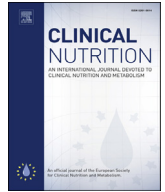




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Randomized control trials

Consuming yellow pea fiber reduces voluntary energy intake and body fat in overweight/obese adults in a 12-week randomized controlled trial

Jennifer E. Lambert^a, Jill A. Parnell^b, Jasmine M. Tunnicliffe^a, Jay Han^c,
Troy Sturzenegger^c, Raylene A. Reimer^{a,d,*}^a Faculty of Kinesiology, University of Calgary, 2500 University Drive NW, Calgary, AB T2N 1N4, Canada^b Physical Education and Recreation Studies, Mount Royal University, 4825 Mount Royal Gate SW, Calgary, AB T3E 6K6, Canada^c Food Processing Development Centre, Alberta Agriculture and Rural Development, 6309 – 45 Street, Leduc, AB T9E 7C5, Canada^d Department of Biochemistry & Molecular Biology, Cumming School of Medicine, University of Calgary, 3330 Hospital Drive NW, Calgary, AB T2N 4N1, Canada

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SUMMARY

Background & aims: The purpose of this randomized, double-blind, placebo-controlled study was to assess the effects of yellow pea fiber intake on body composition and metabolic markers in overweight/obese adults.**Methods:** Participants (9 M/41 F; age 44 ± 15 y, BMI 32.9 ± 5.9 kg/m²) received isocaloric doses of placebo (PL) or pea fiber (PF; 15 g/d) wafers for 12 weeks. Outcome measures included changes in anthropometrics, body composition (DXA), oral glucose tolerance test (OGTT), food intake (*ad libitum* lunch buffet), and biochemical indices.**Results:** The PF group lost 0.87 ± 0.37 kg of body weight, primarily due to body fat (-0.74 ± 0.26 kg), whereas PL subjects gained 0.40 ± 0.39 kg of weight over the 12 weeks ($P = 0.022$). The PF group consumed 16% less energy at the follow-up lunch buffet ($P = 0.026$), whereas the PL group did not change. During the OGTT, glucose area under the curve (AUC) was lower in PF subjects at follow-up ($P = 0.029$); insulin increased in both groups over time ($P = 0.008$), but more so in the PL group (38% higher AUC vs. 10% higher in the PF group). There were no differences in gut microbiota.**Conclusions:** In the absence of other lifestyle changes, incorporating 15 g/day yellow pea fiber may yield small but significant metabolic benefits and aid in obesity management.**Clinical Trial Registry:** ClinicalTrials.gov NCT01719900.

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1. Introduction

Targeted lifestyle interventions are the safest and most economic approaches for both prevention and treatment of obesity, exhibiting potential for multi-faceted health and metabolic

benefits. Dietary fiber contributes to weight control and blood glucose management through a variety of mechanisms, including delayed nutrient absorption, increased satiety, and stimulation of gut hormones that regulate food intake [1]. Fiber may also beneficially modulate the intestinal microbiota, the manipulation of which influences whole-body energy metabolism. For example, in a double-blind placebo-controlled trial in obese women, feeding the prebiotic fibers inulin and oligofructose (16 g/d) for 3 months reduced *Bacteroides intestinalis* and *B. vulgatus*, which was correlated with glucose homeostasis and a slight reduction in fat mass [2]. As such, there is increasing interest in identifying fibers which can be classified as 'prebiotics', meaning they favorably modulate the composition and/or activity of the gut microbiota thereby conferring a health benefit to the host [3].

Abbreviations: DXA, dual X-ray absorptiometry; tAUC, total area under the curve; OGTT, oral glucose tolerance test; PF, pea fiber; PL, placebo; VAS, visual analog scales.

* Corresponding author. University of Calgary, 2500 University Dr. NW, Calgary, AB T2N 1N4, Canada.

E-mail addresses: jel.lambert@gmail.com (J.E. Lambert), jparnell@mtroyal.ca (J.A. Parnell), jasmine.tunnicliffe@gmail.com (J.M. Tunnicliffe), jay.han@gov.ab.ca (J. Han), troy.sturzenegger@gov.ab.ca (T. Sturzenegger), reimer@ucalgary.ca (R.A. Reimer).

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Fiber intake in North America falls short of recommendations [4] and consumers are interested in fortified products that could promote weight loss and improve health. Different fiber types (e.g. inulin, beta-glucan) and/or sources (pulses, grains, etc.) have different physical and biological properties [1], which may affect metabolic health in distinct ways. Therefore, there is value in characterizing diverse fiber sources to ensure a broad range of options in the food supply.

The hulls of yellow peas are comprised of ~82% fiber making them an excellent fiber source for incorporation into food products [5]. In metabolically unhealthy animals (glucose intolerant, hypercholesterolemic), feeding diets containing whole or fractionated (hulls) peas improved fasting and postprandial glucose and insulin levels and reduced body fat in diet-induced obese rats [6–8]. In metabolically unhealthy humans (overweight hypercholesterolemic), 12 g/d of pea fiber intake for 28 d reduced fasting insulin concentrations and improved postprandial glucose responses after a standardized meal [9], although whether or not the benefits were associated with changes in gut microbiota is not known. Given the importance of determining the effects of specific fiber types on metabolic outcomes in overweight and obese adults, the objective of this randomized, double-blind, placebo-controlled study was to determine the effects of yellow pea fiber on body composition, metabolic markers of obesity, and gut microbiota abundance in overweight/obese adults.

