

Influence of pre-meal Inulin consumption on Energy Intake in overweight and obese middle-aged and Older Adults: a pilot study

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Thesis submitted to the faculty of the Virginia Polytechnic Institute and State University in partial fulfillment of the requirements for the degree of

Master of Science

in

Human Nutrition, Foods and Exercise

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April 26, 2016

Blacksburg, VA

Keywords: Inulin, Energy Intake, Appetite, Weight Management, Older Adults

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## **ABSTRACT**

Seventy-six percent of men and 71% of women over the age of 55 in the United States are considered overweight or obese, and the numbers are expected to rise especially since the population is aging. Aside from various metabolic comorbidities, such as hypertension, dyslipidemia, and coronary artery disease, overweight and obesity are also linked to decreased mobility and increased rate of falls in elderly, all of which may lead to premature death. Furthermore, adults over the age of 65 have 339% greater obesity-related medical expenses compared to younger adults (18-30 years old), thus strategies to promote weight management are needed. Belonging to the group of fiber, prebiotics are selectively fermented non-digestible food ingredients that have a favorable impact on the composition and activity of the gut microbiota. Specifically, inulin-type fructans (ITF) including inulin, oligosaccharides, and fructooligosaccharides have been generating interest in the prebiotic area in the past two decades. A lot of attention has been directed at weight management, since ITFs are known to stimulate the excretion of anorectic gut hormones glucagon like peptide-1 and peptide YY upon fermentation in the colon. Research done to date has included samples with wide age and BMI ranges, various doses of inulin, as well as different study designs. More investigations are needed in specific populations, such as older adults who might have age-related alterations in gastric emptying. This pilot research study investigated the effects of short-term pre-meal inulin consumption (10 g, mixed into 500 ml water) on energy intake (EI) and appetite sensations over a 24-hour period, in overweight and obese middle-aged and older adults (n=7, 55-67 years old), in order to determine the potential role of prebiotics in weight loss and weight management. A randomized crossover design was used, with participants completing both pre-meal inulin and control (500 ml water alone) conditions. There were no differences in EI, gram weight, nor energy density of foods consumed between the inulin and control conditions. However, observed subgroup differences suggest variances in response to the inulin preload related to gender, habitual fiber consumption, cognitive dietary restraint, and BMI status.

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**GENERAL AUDIENCE ABSTRACT**

The United States population is expected to grow older during next few decades. Three fourths of adults in the United States over 60 years of age are considered overweight or obese, which is not only associated with conditions, such as hypertension, dyslipidemia, and coronary artery disease, but also with decreased mobility and increased rate of falls in elderly, all of which increase medical costs and can lead to premature death. These statistics call for weight loss strategies applicable to middle-aged and older adult population. Recently, prebiotics, and specifically inulin, have been introduced as a potential aid in weight management. Inulin is found in foods such as bananas, garlic, onions, wheat, oat, leek, and asparagus, and is usually extracted from chicory root or Jerusalem artichokes for supplemental use. Upon ingestion, inulin passes undigested through gastrointestinal tract and is fermented in the colon. Compounds resulting from fermentation may stimulate the release of hormones glucagon like peptide-1 and peptide YY, which may influence food consumption. Research on the role of inulin in eating behavior has been scarce and needs more focus on specific populations, such as middle-aged and older adults, who may have altered gastrointestinal processes due to aging. Hence, this research study investigated the influence of short-term inulin consumption on food intake and appetite sensations over a 24-hour period, with the goal of exploring a possible weight management strategy in overweight and obese middle-aged and older adults. There were no differences observed in food intake between the inulin and the control condition, however, mixed results among subgroups suggest differences in response to inulin consumption related to gender, usual dietary fiber consumption, dietary restraint, and weight status.

## **ACKNOWLEDGEMENTS**

Graduate education has been a unique experience. I would primarily like to thank my mentor Dr. Brenda Davy for giving me an opportunity to be immersed into every aspect of graduate studies. Her exceptional guidance allowed for this dynamic experience to be marked with independency, patience, and positivity. Likewise, I would like to thank my committee members Dr. Kevin Davy and Dr. Andrew Neilson for their support and remarkable suggestions in this process. I greatly appreciate the advice and thoughtfulness Heather Cox diligently provided towards my professional development.

I would like to thank my co-investigator Cassie Mitchell for the incredible support and resourcefulness through the research process. A special thank you to all Davy Lab members for the encouragement and fostering a warm work atmosphere, as well.

Lastly, I would like to thank my family and friends for their optimism, enthusiasm, and understanding. They have made the obstacles on this journey seem trivial.

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## CHAPTER 1: Introduction

The population in the United States is predicted to grow older over the next few decades, with almost 20% of the population being over 65 years of age by 2030.<sup>1</sup> In the period 2007-2012, the prevalence of overweight and obesity in men over the age of 55 was 41% and 35%, respectively, whereas in women 32% and 39%, respectively.<sup>2</sup> Unfortunately, the numbers are still rising, not only in the US, but also worldwide.<sup>3</sup> In addition to chronic diseases such as hypertension, dyslipidemia, and coronary artery disease,<sup>4</sup> overweight and obesity are associated with decreased mobility<sup>5</sup> and the rate of falls in the elderly,<sup>6</sup> all of which may result in premature death. Compared to adults 18-30 years old, adults older than 65 years have 339% higher obesity-related medical expenses.<sup>7</sup> Thus, strategies to prevent and treat obesity are needed, particularly those which are effective in middle-aged and older adults.

Preload foods and beverages, such as soups<sup>8</sup> and salads<sup>9</sup> have been investigated as a simple and effective strategy to influence appetite sensations and, hence, energy intake (EI) at a meal. Water preloads were also proven to reduce EI at a meal in older adults.<sup>10,11</sup> Recently, there has been an interest in fiber, and specifically prebiotics, as a potential strategy for reducing appetite and EI.

Prebiotics are defined as the selectively fermented non-digestible food ingredients that have a beneficial influence on composition and/or activity of gastrointestinal microbota.<sup>12</sup> Inulin-type fructans (ITF) are a subcategory of prebiotics encompassing inulin, oligosaccharides, and fructooligosaccharides (FOS),<sup>13</sup> oligo- and polysaccharide chains primarily composed of  $\beta(2\rightarrow1)$  fructosyl-fructose glycosidic bonds. ITFs are used as functional food ingredients naturally found in many plants. As there is no standardized way for naming ITFs and inconsistent nomenclature, confusion is possible when reviewing the literature.<sup>13</sup> Thus, the stated definitions will be used for

the purposes of this research. Inulin is a generic term for all linear fructans with  $\beta(2\rightarrow1)$  fructosyl-fructose glycosidic bonds, which degree of polymerization (DP) ranges from 2 to 60. It is most commonly extracted from chicory root or Jerusalem artichokes.<sup>14</sup> Native chicory root inulin has an average degree of polymerization (DP) of 10 to 20.<sup>14</sup> Long-chain (or high-molecular weight) inulin is inulin with DP 10-60. Oligofructose is a hydrolyzed form of inulin (DP=2-9), often described as a short-chain (low-molecular weight) inulin. Food sources of inulin are garlic, onions, leek, bananas, wheat, oat, and soybeans. Average daily dietary intake of inulin in male hunter-foragers was 135g,<sup>14</sup> compared to 1-4g and 3-11g in Americans and Europeans, respectively.<sup>15</sup> Inulin is fermented in the colon, producing short-chain fatty acids (SCFA) acetate, propionate, and butyrate, among which propionate stimulates the secretion of anorectic gut hormones glucagon like peptide-1 (GLP-1) and peptide YY (PYY), which influence food intake.<sup>16</sup> Additionally, inulin forms microcrystals undetectable by mouthfeel when combined with water that contribute to creamy texture which may also affect appetite sensations.<sup>17</sup> FOS are short-chain inulin-type prebiotics synthesized from sucrose (DP=2-4), which in the literature is often used interchangeably with oligofructose.

Prebiotic intake may reduce symptoms and inflammation associated with inflammatory bowel disease, exhibit protective effects in preventing colon cancer, enhance bioavailability and uptake of calcium, magnesium, and potentially iron, and lower risk factors for cardiovascular disease.<sup>14</sup> Studies have also investigated the influence of prebiotics on EI and satiety levels, which results are presented in Table 1. In a study by Parnell and Reimer, overweight and obese subjects, 20-70 years old, consumed 7 g of oligofructose three times a day for 12 weeks.<sup>18</sup> Self-reported EI during oligofructose treatment was significantly lower (29%) compared to placebo (maltodextrin) by week six. Weight loss was significantly higher, but there was no effect on satiety levels between

the first and final day of intervention in the oligofructose arm.<sup>18</sup> Results of another long-term pilot study suggested that an oligofructose intake of 8 g twice a day for two weeks significantly enhances satiety after breakfast and dinner, and reduces hunger and food consumption after dinner in normal and overweight young adults.<sup>19</sup> In total, EI at test meals offered upon finishing the oligofructose supplementation period was 5-10% lower than EI at meals for subjects on placebo treatment (dextrin maltose).<sup>19</sup> In contrast to the results of long-term studies, the results of short-term studies suggest minimal or non-existent impact of prebiotics on energy intake and satiety. In the study by Hess, et al., subjects (18-64 years old) were given either 0, 5, or 8 g FOS twice a day and results suggested no increase in satiety and decrease in hunger at lunch and dinner meal within 24 hours post ingestion.<sup>20</sup> In another study done by Karalus, et al., consuming a chocolate bar with 10g oligofructose for dinner and breakfast the following day did not reduce calorie intake in young adults at an *ad libitum* lunch consisting of pizza, nor did effect hunger and satiety.<sup>21</sup> Conflicting results between these studies suggest the importance of dosage, time frame, and the type of given prebiotic.

