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Use of cereal fiber to facilitate adherence to a human caloric restriction program

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Abstract

Background and aims—Caloric restriction (CR) attenuates biological aging in animal models but there is little information on the feasibility and efficacy of CR regimens in humans. We examined the effects of consuming an insoluble cereal fiber supplement on ability to sustain CR over 1 year in healthy overweight adults.

Methods—In 34 healthy overweight women and men (BMI 25–30 kg/m², age 20–42 yr), a 30% CR regimen meeting national recommendations for dietary fiber was provided for 24 weeks, and for an additional 24 weeks subjects were counseled to prepare the same regimen at home. During 5–10 weeks of CR, subjects were randomized to consume an extra 20 g/day of dietary fiber from a high fiber cereal (+F) or to not consume additional fiber (–F). After this time, all subjects were encouraged to consume the extra fiber. Outcomes included adherence to the provided and self-prepared CR regimens (energy intake determined using doubly labeled water), changes in body weight, and self-reported satisfaction with the amount of consumed food.

Results—During 5–10 weeks of CR when all food was provided, both +F and –F groups were highly adherent to the CR regimen and there was no significant difference between groups in energy intake ($p=0.51$), weight change ($p=0.96$), or satisfaction with amount of provided food ($p=0.08$). During self-prepared CR from 25 to 48 weeks, mean adherence was lower than during the food-provided phase and there was a significant association between fiber intake and % CR ($r=0.69$, $p<0.001$), decreased BMI ($r=-0.38$, $p=0.04$) and satisfaction with the amount of consumed food ($r=0.59$, $p=0.002$).

Conclusions—A high fiber cereal intake may facilitate CR in humans self-selecting their own food; longer-term intervention studies are needed to confirm these findings.

Keywords

Caloric restriction; dietary fiber; dietary satisfaction; weight loss

INTRODUCTION

Caloric restriction (CR) is known to retard biological aging, increase maximum lifespan and reduce morbidity in a range of animals (1). The question of whether CR is feasible in humans, and if so whether it has equivalent beneficial effects to those seen in animal models, is not known (2,3).

Dietary fiber has the potential to enhance adherence to a CR regimen by acting as a satiety agent. There are many different types of dietary fibers, and proposed mechanisms relating to hunger and satiety include dilution of energy density, effects on gastric distention and emptying, slowing of digestion and absorption in the small bowel, activation of gut satiety hormones, and increased fecal energy excretion (4–9). A number of intervention studies have investigated the effects of dietary fiber on weight regulation (4,10–15). These studies, typically of several months duration, have resulted in a decrease in energy intake averaging about 10% and/or modest weight loss of ~2 kg (4). However, most of these studies tested small amounts of fiber well below the current national recommendations for dietary fiber intake, were short-term, and/or were changing multiple dietary parameters simultaneously. To our knowledge, only two studies have examined the long-term ability of dietary fiber to sustain reduced energy intake and weight loss over a 1 year period (16). Both studies showed greater weight loss in the fiber supplemented groups, but the low level of fiber supplementation, questionable information on total fiber intake, and high dropout rates make any conclusions about the role for dietary fiber in sustaining human CR very uncertain.

We describe here a study testing the feasibility of adding 20 g/day of additional dietary fiber to an already adequate dietary fiber intake, and its ability to increase adherence to a human CR regimen of 48 weeks duration.

MATERIALS AND METHODS

Subjects

The enrolled subjects were 34 healthy overweight (BMI 25–30 kg/m²) men and women aged 20–42 years who participated in the 30% CR arm of the Tufts University Phase 1 component of the Comprehensive Assessment of Long-term Effects of Reducing Intake of Energy (CALERIE) trial. Four subjects in this arm of the study dropped out of the study before the end of week 36, mostly due to scheduling conflicts.

The study was conducted from the Metabolic Research Unit of the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University with approval by the Institutional Review Board of Tufts-New England Medical Center. All subjects gave written, informed consent prior to participating and were provided a stipend for their time in the study.

