Available online at www.sciencedirect.com

ScienceDirect

www.nrjournal.com

Weight gain in college females is not prevented by isoflavone-rich soy protein: a randomized controlled trial

Paige K. Berger[a], *Jessica L. Principe*[a], *Emma M. Laing*[a], *E.C. Henley*[a], *Norman K. Pollock*[b], *Ruth G. Taylor*[a], *Robert M. Blair*[c], *Clifton A. Baile*[a], *Daniel B. Hall*[d], *Richard D. Lewis*[a,*]

[a] *Department of Foods and Nutrition, The University of Georgia, Athens, GA, USA*
[b] *Department of Pediatrics, Georgia Regents University, Augusta, GA, USA*
[c] *Physicians Pharmaceuticals, Inc., Winston-Salem, NC, USA*
[d] *Department of Statistics, The University of Georgia, Athens, GA, USA*

ARTICLE INFO

Article history:
Received 20 May 2013
Revised 17 September 2013
Accepted 18 September 2013

Keywords:
Soybean proteins
Isoflavones
Caseins
Body weight
Collegiate females

ABSTRACT

Human clinical trials targeted at preventing gains in body weight using soy protein and isoflavones are limited to adults and yield conflicting results. We hypothesized that daily intake of soy protein/isoflavones would attenuate gains in body weight to a greater extent than a casein-based control in 18 to 19 year-old females. To test this hypothesis, we conducted a randomized, double blind, placebo-controlled trial over 16 weeks to examine the effects of a soy protein/isoflavone-based meal replacement (experimental group) versus a casein-based meal replacement (control group) on body weight and body composition variables in female college freshmen (N = 120). Fat mass (FM), fat-free soft tissue mass (FFST), and percent body fat (%BF) were measured using dual energy X-ray absorptiometry (DXA; Delphi A). Repeated measures mixed models were used to determine the effects of treatment on anthropometric and body composition variables (body weight, waist circumference, FM, FFST, and %BF). No significant group × time interactions were observed, even when body mass index was controlled for in the analysis. Over 16 weeks, body weight, FM, FFST, and %BF significantly increased in both groups ($P < .05$). Our findings show that female college freshmen gained a significant amount of weight over the course of the 16-week study. Gains in body weight and FM were similar among participants assigned to the soy protein/isoflavone- and the casein-based meal replacements. Future research is warranted to determine the effects of soy protein/isoflavone- and casein-based meal replacements versus a non-intervention (i.e., non-protein based) control.

1. Introduction

The first, or freshman, year of college has been identified as a period of considerable weight gain in late adolescence [1–4]. On average, freshmen males and females gain three to four pounds during the first semester alone [1–3], and approximately 25% of freshmen students are five pounds heavier by the end of their first school year [2,4]. Excessive weight gain in late adolescence may lead to overweight and obesity in adulthood, placing adolescents at risk for metabolic complications later in

Abbreviations: SOY, soy protein/isoflavone-group; CAS, casein-based group; %BF, body fat percentage; FM, fat mass; FFST, fat-free soft tissue; DXA, dual energy X-ray absorptiometry; LC-MS/MS, liquid chromatography-tandem mass spectrometry; ICCs, intraclass correlation coefficients; Soy FFQ, Seattle Soy Food Frequency Questionnaire.

* *Corresponding author.* Department of Foods and Nutrition, 279 Dawson Hall, The University of Georgia, Athens, GA 30605. Tel.: +1 706 542 4901.
E-mail address: rlewis@fcs.uga.edu (R.D. Lewis).

0271-5317/$ – see front matter © 2014 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.nutres.2013.09.005

life. To help prevent future health implications related to obesity, such as type-2 diabetes mellitus, hyperlipidemia, and hypertension [5–7], researchers must explore innovative and inexpensive dietary strategies to promote weight maintenance in late adolescence. Weight management interventions targeted at college freshmen present a unique opportunity to investigate the efficacy of such dietary strategies.

One dietary strategy that has garnered considerable attention, but warrants further investigation, is the use of supplements containing soy isoflavones. Isoflavones comprise a class of phytoestrogens that first gained popularity as an alternative therapy for menopausal symptoms and the prevention of bone loss. *In vitro* studies [8–10] and animal studies [11–16] support a potential role of soy isoflavones in weight loss and weight maintenance through a reduction in adipocyte accumulation. However, human studies examining the effects of soy protein-based interventions on body weight yield conflicting results [17–21].