When it comes to inulin specifically, a weight loss study in overweight adults over 18 years old with prediabetes who consumed 30 g/d of inulin for 18 weeks resulted in significant weight loss in the inulin group compared to a placebo group (cellulose) during the nine weeks of weight maintenance phase. Lower EI at an *ad libitum* meal in inulin group at week nine was also noted (~270 kcal).<sup>22</sup> In another long-term study, Chambers, et al. showed a trend that 10 g/d inulin consumption over 24 weeks may increase the satiety and fullness, reduce hunger, desire to eat, and EI at *ad libitum* lunch meal post inulin supplementation in middle-aged adults.<sup>16</sup> Heap, et al. reported lower desire to eat and prospective food consumption in young females at an *ad libitum* meal after taking 6 g of inulin with yogurt every day for 8 days.<sup>23</sup> On the other hand, Delavaud, et



al. investigated the impact of long-term inulin consumption on energy expenditure, but the effects were uncertain.<sup>24</sup> Short-term studies showed similar effects to Chambers, et al.<sup>21,25,26</sup> Ingestion of a 5 g inulin-based soluble fiber preload before both *ad libitum* breakfast and lunch meals reduced total daily EI in adults 18-65 years old by 55 kcal when taken with either a Yerba-Mate supplement or water, compared to placebo or only water.<sup>25</sup> Perrigue, et al. showed that high-energy-dense and low-energy-dense yogurts with a 6 g inulin consumed as a preload reduced hunger, suppressed appetite, and significantly reduced EI at a test meal in young adults compared to the water preload.<sup>26</sup> Lastly, Karalus, et al. demonstrated that consuming a chocolate bar with 10 g inulin for dinner and breakfast the following day reduced calorie intake in young adults by 21 kcal at an *ad libitum* lunch consisting of pizza.<sup>21</sup>

Results from studies investigating the chronic and acute effect of ITFs on hunger and satiety may be conflicting, depending on the source, dosage, the chain lengths, and time for completing the fermentation process, as demonstrated *in vitro*.<sup>27</sup> Short-chain ITFs are fermented quicker,<sup>27,28</sup> and therefore may have more impact on acute satiety, hunger, and EI.<sup>20</sup> In investigations involving inulin,<sup>21,25</sup> fermentation was measured up to 6 hours post-ingestion which does not provide sufficient information about its effect on EI due to incomplete fermentation, which is the case in studies with other ITFs.<sup>20,21</sup> *In vitro* studies have demonstrated that short-chain fatty acid production progresses over time, with the highest levels formed at 8-12 hours for short-chain inulin<sup>27</sup> and 24 hours for long-chain inulin.<sup>29,30</sup> Therefore, the effect of inulin ingestion on satiety, hunger, and EI may be more pronounced after those periods of time. Studies in this area have included populations with a wide age and BMI range, however, none have focused specifically on older adults, who may have age-related alterations in gastrointestinal physiology resulting in delayed gastric emptying.<sup>31</sup> Thus, the specific aims of this study are to investigate:

1. The influence of an inulin preload (10 g, mixed into 500 ml water) on *ad libitum* EI at test meals at 10 h and 24 h post ingestion, in overweight and obese middle aged and older adults. We hypothesize that the inulin preload will decrease EI in this population at these time points, when compared to a water-only preload (500 ml).
2. The influence of an inulin preload (10 g, mixed into 500 ml water) on hunger and fullness sensations at 10 h and 24 h post ingestion in overweight and obese middle aged and older adults. We hypothesize that the inulin preload will decrease hunger sensations and increase fullness sensations at these time points, when compared to a water-only preload (500 ml).

If the study outcomes support our hypotheses, this strategy could be used to reduce food and energy (i.e. kcal) consumption, and possibly reduce body weight over time, in overweight and obese middle aged and older adults.

**Table 1. Literature summary\***

Authors	Population	Study type/design; Duration; Fiber type	Dosage/Administration	Measurements	Results
Parnell, Reimer (18)	n=21 experimental, 18 control 20-70 yo BMI >25	Double-blind, randomized, placebo-controlled, parallel  12 weeks  Oligofructose	3x 7g oligofructose (21g/d, 31.5kcal/d) Maltodextrin (31.5kcal/d) (control) in 250 mL drink before meals	BW, every 3 wks Body composition (DEXA); pre, post EI (3d-food diary), every 3 wks Hunger, satiety (VAS); pre, post	<b>BW/composition:</b> significant wt loss (body fat mass) in OFS group <b>EI:</b> 29% less kcal intake by week 6 (significant) <b>VAS:</b> no effect
Cani, et al. (19)	n=10 (5m, 5f) 21-39 yo BMI 18.5-27.4	single-blind, randomized, placebo-controlled, crossover  2 weeks w/ 2 weeks washout  Oligofructose (OFS)	2x 8g OFS (16g/d) 2x 8g dextrin maltose (DM)  w/ bfast and dinner; subjects prepared their own meals	Food diary (daily) Satiety, hunger, fullness, PFC (VAS) (at pre and post-test meals)	<b>EI:</b> 5-10% significantly lower in OFS than DM at final test meal <b>VAS:</b> significantly increased satiety after breakfast and dinner in OFS. Reduced hunger, PFC after dinner.
Hess, et al. (20)	n=20 (10m, 10f) 18-64yo BMI 18-27	double-blind, crossover  acute (24 hours)  short-chain FOS (scFOS)	2x 0 g, 5 g, or 8 g scFOS. 1 <sup>st</sup> dose w/ hot cocoa beverage + fixed breakfast. <i>Ad lib</i> lunch 4h after breakfast. 2 <sup>nd</sup> dose 3 solid chews 2h prior dinner.	Satiety, hunger (VAS), 0-240min EI (24 h) Fermentation (breath hydrogen); 0, 240min	<b>Satiety, hunger:</b> no effect <b>EI:</b> over the remainder of the day, 16g/d scFOS decreased food intake in f, but increased food intake in m <b>Fermentation:</b> breath hydrogen increased in a dose-dependent manner
Karalus, et al. (21)	n=22 18-40 yo BMI 18-29	Randomized, crossover; each participant completed five conditions  Acute  High- and low-molecular weight inulin	10 g oligofructose, 10g inulin, 10g soluble corn fiber 10g resistant wheat starch Control w/ chocolate crisp bars (consumed for dinner and breakfast) <i>Ad lib</i> lunch after 3h (pizza)	Hunger, fullness (VAS), at lunch meal EI ( <i>ad lib</i> lunch, 24h recall)	No differences in satiety, hunger, or energy intake <b>EI:</b> reduced by 21kcal at lunch (inulin bar) (not significant)
Chambers, et al. (16)	n=60 40-65yo BMI 25-40	randomized, double-blind, placebo-controlled, parallel  24 weeks  Inulin	1. 10g/d inulin (control) 2. 10g/d inulin-propionate ester  Mixed in food	EI ( <i>ad lib</i> lunch) Hunger, fullness, desire to eat (VAS) Body composition (MRS)	<b>EI:</b> 4% decrease at wk 24 in inulin-control group (from 678kcal to 645kcal at <i>ad lib</i> lunch) (non-significant) <b>VAS:</b> Trend towards increased fullness, decreased hunger and desire to eat in inulin-control group at wk 24 (non-significant) <b>Body composition:</b> Significant decrease in subcutaneous adipose tissue in inulin group
Guess, et al. (22)	n=32 ≥18 yo BMI 25-35 prediabetic	Double-blind, randomized, placebo-controlled, parallel  18 weeks  Inulin	3x10g inulin (30g/d) 3x10g cellulose (control) (30g/d)	EI ( <i>ad lib</i> meal) Body weight Body composition and distribution (BIA, MRI) Appetite (VAS)  Fermentation (breath hydrogen)	<b>EI:</b> Lower EI in inulin group than control at wk 9 compared to bsl (~270 kcal). No differences at week 18. <b>BW:</b> both groups lost similar amount of wt during wt loss (wk 0-9); inulin group lost more wt in wt maintenance (wk 9-18) (-2.3 ± 0.5% vs -0.6 ± 0.4%, p = 0.012; absolute weight loss: -1.8 ± 0.4 kg vs -0.5 ± 0.3 kg) <b>Body composition:</b> greater fat loss in inulin group at wks 9 and 18 <b>Appetite:</b> lower PFC in inulin group at wk 18. No effect in hunger, desire to eat, and fullness.
Heap, et al. (23)	n=19 females 20-35yo BMI 19-26	Randomized, crossover, preload design  chronic (8 days) 3-wk-washout b/w each preload  Chicory root inulin (DP=10)	<i>8-day consumption:</i> Yogurt + 6g inulin Control yogurt  <i>Lab visits:</i> Yogurt preload 9am → breakfast bar right after → <i>ad lib</i> lunch at noon (pizza)	EI ( <i>ad lib</i> lunch) Hunger, fullness, PFC (VAS); baseline, every 30min for 3 hrs (Days 1 and 8) GI distress (bsl, day 2 and 7)	<b>Desire to eat, PFC:</b> * lower AUC at day 8 at yogurt + inulin (→ inulin consumption associated w/ appetite reduction) <b>EI:</b> no sig. differences b/w conditions <b>GI:</b> no sig. differences b/w conditions