Main Study Protocol

Details of the Tufts CALERIE trial are described elsewhere (17). Briefly, baseline energy requirements were determined using the doubly labeled water (DLW) technique during a 7-week weight-stable baseline period when subjects ate their usual diet at home. They were then randomized to either a high glycemic load (HG) diet [60% carbohydrate, 20% protein, 20% fat, fiber 15 g/1000 kcal (4.184 MJ), mean estimated daily glycemic index of 86 and glycemic load of 116 g/1000 kcal (4.184 MJ)], or a low glycemic load (LG) diet [40% carbohydrate, 30% protein, 30% fat, fiber 15 g/1000 kcal (4.184 MJ), mean estimated daily glycemic index of 53 and glycemic load of 45 g/1000 kcal (4.184 MJ)]. Both diets incorporated a 30% calorie restriction compared to baseline individual assessment of usual energy needs. Weight loss on the two diets was not significantly different (17), and therefore the groups are combined in the present analysis. Subjects were provided with all food and caloric beverages during 0–24 weeks

of the intervention and were then instructed to prepare their own food to provide an equivalent diet (food types and energy level) during weeks 25–48 of the intervention. Subjects worked individually with a dietitian to plan and maintain their menus for the self-provided component of the study, and also had regular group meetings with a behavior modification counselor (17). One of the primary goals of CALERIE was to identify dietary macronutrient compositions that subjects can tolerate at prescribed CR levels. In addition, a secondary outcome was to see the effects of increased fiber above the Dietary Reference Intake (DRI) recommendation of 14 g fiber/1000 kcal (14 g/4.184 MJ) on hunger and CR adherence.

Fiber Randomization

As shown in Figure 1, during 5–10 weeks CR, subjects in both diet groups were further randomized to receive 20 g/day extra dietary fiber (+F) from a commercial high fiber cereal (Fiber One™, General Mills) or no extra fiber (–F). Half of the high fiber cereal was given to +F subjects during the first week, and then increased to the full amount for the remaining period, to allow for adjustment to higher fiber intakes. Subjects were instructed to consume all of the high fiber cereal daily but could choose when and how they ate it. At the end of the randomization period, all subjects (including –F subjects) were provided with the high fiber cereal until week 24 of CR and were encouraged to consume it. Subjects could choose to continue eating the fiber cereal (or an equivalent cereal with similar fiber and macronutrient content) during weeks 25–48 of CR if they wished but were no longer provided with the product.

Outcome Measurements

Total energy expenditure (TEE), energy intake and physical activity level (PAL)

—The DLW method was used to determine TEE and PAL (17) over 28 days at baseline, and over 14 days around weeks 4, 12, 24, 36 and 48 of CR. Resting metabolic rate (RMR) was measured at the same time points as TEE by indirect calorimetry (17). PAL was calculated as TEE/RMR. The measurements of TEE were also used to calculate the actual energy intake of the subjects (18) and these values were used to calculate % CR relative to baseline TEE. For the calculation of energy intake, body energy change during DLW periods was calculated from regression of daily measurements of body weight (see below) made for up to 7 days before and 7 days after the TEE measurements, and the energy content of weight change was assumed to be 7.4 kcal/g (31 kJ/g) (19).

Body weight and height—At baseline, height was measured using a wall-mounted stadiometer to ± 0.1 cm. Weight was measured weekly to ± 0.01 kg using a calibrated scale (DETECTO-Cardinal Scale Manufacturing Co. Model CN-20, Webb City, MO). Subjects were also provided with a body weight scale (Tanita HS301, Tanita Corporation of America, Inc., Arlington Heights, IL) and instructed to measure fasting weights at home every morning for the study duration.

Hunger and dietary satisfaction—At the end of each day before bedtime, subjects completed 100 mm visual analog scales on level of hunger for the day, desire to eat non-study foods, and satisfaction with the amount and type of consumed foods. The scales were 5-point anchored scales with descriptors such as “Not at all hungry” to “Extremely hungry” at opposite ends. Measurements of the analog scales were taken and averaged over pre-selected time points to determine mean absolute values and changes over time.

Reported energy and fiber intake—During 0–24 weeks of CR (which included the period of fiber randomization), subjects completed a daily meal checklist to record provided, leftover, and any additional foods consumed, from which reported energy intake was calculated. A 7-day diet record was collected at weeks 2 and 4 (baseline) and weeks 35 and 47 (self-selected

phase). Nutrient calculations were performed using the Nutrition Data System for Research software version 4.05_33, developed by the Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN, Food and Nutrient Database 33, released 2002 (20,21). Fiber density [g/1000 kcal, (4.184 MJ)] during the self-selected phase of the study was calculated for each subject by using calculated energy intake from DLW. This calculated energy intake was used instead of reported energy intake to account for the known selective underreporting of energy intake from low fiber, high fat, high sugar foods (22,23).