2. Materials and methods

2.1. Subjects

Overweight and obese adults (age 18–70 y; BMI 25–38 kg/m²) were recruited from the community in Calgary, Alberta, Canada in 2012 and 2013. Eligible subjects included adults with stable body weight (defined as <3 kg lost or gained within the last 3 months), and exclusion criteria as has been described previously [10]. Eligibility was assessed using a screening questionnaire and phone interview. After screening, participants were randomly assigned using computer generated numbers (and stratified according to age, sex, and BMI) to either placebo (PL) or pea fiber (PF; 15 g/d yellow pea fiber) for 12 weeks. The randomization sequence was generated by an investigator not involved in recruiting participants and sequences were not revealed to study staff. One research assistant was responsible for product distribution to ensure the correct product was provided to the groups. Study personnel were unaware of treatment allocation prior to the assignment of interventions and participants and research staff were blinded to treatments. As previously described [10], sample size was determined from anticipated changes in body fat based on data from our previous work on prebiotic fiber supplementation in overweight and obese adults [11]. This proposal was approved by the Conjoint Health Research Ethics Board of the University of Calgary, and voluntary, written informed consent was obtained from each participant.

2.2. Study design

The detailed design of this double-blind, placebo-controlled parallel group design has been previously described [10] and therefore is described briefly here. Prior to testing days (at baseline and follow-up), subjects completed a 3-day weighed food record (analyzed using FoodWorks software, The Nutrition Company, Long Valley, NJ) and a physical activity record (Godin's Leisure Time Exercise Questionnaire), and collected a stool sample for analysis of gut microbiota. Validated 100 mm visual analog scales (VAS) [12] were completed by participants at home on a weekly basis to

assess subjective ratings of appetite (including hunger, satiety, desire to eat, feeling of fullness) as described previously [10].

On testing days at 0 and 12 wk, anthropometrics (height, weight, BMI, waist circumference) were measured and a fasting blood sample taken to assess inflammatory markers, lipids, and satiety hormones. A standard oral glucose (75 g) tolerance test (OGTT) was performed, and glucose, insulin, and gut hormones assessed at 0, 30, 60, 120, and 180 min. Body composition was measured by whole body dual-energy X-ray absorptiometry (DXA) scan (Hologic QDR 4500, Hologic, Inc., Bedford, MA, USA). An *ad libitum* lunch buffet [13] consisting of savory (pizza) and sweet (cookies) food options was provided to subjects to objectively assess food intake. Subjects were instructed to eat until "comfortable satisfaction," and each individual's energy intake was measured. Conversation between subjects was monitored such that topics did not involve food, appetite, or related issues [13]. Subjective ratings of appetite were measured using validated VAS before and after the lunch.

2.3. Dietary intervention

The PF group received wafers containing 5 g/serving of yellow pea fiber ('Best' Pea Fiber, Best Cooking Pulses Inc., Portage la Prairie, MB, Canada), while the placebo group received an isocaloric dose of control wafers with no pea fiber (204 kcal of total additional energy per day in each group). The wafers were formulated and produced by the Leduc Food Processing Development Centre (Leduc, AB, Canada). The fiber was supplied to the Centre by Best Cooking Pulses Inc. (Portage la Prairie, MB, Canada) and was dry milled from the outer hull of yellow peas, having a 92% total dietary fiber content of which 8% was soluble. Subjects were instructed to consume the wafers approximately 30 min before their 3 largest daily meals. Subjects returned all packages (both empty and unconsumed) to assess compliance. To minimize gastrointestinal discomfort associated with a rapid increase in fiber intake, the dose was increased incrementally during the first 3 weeks of the study (week 1 = 5 g/d; week 2 = 10 g/d; week 3 = 15 g/d). The study was designed to examine the effects of pea fiber supplementation in a real-life setting, independent of any other diet or exercise intervention; therefore, subjects were encouraged to maintain their usual lifestyle and habitual food intake, eat until comfortably full, and not consciously try to gain/lose weight throughout the study.

2.4. Laboratory analyses

Blood was centrifuged immediately and plasma and serum aliquots frozen at –80 °C for subsequent analyses. Glucose was quantified using a trinder assay (Stan Bio, Boerne, TX, USA). Samples were sent to Calgary Laboratory Services for measurement of plasma HbA1c, serum lipids (total, LDL- and HDL-cholesterol, and triglyceride), and serum CRP. For gut hormones, blood was drawn into cooled EDTA vacutainers containing inhibitors as previously described [10,11], and centrifuged within 30 min. Milliplex kits (Millipore, Billerica, MA, USA) were used to measure plasma insulin, GIP (total), amylin, ghrelin (active), leptin, and PYY (total). Active GLP-1 was measured with ELISA (Millipore, EGLP-35K). Serum adiponectin, resistin, IFN γ , IL12P40, IL-1B, IL-6, IL-8, MCP1, and TNF- α were measured with human cytokine and adipokine Milliplex kits (Millipore).

2.5. Gut microbiota analysis

Subjects collected stool specimens as previously described [10]. Samples were kept at –80 °C until analysis. Total microbial DNA was extracted from frozen fecal samples using the QIAamp DNA

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