Delavaud, et al. (24)	n=9 males 21yo BMI <25	Latin square design (3x3) Controlled feeding  28 days  Non-starch polysaccharide (NSP) Inulin from chicory root	1. Control diet (22 g of NSP/d); 2. Control + 50g/d sugarbeet fiber 3. Control + 50g/d inulin (total for twice a day; 30g in bread, 20g in liquid; inulin hydrolyzed when making bread so only 22g total)	EE (indirect calorimetry)	Inulin ingestion caused slight but non-significant increases in EE, especially after dinner and during sleep.
Harrold, et al. (25)	n=58 females 18-65yo BMI 18.5-29.9	Double-blind, placebo controlled, crossover  Acute  Inulin-based soluble fermentable fiber (SFF) from chicory root	15min before meals: 1. YGD (3 tablets) + SFF (5g in 100ml water) 2. YGD (3 tablets) + water (100ml) 3. SFF + placebo (3 tablets) 4. water + placebo (3 tablets)  fixed-load breakfast w/ preload followed by <i>ad lib</i> lunch w/ the same preload 4h later)  <i>Placebo kcal not matched with SFF kcal.</i>	Appetite (VAS), up to 8h after the first dose EI ( <i>ad lib</i> lunch)	<b>EI:</b> Significant reductions in food intake (g, kcal) and EI when YGD present or SFF present. Significant main effect of SFF on gram and kcal intake at lunch, and total daily EI. A reduction of 31.9g (9.1%), 80kcal (11.7%), and 55kcal (4.7%) when SFF present (YGD + SFF, SFF + water) compared to when SFF absent.  Trend towards lower g, kcal, and total kcal intake in SFF + water when compared to control.
Perrigue, et al. (26)	n= 38 (18m, 20f) 18-35yo BMI 18-30	Randomized, crossover, preload design; each participant completed six conditions  Acute 1wk washout b/w each ingestion  Inulin added by the manufacturer (Yoplait)	High E dense yogurt + 6g inulin High E dense yogurt Low E dense yogurt + 6g inulin Low E dense yogurt OJ (equicaloric, equivolume to low-E d y) No beverage  Breakfast bar 8am → treatment 10am → <i>ad lib</i> lunch 2h after	EI ( <i>ad lib</i> lunch)  Hunger, fullness, thirst, nausea, desire to eat (VAS); baseline, every 20min	<b>EI:</b> both HED preloads and LED + inulin significantly reduced EI compared to no beverage <b>Hunger, desire to eat:</b> all preloads significantly reduced hunger. Both HED and LED + inulin significantly reduced desire to eat compared to OJ <b>Appetite:</b> HED (both w/ & w/o inulin) significantly suppressed appetite compared to LED w/o inulin. LED yogurt+ inulin significantly suppressed appetite compared to OJ and LED. <b>Satiety:</b> The satiating power of LED + inulin was comparable to that of HED, all significantly higher than LED w/o inulin

\*Abbreviations:

BW = body weight

BIA = bioelectrical impedance

EI = energy intake

VAS = visual analog scale

PFC = prospective food consumption

EE = energy expenditure

YGD = Yerba Mate, Guarana and Damiana supplement

HED = high-energy density yogurt

LED = low-energy density yogurt

OJ = orange juice

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## CHAPTER 2: Influence of pre-meal inulin consumption on energy intake in overweight and obese middle-aged and older adults: a pilot study

### ABSTRACT

The prevalence of overweight and obesity among adults older than 55 years is 71-76%, putting them at risk for premature death as a result of chronic diseases, decreased mobility, and increased rate of falls. Strategies for obesity treatment and weight management are needed, especially those effective in middle-aged and older adult populations. Research related to prebiotics, and specifically inulin-type fructans (ITF) including inulin, oligosaccharides, and fructooligosaccharides (FOS) shows potential benefits of ITF consumption for weight loss and weight management. This randomized controlled pilot study investigated the acute effects of inulin consumption on 24-hour energy intake (EI) and appetite sensations. Seven sedentary, overweight or obese middle-aged and older adults ( $60.9 \pm 4.4$  years, BMI  $32.9 \pm 4.3$  kg/m<sup>2</sup>) were recruited, and each completed two test conditions in a randomly assigned order. Participants were given either inulin (10 g, mixed into 500 ml water) or a water preload (500 ml) before breakfast the morning of each period after which their *ad libitum* EI, appetite sensations, and gastrointestinal side effects were monitored at each meal for the remainder of the day (lunch, dinner) and at breakfast the following day. No differences in EI, gram weight of food eaten, or energy density were noted between conditions (all  $p > 0.05$ ). However, differences were noted among subgroups in the sample. Females, high habitual fiber consumers, and subjects with higher cognitive dietary restraint had a greater absolute difference in EI between conditions with a lower EI noted in the inulin condition ( $390 \pm 124$  kcal,  $424 \pm 245$  kcal, and  $424 \pm 245$  kcal mean difference among subgroups,  $p < 0.05$ , respectively). Greater relative EI difference was also noted in participants with lower BMI in the inulin condition ( $-9 \pm 14\%$ ;  $21 \pm 8\%$  mean difference,  $p < 0.05$ ). These results suggest there is a potential gender difference, as well as differences in individual response to inulin consumption. Future research focusing on gender differences and differences among individuals in cognitive restraint and gut microbiota is needed to investigate effects of various inulin doses on EI as a possible weight management strategy.

## INTRODUCTION

Seventy-one to 76% of US adults over 55 years old are overweight or obese,<sup>1</sup> and the numbers continue to rise.<sup>2,3</sup> Overweight and obesity are associated with a spectrum of comorbidities,<sup>4</sup> higher medical expenses,<sup>5</sup> decreased mobility,<sup>6</sup> and the rate of falls in the elderly,<sup>7</sup> all of which can result in premature death. Therefore, strategies for the prevention and treatment of overweight and obesity, particularly among older adults, are needed.

The prebiotic inulin, a member of inulin-type fructans (ITF), has beneficial properties on metabolism<sup>8</sup> and specifically gut microbiota<sup>9</sup> with minimal gastrointestinal (GI) disturbances. For these reasons, inulin has recently garnered attention in the area of weight management research. Short-chain fatty acids (SCFA) produced upon the fermentation of inulin in the colon, stimulate production of glucagon like peptide-1 (GLP-1) and peptide YY (PYY), anorectic gut hormones that influence food intake.<sup>10</sup> Inulin also increases the viscosity of the solution in which it is being dissolved,<sup>11</sup> potentially influencing EI, as well. Due to inconsistency in the ITF nomenclature, the following definitions will be used for the purposes of this study: long-chain inulin is a linear fructan with degree of polymerization (DP) 10-60, whereas short-chain inulin (oligofructose) has DP of 2-9.

Chronic oligofructose and inulin consumption may decrease body weight<sup>12,13</sup> and adiposity,<sup>11,13</sup> and decrease<sup>12-14</sup> or not change<sup>11,15</sup> energy intake (EI). Acute trials also report conflicting effects on EI.<sup>16-18</sup> Findings related to appetite sensations (hunger, satiety, prospective food consumption) have also varied across both chronic and acute studies. Mixed results of these investigations may be attributed to varying inulin doses and different means of inulin administration, as well as to wide age and BMI ranges in the samples studied. Research on inulin and weight management is particularly scarce in specific populations such as middle-aged and



older adults, who may also have an age-related reduction in gastric emptying rate.<sup>19</sup> In this pilot study, we hypothesized that pre-meal inulin consumption would suppress appetite and decrease EI in overweight and obese middle-aged and older adults, and therefore represent a potential weight management strategy.

## **METHODS**

### ***Participants***

The study was designed based upon our prior work in older adults.<sup>20,21</sup> Overweight or obese (BMI 25-40 kg/m<sup>2</sup>), sedentary or minimally active older adults (Godin Leisure-Time Exercise Questionnaire,<sup>22</sup>  $\leq 120$  min/wk of mild activity), 50-75 years of age were recruited. Subjects were initially screened via online survey, and later via more extensive health history questionnaire. Exclusion criteria included current history of unstable coronary heart disease (resting or exertional chest pain or heart failure), thyroid disease, diabetes, inflammatory bowel diseases, food allergies or restrained eating, as assessed via questionnaire (Three Factor Eating Questionnaire,<sup>23</sup> cognitive dietary restraint score  $>11$ ) that would compromise the study or the health of the subject. To be eligible, individuals could not currently be consuming fiber supplements. Participant's habitual dietary intake was assessed through a 24-hour food recall and a three-day food diary. All subjects provided informed consent approved by Institutional Review Board at Virginia Tech prior to enrollment, but they were not aware of the specific purpose of the study.