Adverse events—Subjects completed a weekly health log, which documented specific health and medication changes. Adverse events were also reported spontaneously to study personnel.

Statistics—All statistical analyses were performed using SAS software (version 9.1 SAS Institute, Cary, NC) and Systat software (version 11.0 Systat Software, Inc., Richmond, CA). The baseline and 6-week fiber randomization analyses were performed on all subjects who completed the fiber randomization (n=33); analyses on the self-selected phase included all subjects who completed at least through week 36 (n=30). Student's *t*-test for independent samples was used for comparison between fiber groups at various time points and two-way analysis of variance was used during the randomized fiber period to compare fiber groups while controlling for the diet randomization. Linear regression and Pearson correlation coefficients were calculated to assess the relationship between fiber intake and BMI and diet satisfaction. All *p*-values were two-sided and considered to be statistically significant if less than 0.05.

RESULTS

Baseline

Table 1 shows subject characteristics, PAL and self-reported diet composition at baseline. At baseline, there was a significant difference between fiber groups in percent energy from fat ($p=0.04$). However, no statistically significant differences were found between +F and -F subjects for any other variable. Mean baseline fiber intakes did not reach the DRI for either group (25 g/day for women and 38 g/day for men). There was a statistically significant inverse association between total fiber and BMI and a statistically significant positive association between total dietary fiber and satisfaction with the amount of consumed food (Fig. 2).

CR at 0–24 weeks (provided food, including fiber randomization at 5–10 weeks CR)

Significant differences in total and insoluble fiber intake were achieved during the fiber randomization period (Table 2). Despite the increased fiber intake in the +F group, there were no statistically significant differences between the groups in absolute weight loss or visual analog scale measures. There was a trend toward greater satisfaction with the amount of food in the +F group compared to the -F group ($p=0.08$). There were no statistically significant differences between groups in changes from baseline for the different outcome variables (data not shown). Over the 6 week fiber randomization, no subjects in the -F group and 2 subjects in the +F group reported gastrointestinal-related symptoms (Table 2). Adherence to the % CR regimen was measured at 4 weeks of CR, just before subjects were randomized to +F and -F groups, at which time there was no significant difference in % CR between groups ($p=0.41$) and mean values exceeded the target of 30% CR, indicating essentially 100% adherence. However, at 12 and 24 weeks of CR, when adherence was next measured, % CR had decreased to a mean of $20.4 \pm 10.2\%$ and there was a significant positive association between total fiber intake and % CR (Fig. 3).

CR at 25–48 weeks (self-prepared food)

During 25–48 weeks of CR, 73% of subjects reported voluntary use of a high fiber cereal. Individual intakes of fiber reported from the high fiber cereal during the self-selected phase ranged from 0–26 g fiber/day. To identify more consistent users of the high fiber cereal, subjects were classified into *Non-users* and *Users* of the high fiber cereal based on the reported frequency of intake (Table 3). Subjects who consumed the cereal an average of ≥ 2 occasions/week were defined as *Users* (57% of subjects) and had statistically significant greater total dietary fiber intakes than individuals who consumed the high fiber cereal < 2 occasions/week or never (*Non-users*). No statistically significant differences between groups were found for potential confounders such as baseline BMI, age, gender, RMR, or PAL or percentage of energy from the different macronutrients. However, *Users* had significantly greater % CR that was closer to the CR goal of 30% than *Non-users*. No gastrointestinal adverse events that could be attributed to diet were reported by either *Non-users* or *Users* during this time period. Fiber intakes were higher than at baseline on average, but (as at baseline) there was a statistically significant inverse relationship between total fiber and BMI and a statistically significant positive correlation between total dietary fiber and satisfaction with the amount of food (Fig. 4). As shown in Figure 5, the relationship between total fiber intake and % CR was also significant.