Most researchers have investigated the influence of soy protein/isoflavones on body weight in older adult women, not college-age women during a period associated with significant weight gain. In addition, few have compared soy isoflavones versus control treatment using meal replacements, an effective vehicle for weight management [22–24]. We hypothesized that daily intake of soy protein/isoflavones would attenuate gains in body weight to a greater extent than a casein-based control in 18 to 19 year-old females. To test this hypothesis, we conducted a randomized, double blind, placebo-controlled trial to examine the effects of a soy protein/isoflavone-based meal replacement versus a casein-based meal replacement on body weight and body composition variables in female college freshmen over 16 weeks. Sixteen weeks is a sufficient time period to observe significant changes in weight and body composition with dietary interventions [18,25,26], and also aligned with the first semester of college.

2. Methods and materials

2.1. Study design and participants

Healthy female college freshmen, 18 to 19 years of age (N = 120), participated in this 16-week, randomized, double blind, placebo-controlled, parallel-group dietary soy protein/isoflavone intervention trial. Participants were recruited beginning in the summer of 2005 from the University of Georgia through newspaper advertisements, campus fliers, and presentations given to large freshman classes. Trained study personnel administered a telephone screen to prospective participants to determine eligibility. During the telephone screen, prospective participants were informed that the purpose of the study was to investigate the effects of soy on bone health. In addition to exclusion for soy or chocolate allergies, variability among participants was reduced by excluding those who reported significant weight loss or weight gain in the previous six months (± 10% initial body weight), were vegetarians, competed in National Collegiate Athletic Association Division-I athletics, had been diagnosed with an eating disorder, experienced irregular menstruation (less than 4 out of 6 periods in the last 6 months), or took medications known to affect body weight. These exclusion criteria were determined in order to recruit a homogenous group that did not engage in extreme levels of activity or dietary practices and had the greatest likelihood of weight gain during their freshman year. All study procedures were approved by the Institutional Review Board for Human Subjects at the University of Georgia, and written informed consent was obtained from each participant.

At enrollment, eligible participants were assigned a participant ID number and scheduled for testing at baseline, 8 weeks, and 16 weeks. All testing procedures were conducted at the Bone and Body Composition Laboratory at the University of Georgia through the spring of 2006. Participants arrived at the baseline visit for a blood draw and completion of study questionnaires. Participants were randomly assigned following simple randomization procedures (random-number table) to either the soy protein/isoflavone- (SOY; n = 62) or casein-based (CAS; n = 58) groups based on their participant ID number. A non-biased individual with no direct involvement in the clinical trial was responsible for labeling shake packets with the appropriate corresponding code. All investigators, research personnel, and participants remained blinded to these codes.

All meal replacement shake packets were provided by Revival Soy (Kernersville, NC). Shakes were available in chocolate and vanilla flavors, and an equal assortment of each flavor was distributed to participants unless only one flavor was requested. Chocolate and vanilla SOY shakes were identical in taste, color, odor, and texture to corresponding flavors of CAS shakes. SOY shakes contained 20 g soy protein and 161 mg total isoflavones per serving (95 mg aglycone equivalents: 39% daidzein, 40% genistein, 21% glycitein). CAS shakes contained 20 g casein protein and were identical to the SOY shakes in kilocalories (kcals), fat, carbohydrates, fiber, and calcium content (Table 1). Trained study personnel provided information on how to prepare shakes. Participants were instructed to replace breakfast with one study shake per day and to limit soy intake to less than one serving per week.

2.2. Adherence measures

Participants were asked to return empty shake packets along with any unused products at 8 weeks and 16 weeks. Adherence was measured in all participants as percent of shakes consumed (number of shake packets/number of days in the study). Adherence was confirmed through assessment of serum isoflavones in a random subsample of participants at baseline (N = 32) and 16 weeks (N = 94). A rapid 2-minute liquid chromatography-tandem mass spectrometry (LC-MS/MS) method operating in multiple reaction ion monitoring mode was used for the measurement of daidzein, genistein, and glycitein, as described by Prasain et al. [27]. This assay demonstrated a linear response for each analyte observed over a range of 1 to 5000 ng/mL (all $R \geq 0.99$).

2.3. Anthropometric measures

Height was measured using a wall-mounted stadiometer (Novel Products Inc., Rockton, IL) to the nearest 0.1 cm. Weight was measured using an electronic scale (Seca Bella 840, Columbia, MD) to the nearest 0.1 kg. Waist circumference was measured using a flexible measuring tape to capture the