### ***Procedures***

Subjects were randomized, in a double-blind crossover design, to consume a preload of either 10 g of short-chain chicory inulin (Frutafit IQ, DP 9-12) mixed into 500 ml water, or 500 ml plain water. Preload volumes were determined based upon the previous studies in older adults

done by this research group.<sup>20</sup> The inulin dose was determined based upon the existing research on inulin tolerability in adults.<sup>24</sup> Preloads were given to participants 30 minutes before an *ad libitum* breakfast (breakfast 1), followed by an *ad libitum* lunch (4 hours post ingestion) and an *ad libitum* dinner (10 hours post ingestion) the same day. Another *ad libitum* breakfast (breakfast 2) was provided 24 hours following the preload consumption. After a one week washout period, the second 24-hour testing period followed the same procedures, except the participants went through the other preload condition. Due to non-viscousness of inulin, the mixed drink appeared and tasted identical to plain water, which served as the control. Meal testing times were 8 am for breakfast meals and 6 pm for dinner in the Wallace Dining Laboratory, whereas lunch meals were provided to participants in coolers to consume outside of the laboratory at noon. Subjects had 30 minutes at each meal to consume as much or as little food as they wanted. (See Figure 1.)

### ***Measurements***

Height and weight were measured without shoes using a wall-mounted stadiometer (Seca GmbH & Co. KG, 216) and a digital scale (Scale-Tronix, 5002, Wheaton, IL, to the nearest 0.1 kg), respectively. Body mass index was calculated as weight (kg) divided by height (m)<sup>2</sup>. Body weight was measured at the initial visit and before each breakfast test meal to insure weight stability. Habitual fiber and overall dietary intake was determined over four days by using a self-reported 24-hour-food recall and a 3-day-food diary. Energy, macronutrient, and fiber intake were assessed using nutritional analysis software (NDS-R 2014, 2014, University of Minnesota, Minneapolis). Habitual physical activity was recorded using Godin Leisure-Time Exercise Questionnaire<sup>22</sup> as minutes per week spent doing mild, moderate or vigorous physical activity. Participants were also asked to wear an accelerometer (Actigraph GT3X+) for 24 hours during each study period, to insure their physical activity levels were consistent on each testing day.

Participants were instructed to keep their physical activity at habitual levels the day prior each study period for the same reason.

Participants were provided with all foods and beverages for each 24-hour testing period. Food items offered at test meals were weighed (Sartorius Practum 5101-1S, Goettingen, Germany) to the nearest 0.1 g before and after consumption (covertly) to calculate subjects' gram weight of food consumed, EI, and energy density (kcal/gram weight of food). Visual analog scales<sup>25</sup> (VAS) reflecting prospective consumption, hunger, fullness, and thirst, were completed at the *ad libitum* breakfast and dinner meals. (See Appendix B). The VAS consists of questions such as “How hungry are you?” and subjects were asked to mark a 100-mm line corresponding to the position between “not at all hungry” and “extremely hungry” scale. The VAS were completed just prior to the preload consumption before breakfast 1 (0 min), before the meal is served (30 min), after the meal (60 min), and every 30 minutes thereafter up to 150 minutes. VAS at dinner and breakfast 2 started prior to serving the meals (0 min), and continued after the meal consumption (30 min), following the same 30-minute interval pattern up to 150 minutes.

Participants filled out Sensory Evaluation Form after the preload ingestion, asking to rate the taste, smell, appearance, texture, and overall acceptability of the preload on a scale from 1 (“dislike extremely”) to 9 (“like extremely”) (See Appendix B). Subjects completed the GI side effects questionnaire prior to breakfast and dinner meals to assess GI tolerance and any discomfort associated with preload consumption (See Appendix B). They rated potentially occurring side effects (bloating, flatulence, diarrhea, constipation, rumbling, nausea, and cramping) on a scale from 0 (“none”) to 3 (“severe”). At their final visit, subjects filled out Debriefing Questionnaire to determine if they were aware of which preload they were given on each occasion (See Appendix B).

### ***Ad libitum Test Meals***

Test meals were evaluated for palatability prior to the beginning the study. The energy content of the offered meals was 1876-1931 kcal (41-54% carbohydrates, 12-16% protein, 32-45% fat). Meals consisted of food items typical for an American diet (*See Appendix B*). Breakfast items included bagels, bread, sausage, cheese sticks, butter, cream cheese, peanut butter, jelly, cereal bars, yogurt, bananas, sugar, cream, coffee or tea, milk, orange juice, and water. Lunch items were prepared by research staff and provided in coolers for participants to bring with them and consume at a designated time. These items included bread, deli meat, cheese, cheese sticks, potato chips, cookies, cereal bar, pudding, applesauce, lettuce, carrots, mustard, mayo, ranch dressing, orange juice, and water. Dinner meals consisted of two entrees (meat lasagna and spaghetti with meat sauce), bread, cucumbers, carrots, cookies, pudding, fruit cups, ranch dressing, butter, milk, orange juice, and water. At each meal, participants were asked to self-select offered items and consume them over a 30-minute-period. They were able to consume water in *ad libitum* amounts throughout the day. Meals were offered in the same manner, under the same temperature, at the same location in every testing period. Foods were weighed ( $\pm 0.1$  g) before being served and again upon finishing the meal (covertly) to determine the amount consumed. Meal energy and macronutrient intake was calculated using nutritional analysis software (NDS-R 2014, 2014, University of Minnesota, Minneapolis).

The inulin supplement in powder form (10 g) was mixed into cold tap water. Its solubility in cold water was tested prior to the start of the study. Both plain water used as a control treatment, and the inulin in water preload were served chilled (1-3°C).

### ***Statistical Analysis***

Statistical analyses were performed using SPSS statistical analysis software (v23.0, IBM SPSS, 2015, Chicago, IL). Descriptive statistics (mean  $\pm$  standard deviation (SD) and frequencies) were assessed for subject demographic characteristics and habitual mean fiber intake and total habitual calorie intake. Paired sample *t* tests were assessed to compare EI, gram weight of food consumed, and energy density (kcal/gram weight of food) at each meal of the two 24-hour periods, over the course of the day (three meals), as well as over each 24-hour period overall. Independent sample *t* tests were used to assess potential sex differences in absolute and relative change in meal EI, as well as possible differences between fiber consumers and non-consumers (defined as those with a habitual fiber intake above and below the mean grams of fiber consumed in the sample). Repeated measures ANOVA were assessed to compare VAS and GI distress ratings between the two preload conditions. Associations among variables were assessed by simple correlational analyses (Pearson *r*). The  $\alpha$  level was set a priori at  $P < 0.05$ .

## **RESULTS**

### ***Participants***

Out of twenty-one individuals that completed an online pre-screening survey, seven (five female, two male; all Caucasians) were enrolled in the study after determination of eligibility. Major reasons for exclusion were food allergies (two individuals), vegetarianism (one individual), age (one individual), high physical activity levels (two individuals), high cognitive dietary restraint (two individuals), unstable weight in the past six months (one individual), and personal reasons (five individuals). Descriptive characteristics of eligible participants are reported in Table 2.

### ***Body Weight***

Body weight did not differ on days 1 and 2 of each condition (inulin:  $90.0 \pm 20.5$  kg vs.  $89.0 \pm 18.8$  kg,  $p=0.400$ , control:  $89.4 \pm 18.9$  kg vs.  $89.4 \pm 18.9$  kg,  $p=0.754$ ), nor did it differ across the two testing conditions ( $90.0 \pm 20.5$  kg vs.  $89.4 \pm 18.9$  kg,  $p=0.607$ ).

### ***Physical Activity***

Participants kept their physical activity at similar levels over both testing periods, with the exception in the amount of light physical activity (21 min difference,  $p=0.011$ ) (Table 3.)

### ***Energy Intake at Test Meals***

There were no differences in EI, gram weight of food, and energy density of food consumed at each meal, over the course of the day, and over the course of 24 hours (entire condition) between conditions (Table 4). However, differences between several subgroups were noted.

### ***Gender and Weight Subgroup***

Male participants ( $n=2$ ) consumed significantly more weight of food during entire inulin condition compared to the control condition (inulin:  $5787 \pm 1170$  g, control:  $5559 \pm 1177$  g,  $p=0.013$ ). Females ( $n=5$ ) demonstrated lower EI over the course of the day than males following the inulin preload compared to control (females:  $-97 \pm 258$  kcal, males:  $293 \pm 66$  kcal,  $p=0.027$ ). Participants with lower BMI ( $<32$  kg/m<sup>2</sup>,  $n=3$ ) had a higher EI at lunch in the inulin condition compared to control (inulin:  $723 \pm 68$  kcal, control:  $675 \pm 72$  kcal,  $p=0.007$ ), and consumed less gram weight of food at breakfast 2 (inulin:  $697 \pm 30$  g, control:  $1020 \pm 151$  g,  $p=0.049$ ). The same group of participants also demonstrated greater relative EI difference than participants in the higher BMI category ( $>32$  kg/m<sup>2</sup>,  $n=4$ ) at the dinner meal in the inulin condition ( $-9 \pm 14\%$ ;  $21 \pm 8\%$  mean difference,  $p=0.046$ ).

