:	Comments:	Comments:	Comments:	Comments:

Remember! Please eat one serving of each study food item per day for 5 days of the week. The study foods should be eaten as a part of your regular diet (i.e. Replace something in your meal with the study food item). Do not eat more than one study food item per day. Drink fluids when you eat the study foods and consume fluids each day. This week remember to fill out each of the following questionnaires:

□ 3-day food record (remember to track your food for at least one weekend day) □ This week you can expect a call from the study coordinator

Week 3:

Instructions – For each study food item you eat, please add a short comment about the food, such as how it tasted, whether you enjoyed it, or any other comments you think are important for us to know. On the days where a study food was not consumed, mark an X over that day of the week. You must consume **5** study foods per week. *Study Coordinator to fill in dates.*

Day 1 DATE	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
Study Food Name	Study Food Name	Study Food Name	Study Food Name	Study Food Name	Study Food Name	Study Food Name
How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**	How much did you eat? (*circle one*) **None** ¼ ½ ¾ **All**
Comments:	Comments:	Comments:	Comments:	Comments:	Comments:	Comments:

Remember! Please eat one serving of each study food item per day for 5 days of the week. The study foods should be eaten as a part of your regular diet (i.e. Replace something in your meal with the study food item). Do not eat more than one study food item per day. Drink fluids when you eat the study foods and consume fluids each day.

This week remember to fill out each of the following questionnaires: □ GI Questionnaire □ Satiety Questionnaire

For your next study visit on _____ at _____, please remember to fast (i.e. no food or beverage intake for 12 hours), and bring your study binder with completed questionnaires. Remember, it is okay to drink water during a fast and may actually make the blood draw easier if you are hydrated!

Appendix J. GI questionnaire

Beans and Peas – GI Questionnaire
Complete at Screening, Week 1, 3 and 6

Study ID: _____
Study Week: _____
Date Completed ___/___/___

As part of the study, we want to know if participants are experiencing any changes in their stomach/intestines or other related symptoms after eating. All questions ask you to think about how you have felt for the past week or 7 days. Please do not report events or changes again from a previous questionnaire unless the symptom or change also occurred again within the past 7 days.
If you have any questions, please contact Ms. Janis Baarda at 780-492-4182 or pulseRCT@ualberta.ca.

1.a. Have you experienced any changes in **flatulence (gas) frequency** over the past week?

No …… □1 Go to next question
Yes …… □2

b. If yes, has the frequency increased or decreased?

Increased …… □1
Decreased ..…… □2

c. If increased or decreased, how would you rate the amount of change on a scale from 1-5 as compared to the previous week
(PLEASE CIRCLE THE NUMBER THAT BEST CORRESPONDS TO YOUR EXPERIENCE)

1…….2…….3…….4…….5
Little change A lot of change

2. a. Have you experienced any changes in **stool frequency** over the past week?

No change…… □ 1 Go to next question
Increased…… □2
Decreased…….. □3

b. If increased or decreased, how would you rate the amount of change on a scale from 1-5 as compared to the previous week.
(PLEASE CIRCLE THE NUMBER THAT BEST CORRESPONDS TO YOUR EXPERIENCE)

1…….2…….3…….4…….5
Little change A lot of change

3.a. Have you experienced any changes in **stool consistency** such as the stool becoming softer or looser or harder or firmer?

No …… □1 Go to next question
Yes …… □2

b. If Yes, has the stool consistency been softer or harder?

Softer …… □1
Harder …..……□2

c. If softer or harder how would you rate the amount of change in stool consistency on a scale from 1-5 as compared to the previous week?

1…….2…….3…….4…….5
Little change A lot of change

4. a. Have you felt any **bloating** during the past week?

No …… □1 Go to next question
Yes ……. □2

b. **If yes,** how would you rate the amount of change in your feelings of bloating on a scale from 1-5 as compared to the previous week?

1…….2…….3…….4…….5
Little change A lot of change

5. a. Were any of your normal daily activities affected during the past week by the following symptoms? (CHECK ALL THAT APPLY)

Yes – flatulence (gas) frequency…… □1
Yes – stool frequency …… □2
Yes – stool consistency……...□3
Yes – bloating ……..….□4
No changes to normal daily activities……..□5

b. Did you change or avoid any social activities during the past week because of these symptoms?

No …… □1
Yes……. □2

c. **If yes,** describe symptoms and activities that were changed or avoided: _____
_____

6. Have you experienced any other stomach/gastrointestinal discomforts? If yes, please describe, including their severity.

_____

THANK YOU!

Appendix K. Satiety questionnaire

Beans and Peas – Satiety Questionnaire **Study ID: _____**
Completed Week 1, 3 and 6 **Study Week: _____**

As part of the study, we would like to know how satisfied participants are feeling after consuming the study food items. Complete the following questions by making a mark on the horizontal line expressing how you feel **30 minutes** after consuming one of the study food items near the end of the week.

Date study food consumed: _____

Time of day study food consumed: _____

Name of study food consumed: _____

How hungry do you feel?

I am not hungry at all _____ I have never been more hungry

How satisfied do you feel?

I am completely empty _____ I cannot eat another bite

How full do you feel?

Not full at all _____ Totally Full

How much more do you think you can eat?

Nothing at All _____ A lot

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