DISCUSSION

Dietary fiber has multiple properties that theoretically should promote negative energy balance and facilitate greater adherence to a CR regimen (4). However, studies on dietary fiber and energy regulation were not considered consistent enough to support national recommendations on the use of dietary fiber for weight control in the most recent edition of the DRI (24), and further studies in this area are recognized to be needed. The present investigation included a period when subjects were randomized to DRI levels of dietary fiber vs DRI levels + 20 g/day of an insoluble dietary fiber preparation, and an additional 9-month period of voluntary consumption of the same type of fiber in all subjects. We found no significant effect of dietary fiber intakes above DRI levels on weight change during the short period of the RCT. However, this study was conducted as part of a larger investigation of factors influencing adherence to a CR regimen, and during the interval when all food was provided (which included the fiber randomization period), adherence was high irrespective of the fiber randomization group. In the subsequent 9-month period when fiber intake was voluntary (and for most of this time subjects self-prepared their regimen), those who continued consuming high levels of dietary fiber sustained significantly greater levels of CR, equilibrated at a lower BMI, and experienced greater dietary satisfaction than subjects who ate less dietary fiber. Although the fiber results during the self-selected phase of the study were observational and need to be supported by further RCTs, they are consistent with the suggestion that dietary fiber has small but cumulative effects on energy balance that promote greater weight loss over time (4,25,26) and that high fiber cereal preparations may have value for facilitating adherence to human CR regimens.

Although this study is relatively small, to our knowledge it is the longest trial that achieves such a sustained high level of fiber intake of any study designed to examine the effects of fiber on weight regulation and adherence to long-term CR. Other long-term *ad libitum* high-fiber diet interventions showed mixed results on the effects of fiber on weight loss (27–30), but no food was provided in those trials and often other dietary variables were being changed along with fiber (e.g., fat or calcium), which confounded the results obtained for fiber. Additionally, no previous studies have measured the effects of fiber on adherence to a CR regimen with an objective method such as the doubly labeled water technique (31). Fiber intakes in the present study were very high - over 50 g/day in some individuals - which was made possible by the use of a commercially available cereal containing a very high concentration of dietary fiber.

The finding of no effect of the extra fiber on change in body weight during the short-term randomized controlled trial would appear to be at odds with the later finding of an association between voluntary fiber consumption and % CR. However, the lack of difference between the groups at this time can potentially be explained by the overall high adherence at this period of the study; an effect of the high fiber cereal on adherence would be more likely to be expressed during the later period of the study when subjects self-selected their own food, and this in fact was observed. It is alternatively possible that subjects who ate more fiber during the follow-up period were also practicing other strategies (behavioral or dietary) that enhanced adherence to CR. However, we were unable to detect any such confounding differences between high and low fiber users, such as differences in physical activity level or dietary macronutrient balance.

Adverse events were also monitored in this study out of concern that high fiber intakes might result in unacceptable side effects. However, reported symptoms were minimal, with only 2 subjects in the +F group reporting gastrointestinal-related symptoms during the 6-week fiber randomization period and no adverse events reported during the subsequent self-selection phase of the study. No tolerable upper limit has been set for dietary fiber in the Dietary Reference Intakes, because it has been concluded that in healthy people following an overall healthful diet, a high intake of dietary fiber will not cause significant adverse events (24). Of relevance to high levels of fiber that are sustainable, it is noteworthy that Paleolithic man is estimated to have consumed approximately 100 g fiber per day (32), suggesting that much higher intakes than tested in the current study are tolerable.

In conclusion, the results of this study provide the first evidence that the addition of insoluble fiber in the form of a high fiber cereal may facilitate CR in humans self-selecting their own food. Further randomized controlled trials are needed to confirm these findings and study the long-term effects of high dietary fiber intakes on CR and body weight.

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Fig. 1.
Protocol figure.

Fig. 2. Baseline relationship between dietary fiber intake and BMI and satisfaction with amount of provided food. Relationship between fiber intake (g/1000 kcal) and both BMI (Panel A) and satisfaction with the amount of food (Panel B) consumed at baseline. 1000 kcal= 4.184 MJ. o= HG diet, x= LG diet.

Fig. 3.

Relationship between % CR and dietary fiber intake during the provided food phase of the intervention (mean of assessments at weeks 12 and 24). Relationship between % CR and fiber intake (g/1000 kcal) during the provided food phase. The dotted line from the x axis represents the DRI for fiber for this age group (14 g/1000 kcal). 1000 kcal= 4.184 MJ. o= HG diet, x= LG diet.