### *Eating Behavior Subgroups*

Lower-fiber consumers (<17 g/d, n=4) and subjects with lower cognitive restraint score (<6, n=4) had a higher EI over the course of the day during the inulin condition than control (inulin: 3218 ± 1138 kcal, control: 3022 ± 1029 kcal,  $p=0.045$ ), as well as a higher gram weight of food consumed at the dinner meal (inulin: 1619 ± 319 g, control: 1447 ± 252 g,  $p=0.043$ ). Higher fiber consumers (>17 g/d, n=3) and participants with higher cognitive restraint scores (>6, n=3) demonstrated a greater absolute EI difference over the course of the day compared to lower-fiber consumers and participants with lower cognitive restraint scores, between inulin and control condition (higher-fiber: -228 ± 262 kcal, lower-fiber: 196 ± 118 kcal; 424 ± 145 kcal mean difference,  $p=0.032$ ).

### *Appetite Sensations*

A significant time effect was detected in hunger (all  $p<0.005$ ) and fullness (all  $p<0.001$ ) sensations at each meal (Figure 2). As expected, hunger decreased upon finishing each meal, whereas satiety increased. There was no significant difference in ratings of nausea at any meal, nor in changes in hunger, fullness and nausea ratings between conditions.

### *GI Side Effects*

A time effect in each condition was present in ratings for gas/bloating ( $p=0.005$ ), flatulence ( $p=0.009$ ), and constipation ( $p=0.049$ ) (Figure 3), as the symptoms progressively increased throughout the day and peaking at dinner time (gas/bloating, flatulence) and at the breakfast 2 meal (constipation). Diarrhea, nausea, and rumbling ratings showed no effect in changes over time. None of the item ratings were significantly different between conditions, except increased rumbling in the inulin condition ( $p=0.048$ ).

### ***Sensory Evaluation***

There were no significant differences in appearance, taste, texture, smell, and overall evaluation of the preloads between conditions. The means of each variable participants rated ranged from  $4.9 \pm 0.4$  (smell) to  $6.4 \pm 1.6$  (texture), on a scale where 4 indicates “dislike slightly”, 5 “neither like nor dislike”, and 6 “like slightly”.

### ***Debriefing Questionnaire***

Four participants correctly assumed which preload they were given in each condition based on gas and bloating (n=3), and hunger and fullness (n=2) cues. Three participants reported no awareness of differences between given preloads in either condition.

## **DISCUSSION**

Overall these findings do not suggest that pre-meal ingestion of inulin mixed into water reduces EI, energy density, or weight of food consumed at any meal, over the course of the day, nor over 24 hours. This study supports the results of Karalus, et al., in which participants’ EI was monitored for 15 hours post inulin ingestion and finished with a self-reported EI over the next nine hours to conclude a 24-hour testing period.<sup>16</sup> However, subgroup differences were observed in the present study. A greater absolute change in EI among females than men between the inulin and control conditions implied there may be a gender difference in EI consumed between conditions, as observed by Hess, et al.<sup>26</sup> Greater EI and gram weight of food consumed observed in some subgroups could be attributed to a tendency to consume higher amounts of food when a larger energy content and volume of meals is provided,<sup>27</sup> as it was with these buffet-style meals compared to habitual daily meals. Obesity has been linked to dysbiosis in gut microbiome<sup>28</sup> which can be induced by diets higher in fat, such as Western diet,<sup>29</sup> thus variations among subgroup responses



to inulin consumption could also be attributed to differences in GI microbiota. For example, greater absolute EI difference over the course of the day between the two conditions was observed among higher habitual fiber consumers compared to lower-fiber consumers. Similarly, participants with a lower BMI consumed less gram weight of food at breakfast 2 in the inulin condition compared to control, and have also demonstrated greater relative EI difference between conditions at the dinner meals than participants with higher BMI. Additionally, participants with a higher cognitive restraint score (i.e., the higher end of the normal range of cognitive restraint) may be more in tune with their physiological responses to preload ingestion and food intake, and thus appetite sensations, resulting in greater absolute EI difference over the course of the day compared to participants with lower cognitive restraint scores. Strong positive correlations between the habitual dietary fiber intake and dietary restraint score indicate it is difficult to determine the exact predictor of the EI difference between the two conditions ( $r=0.755$ ,  $p=0.05$ ). Finally, it is possible that the volume of the preload itself had an impact on EI in participants, and overshadowed any possible difference with the addition of inulin, as the reduction in EI after the ingestion of 500 ml water preload was noted in obese older adults in our previous study.<sup>20</sup>

Appetite sensations did not differ between conditions, suggesting that 24 hours is not enough for inulin to elicit a reduction in perceived appetite. These outcomes support the results of a systematic review by Wanders, et al., that in only 14% of cases less viscous fiber (e.g. inulin) reduced appetite in preload-design studies (1.3% over 4 hours at a dose of 8.4 g).<sup>30</sup> Acute studies showing lower EI with inulin supplementation<sup>17,18</sup> utilized Yerba Mate, Guarana and Damiana, and yogurts as means of inulin administration, which itself can increase satiety and slow gastric emptying.<sup>31,32</sup> On the contrary, long-term ingestion of inulin or oligofructose seems to suppress appetite,<sup>10,13,14</sup> suggesting a cumulative effect of ITFs on appetite sensations. In addition, the effect

of acute inulin consumption on appetite suppression might have not been detected if slower rate of gastric emptying is already present in the older adult population. GI side effects did not change between conditions, with the exception of slightly increased rumbling noted in the inulin condition. However, GI side effects are likely to subside with adaptation, as reported in long-term studies.<sup>12,14</sup> In addition, participants reported being indifferent or slightly liking both preloads. These results imply that a 10 g dose of inulin is palatable and well tolerated, supporting the results of Bonnema, et al.,<sup>24</sup> and further establishing tolerability in a middle-aged and older population.

### *Limitations*

A small number of participants included in the study limits the statistical power. The present study was powered to detect an 1802 kcal difference between the two conditions ( $n=7$ , SD between the two conditions = 1000 kcal,  $1-\beta=0.8$ ,  $p=0.05$ ). In order to detect 200 kcal difference ( $1-\beta=0.8$ ,  $p=0.05$ ), 395 subjects would be needed. However, the obtained outcomes are consistent with the results of other acute studies,<sup>16-18</sup> questioning the need for a study with a larger sample size. Additionally, due to the noninvasive nature of this study, increased gut hormone levels and peaks of inulin fermentation are only assumed based on previous research.<sup>10,33-35</sup> Even though peaks of inulin fermentation were targeted by carefully timed meals (4, 10, 24 hours), it did not allow us to specifically target a time point at which fermentation was the highest and food consumption potentially the lowest. To control for the possible effect of solely water preload on EI and appetite, a control condition in which participants would receive no preload could have been included in the study design. Furthermore, it is also possible that food intake and activities of daily living on the day prior to each test day impacted energy consumption during test meals, however the randomized crossover design controls for these limitations. To our knowledge, this is

the first study investigating EI upon acute inulin consumption in overweight and obese middle-aged and older adults.

## **CONCLUSION**

Although these findings suggest no overall differences in energy intake following inulin consumption, the subgroup findings imply that there may be differences in metabolic responses to pre-meal inulin consumption on the individual level. As microbiota research is expanding, inulin should continue to be evaluated from future investigations, due to other potential health benefits. Future research should focus on investigating the effects of inulin supplementation on EI administering a higher inulin dose and utilizing more invasive methods, such as hydrogen breath test, blood samples, and stool samples.

## TABLES

Table 2. Participant descriptive characteristics (n=7)

	<b>Mean±SD</b>	<b>Range</b>
<b>Age (yrs)</b>	60.9 ± 4.4	55 - 67
<b>Height (cm)</b>	163.5 ± 6.8	153 - 174
<b>Weight (kg)</b>	88.7 ± 18.0	65.5 – 112.3
<b>BMI (kg/m<sup>2</sup>)</b>	32.9 ± 4.3	26.2 - 38.3
<b>Cognitive dietary restraint (TFEQ)</b>	6.3 ± 2.6	4 - 11
<b>Physical activity (min/wk)<sup>a</sup>:</b>		
<b>Mild</b>	36 ± 38	0 – 105
<b>Moderate</b>	6 ± 8	0 - 15
<b>Self-reported dietary intake:</b>		
<b>Energy (kcal)</b>	1876 ± 479	1419 – 2741
<b>Energy density (g/kcal)</b>	0.733 ± 0.262	0.409 – 1.193
<b>Carbohydrates (%)</b>	42 ± 6	33 – 50
<b>Protein (%)</b>	16 ± 2	14 – 20
<b>Fat (%)</b>	37 ± 8	28 – 47
<b>Fiber (g)</b>	18 ± 9	10 – 34
<b>Soluble (g)</b>	7 ± 3	4– 11
<b>Insoluble (g)</b>	11 ± 7	5 – 24
<b>Water (mL), as beverage</b>	40 ± 43	0 – 123

<sup>a</sup>Assessed using Godin Leisure Time Physical Activity Questionnaire.

Table 3. Physical activity during the two test conditions<sup>b</sup>

<b>Physical activity (min)</b>	<b>Inulin + water preload</b>	<b>Water preload</b>	<b>p-value</b>
<b>Sedentary</b>	902 ± 79	886 ± 90	0.775
<b>Light</b>	134 ± 31	155 ± 29	0.011
<b>Moderate</b>	25 ± 10	33 ± 18	0.391
<b>Strenuous</b>	0.3 ± 0.4	0.4 ± 0.3	0.302
<b>Steps</b>	5044 ± 1474	5532 ± 3393	0.716

<sup>b</sup>Determined using accelerometry.

Table 4. Energy intake at test meals

	<b>Inulin + water preload</b>	<b>Water preload</b>	<b><i>p</i>-value</b>
<b>Breakfast 1:</b>			
<b>Energy (kcal)</b>	803 ± 312	750 ± 342	0.358
<b>Weight of food (g)</b>	1149 ± 359	1016 ± 361	0.469
<b>Energy density</b>	0.740 ± 0.316	0.729 ± 0.140	0.929
<b>Lunch:</b>			
<b>Energy (kcal)</b>	948 ± 377	889 ± 317	0.250
<b>Weight of food (g)</b>	1129 ± 291	1078 ± 283	0.113
<b>Energy density</b>	0.853 ± 0.305	0.847 ± 0.281	0.820
<b>Dinner:</b>			
<b>Energy (kcal)</b>	1029 ± 365	983 ± 271	0.426
<b>Weight of food (g)</b>	1328 ± 472	1167 ± 394	0.124
<b>Energy density</b>	0.788 ± 0.119	0.872 ± 0.159	0.152
<b>Day 1 total:</b>			
<b>Energy (kcal)</b>	2636 ± 1087	2622 ± 885	0.900
<b>Weight of food (g)</b>	3606 ± 884	3260 ± 944	0.204
<b>Energy density</b>	0.715 ± 0.148	0.811 ± 0.154	0.317
<b>Breakfast 2:</b>			
<b>Energy (kcal)</b>	745 ± 339	706 ± 312	0.532
<b>Weight of food (g)</b>	857 ± 208	1006 ± 314	0.163
<b>Energy density</b>	0.857 ± 0.241	0.714 ± 0.248	0.262
<b>Condition total:</b>			
<b>Energy (kcal)</b>	3524 ± 1327	3328 ± 1172	0.193
<b>Weight of food (g)</b>	4463 ± 1073	4267 ± 1216	0.548
<b>Energy density</b>	0.774 ± 0.126	0.779 ± 0.129	0.929

**FIGURES**

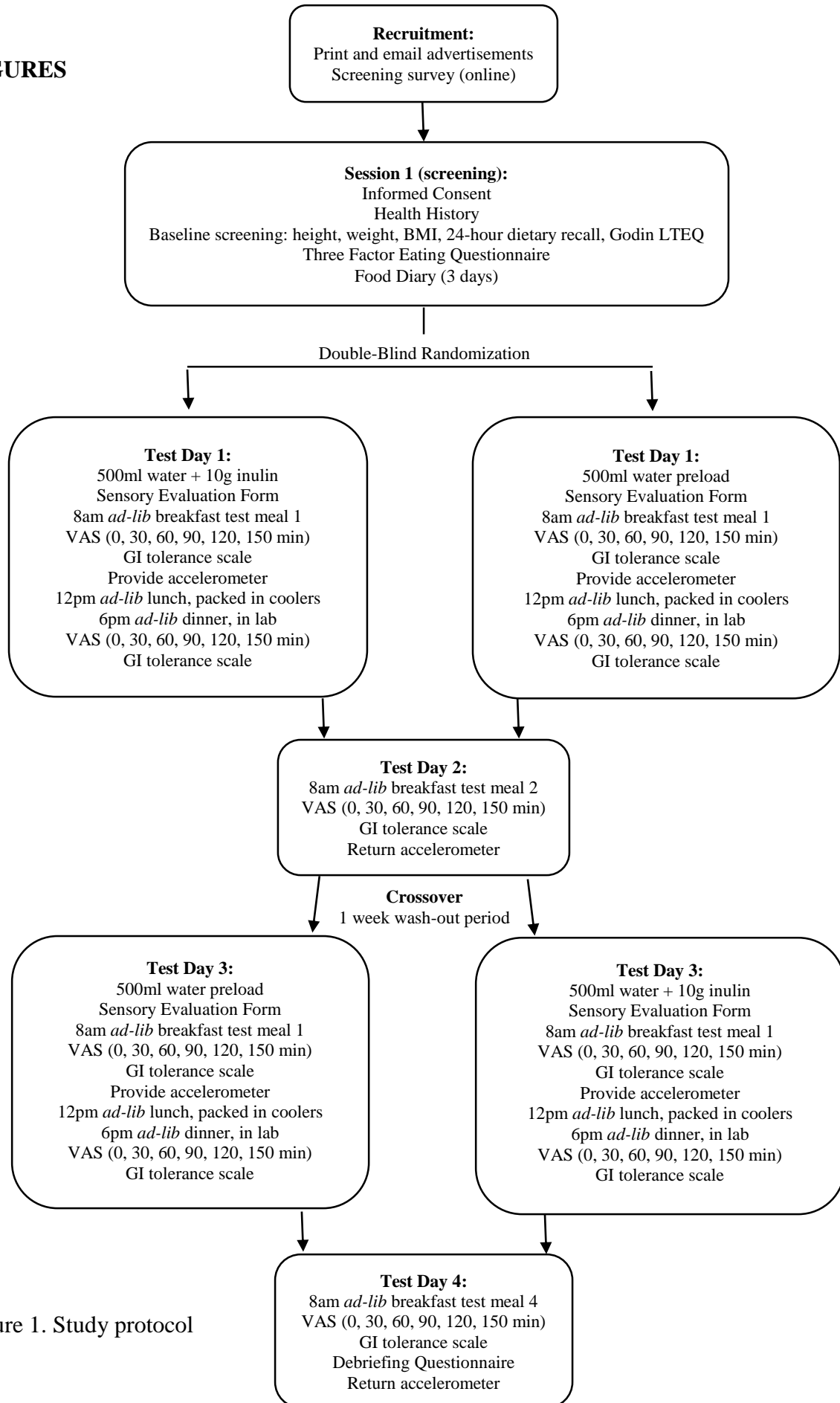


Figure 1. Study protocol

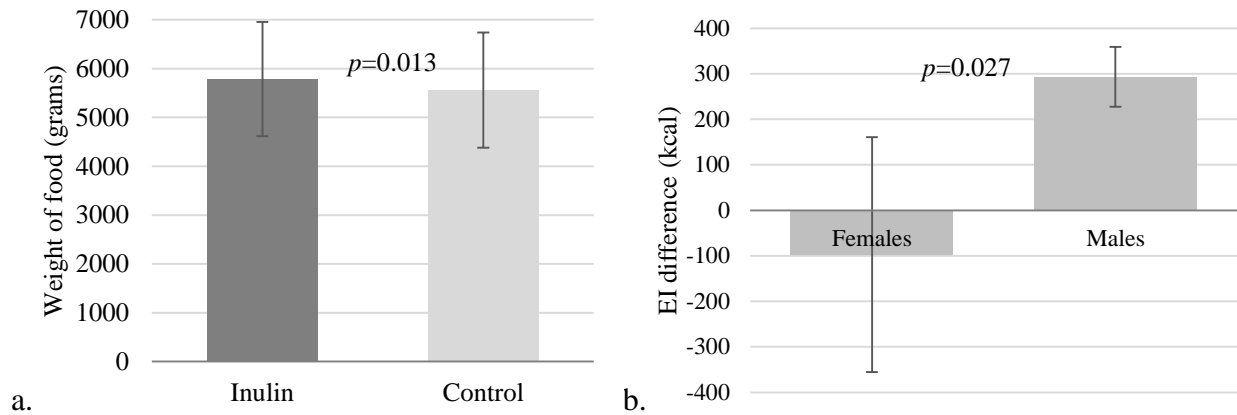


Figure 2. Gender subgroups: a. Gram weight of food consumed over 24 hours by males in 24h; b. EI difference between the inulin and control conditions over three meals in females and males

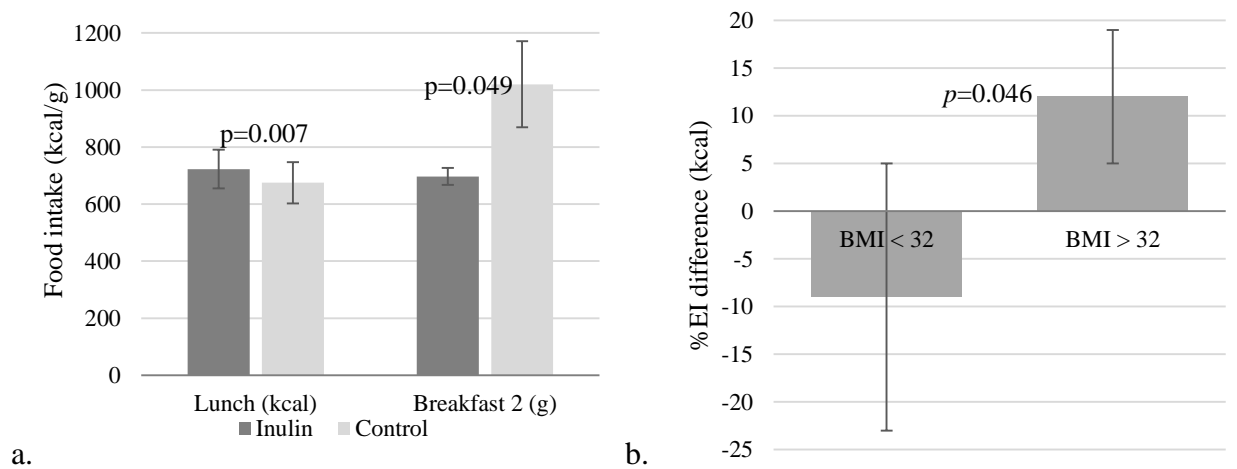


Figure 3. BMI status subgroups: a. Lower BMI group. (<32 kg/m<sup>2</sup>); b. %EI difference between inulin and control conditions at the dinner meal in BMI subgroups

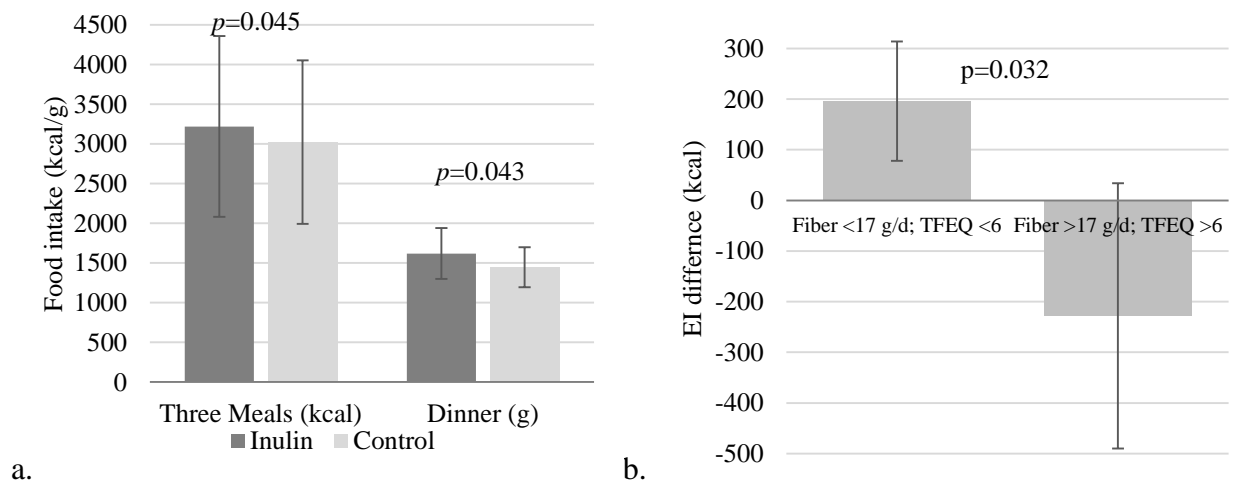


Figure 4. Fiber and cognitive restraint subgroups: a. Lower fiber (<17 g/d); lower cognitive restraint (TFEQ <6); b. EI difference between inulin and control conditions over three meals

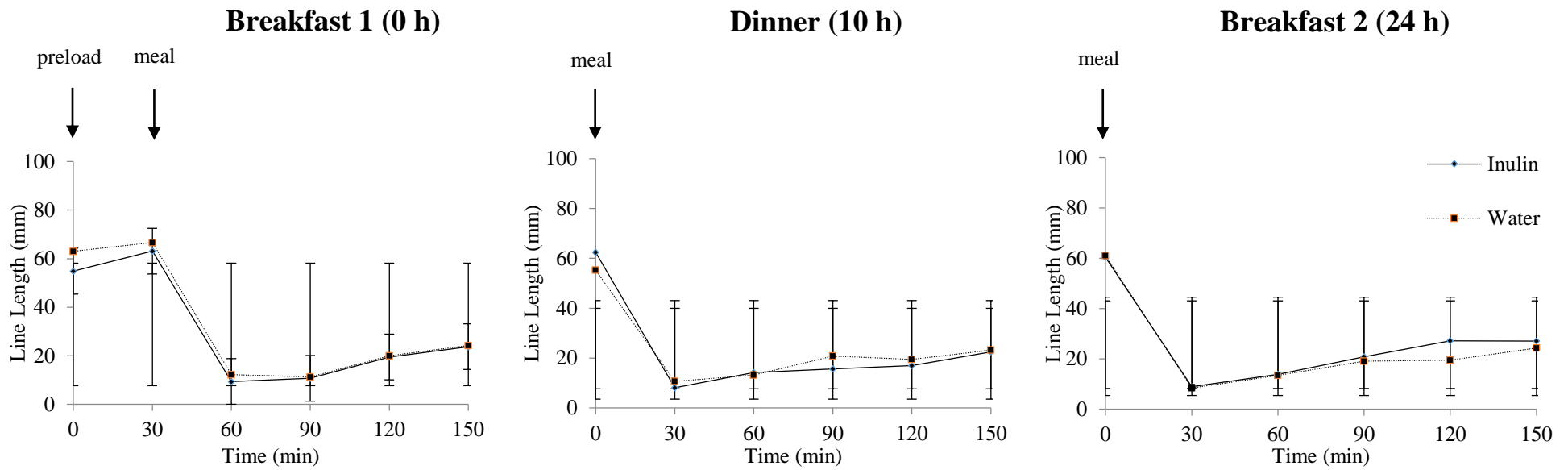


Figure 5. Hunger at each meal (VAS) (mean  $\pm$  SD)

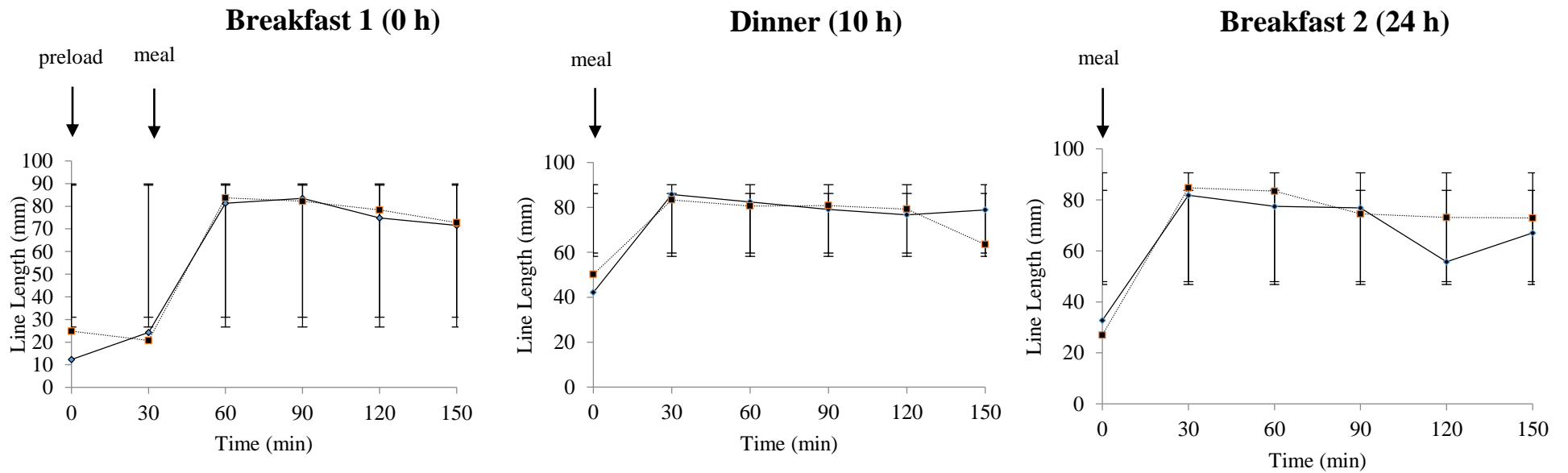


Figure 6. Fullness at each test meal (VAS) (mean  $\pm$  SD)



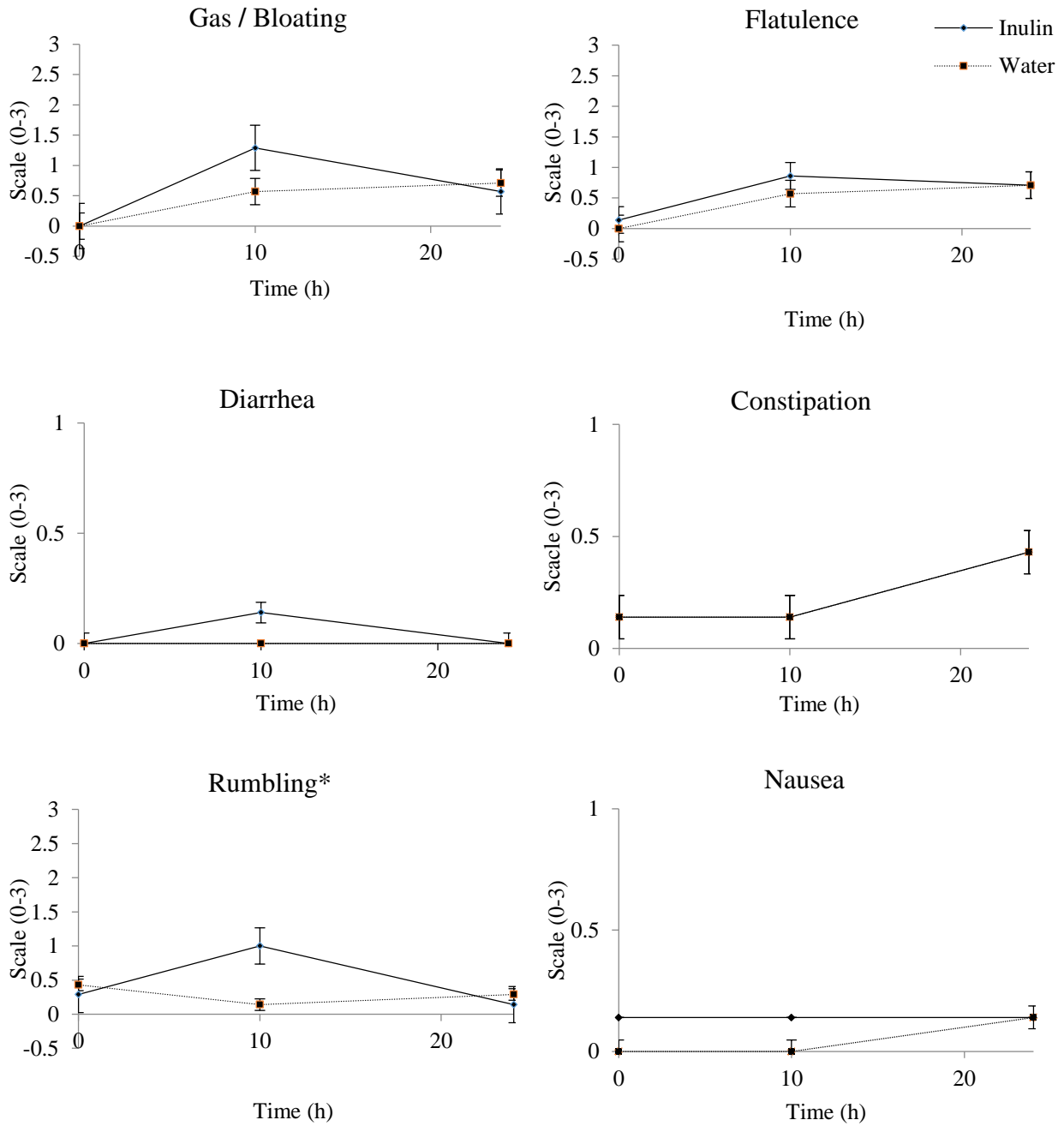


Figure 7. GI side effects ratings at test meals (breakfast 1, 0 h; dinner, 10 h; breakfast 2, 24 h) (mean  $\pm$  SD). \* $p < 0.05$

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### CHAPTER 3: Conclusions and Future Directions

Studies investigating the effect of ITFs on EI and appetite sensations as a possible approach to weight management are limited. Existing research has resulted in mixed outcomes and none has focused on overweight and obese middle-aged and older adults. The results of this pilot study showed no difference in EI between the inulin and water conditions, confirming the results of other acute studies.<sup>1,2</sup> However, differences among subgroups were observed. A greater absolute difference in EI between the two conditions was seen in females, suggesting there may be a gender difference in EI. In addition, EI between conditions differed among subgroups based on habitual fiber consumption and cognitive dietary restraint. These outcomes imply individuals may have different responses to inulin consumption based upon their habitual dietary habits, microbiome profile and degree of awareness of physiological cues with regard to food intake.

Acute effects of ITFs on EI would greatly depend on intestinal transit time, the increase of intestinal bulk, and fermentation time. Fermentation period is positively correlated with ITF chain length,<sup>3,4</sup> and administered dose. The amount of inulin effective in acute reduction of EI and its tolerance has not been established in humans, however animal models imply an equivalent dose of 40-60 g oligofructose/d dietary intake in humans, which is highly unlikely to be achieved and tolerated.<sup>5,6</sup> In contrast, long-term studies report an impact of ITFs on EI,<sup>7-9</sup> suggesting a delayed effect with chronic consumption.<sup>1,2</sup> Concentrations of anorectic gut hormones PYY and GLP-1 were also reported to be higher after prebiotic consumption of at least two weeks.<sup>10</sup> The means of inulin administration should also be accounted for, since, in this particular case, water itself might have had an appetite suppressing effect in older adults.<sup>11</sup> In addition, microbiota evaluation is a rapidly developing area which should also be included in future studies, as microbiota composition has been correlated with weight management.<sup>12</sup> To date, no trials have evaluated stool samples to

associate EI and appetite sensations with potential changes in microbiota,<sup>10,12,13</sup> which is certainly an aspect that should be investigated.

In conclusion, the results of this pilot study largely supported existing research on the acute effects of ITFs on EI. The role of ITFs in weight management is a growing field and their presence is expected in future studies, which should account for variations in gender, cognitive dietary restraint, microbiota profile, and weight status among individuals in all age groups.

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## APPENDIX A: Institutional Review Board Approval



Office of Research Compliance  
Institutional Review Board  
North End Center, Suite 4120, Virginia Tech  
300 Turner Street NW  
Blacksburg, Virginia 24061  
540/231-4606 Fax 540/231-0959  
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### MEMORANDUM

**DATE:** July 22, 2015  
**TO:** Brenda Davy, Kevin Davy, Andrew P Neilson, Katarina Smiljanec  
**FROM:** Virginia Tech Institutional Review Board (FWA00000572, expires April 25, 2018)  
**PROTOCOL TITLE:** Influence of pre-meal inulin consumption on food choices in overweight and obese older adults  
**IRB NUMBER:** 15-725

Effective July 21, 2015, the Virginia Tech Institution Review Board (IRB) Chair, David M Moore, approved the New Application request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at:

<http://www.irb.vt.edu/pages/responsibilities.htm>

(Please review responsibilities before the commencement of your research.)

### PROTOCOL INFORMATION:

Approved As: Expedited, under 45 CFR 46.110 category(ies) 1,4,7  
Protocol Approval Date: July 21, 2015  
Protocol Expiration Date: July 20, 2016  
Continuing Review Due Date\*: July 6, 2016

\*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

### FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

The table on the following page indicates whether grant proposals are related to this IRB protocol, and which of the listed proposals, if any, have been compared to this IRB protocol, if required.

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Date*	OSP Number	Sponsor	Grant Comparison Conducted?

\* Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.

If this IRB protocol is to cover any other grant proposals, please contact the IRB office (irbadmin@vt.edu) immediately.

## APPENDIX B: Questionnaires & Food Items at *Ad Libitum* Meals

### Sensory Evaluation Form

Directions: Check one rating (using an “x”) for each of the following: Appearance, Taste/Flavor, Texture/Consistency, Aroma/Smell, and Overall Acceptability

Rating Scale	Appearance	Taste/Flavor	Texture/ Consistency	Aroma/Smell	Overall Acceptability
9. Like Extremely					
8. Like Very Much					
7. Like Moderately					
6. Like Slightly					
5. Neither Like or Dislike					
4. Dislike Slightly					
3. Dislike Moderately					
2. Dislike Very Much					
1. Dislike Extremely					

## Visual Analog Scales

Directions: Place an “x” on the line to indicate your response:

1. How strong is your desire to eat right now?  
Very strong Very weak  
\_\_\_\_\_
  
2. How hungry do you feel right now?  
Not hungry at all Extremely hungry  
\_\_\_\_\_
  
3. How full do you feel right now?  
Not at all full Extremely full  
\_\_\_\_\_
  
4. How much food do you think you could eat?  
Nothing at all A large amount  
\_\_\_\_\_
  
5. How thirsty do you feel right now?  
Not at all thirsty Extremely thirsty  
\_\_\_\_\_
  
6. How pleasant do you find the food right now?  
Very pleasant Not at all pleasant  
\_\_\_\_\_
  
7. How nauseated do you feel right now?  
Not At all Nauseated Very Nauseated  
\_\_\_\_\_

## GI Tolerance Scale

The following items are intended to help monitor any symptoms you may be experiencing while participating in this study. Please, rank the following items on a scale of 0-3 as honestly and accurately as possible: 0=none 1=mild 2=moderate 3=severe

### Gas/Bloating

0      1      2      3

### Flatulence

0      1      2      3

### Diarrhea

0      1      2      3

### Constipation

0      1      2      3

### GI Rumbling

0      1      2      3

### Nausea

0      1      2      3

### Cramping

0      1      2      3

## Debriefing Questionnaire

The purpose of this questionnaire is to find out if participants were aware of which preload they were given during the study.

1. Do you have an idea which preload you were given during the first 24-hour-study-period, i.e. on Test Day 1? Please circle.

Inulin mixed into water

Plain water

2. What makes you believe you were given that preload?

3. Do you have an idea which preload you were given during the second 24-hour-study-period, i.e. on Test Day 2? Please circle.

Inulin mixed into water

Plain water

4. What makes you believe you were given that preload?

## Food Items at the *Ad libitum* Meals

### Breakfast

Bread  
Bagels  
Turkey sausage  
Cheese sticks  
Yogurt  
Cereal bar  
Bananas  
Butter, peanut butter, jelly,  
cream cheese  
Orange juice, coffee, tea,  
milk (1%), water  
Sugar, cream

### Lunch

Bread  
Deli meat  
Cheese  
Cheese stick  
Potato chips  
Cookies, Pudding,  
Applesauce, Cereal bar  
Lettuce, carrots  
Mustard, mayo, ranch  
Orange juice, water

### Dinner

Bread  
Meat lasagna  
Spaghetti with meatballs  
Animal crackers, Pudding,  
Peach cups  
Cucumbers, carrots  
Butter, ranch  
Orange juice, milk (1%),  
water