Fig. 4. Relationship between dietary fiber intake and BMI and satisfaction with amount of consumed food during the self-selected phase of the intervention. Relationship between fiber intake (g/1000 kcal) and both BMI (Panel A) (mean of assessments at weeks 35/36 and 47/48) and satisfaction with the amount of food (Panel B) (mean of weeks 25–48). 1000 kcal= 4.184 MJ. o= HG diet, x= LG diet.

Fig. 5. Relationship between % CR and dietary fiber intake during the self-selected phase of the intervention (mean of assessments at weeks 36 and 48). Relationship between % CR and fiber intake (g/1000 kcal) during the self-selected phase of the intervention. The dotted line from the x axis represents the DRI for fiber for this age group (14 g/1000 kcal). 1000 kcal= 4.184 MJ. o= HG diet, x= LG diet.

Table 1

Subject characteristics at baseline (means±SD)

	–Fiber	+Fiber
n (Male/Female)	17 (4/13)	16 (4/12)
Age (yrs)	35.1±5.4	34.2±5.6
Height (cm)	170.4±11.3	167.5±9.7
Weight (kg)	80.3±11.2	77.3±10.3
BMI (kg/m ²)	27.6±1.2	27.4±1.6
PAL (TEE/RMR)	1.8±0.2	1.7±0.3
Reported dietary intake:		
Energy intake ^I (kcal/day)	2011±587	2176±438
Fat (%) *	32.3±5.0	35.8±4.0
Carbohydrate (%)	48.5±6.7	47.8±4.4
Protein (%)	17.5±3.7	16.6±1.8
Alcohol (%)	2.6±3.2	1.4±1.3
Total dietary fiber (g/day)	17.0±5.7	17.7±4.6
Insoluble (g/day)	10.5±3.6	10.9±2.9
Soluble (g/day)	5.3±1.5	5.5±1.2

^I 1 kcal=4.184 kJ.

* $p<0.05$, difference between groups by independent *t*-test.

Table 2

Summary of 6-week fiber randomization period (weeks 5–10 of CR) (means±SD).

	–Fiber	+Fiber	Difference in adjusted means (95% CI) ¹
Reported Dietary Intake			
n	17	16	
Reported energy intake ² (kcal/day)	2008±366	1932±291	–83 (–322, 156)
Fat (%)	26.5±4.4	25.3±4.5	–0.4 (–1.3, 0.6)
Carbohydrate (%)	49.7±9.1	55.5±9.3	4.1 (2.6, 5.7)
Protein (%)	24.9±4.7	24.2±4.6	0.2 (–0.4, 0.8)
Alcohol (%)	1.1±1.7	0.4±0.5	–0.8 (–1.7, 0.2)
Total dietary fiber (g/day) [*]	28.5±5.6	44.0±5.1	15.5 (11.6, 19.4)
Insoluble (g/day) [*]	18.7±3.6	33.5±3.8	14.9 (12.2, 17.6)
Soluble (g/day)	9.3±2.2	9.7±1.5	0.3 (–1.0, 1.6)
Fiber from high fiber cereal (g/day) [*]	0	16.9±2.0	16.9 (15.9, 17.9)
Insoluble (g/day) [*]	0	15.8±1.9	15.8 (14.8, 16.7)
Soluble (g/day) [*]	0	0.8±0.1	0.8 (0.7, 0.8)
Daily Weights, Visual Analog Scales and % CR^{3,4}			
Weight change (g/day)	–63.7±38.4	–64.3±21.4	–0.9 (–25.0, 23.3)
Hunger (mm)	41.1± 15.4	39.2±19.0	–1.8 (–14.8, 11.1)
Desire to eat non-study food (mm)	39.9±15.7	38.9±18.9	–0.6 (–13.5, 12.3)
Satisfaction with amount of food (mm) ⁵	58.8±11.3	68.1±16.0	9.4 (–1.0, 19.7)
Satisfaction with type of food (mm)	56.8±10.7	58.2±26.1	1.9 (–12.5, 16.2)
% CR by DLW at 1 month	36.2±14.2	40.2±13.6	4.3 (–5.8, 14.3)
Diet Related Gastrointestinal Adverse Events			
Total number of symptoms reported:			
Hard stools	0	1	
Gastro-esophageal reflux	0	1	

¹ Controlled for diet randomization

² 1 kcal=4.184 kJ

³ +Fiber group: n=14 for daily log values, 1 dropout and 2 subjects missing daily log values

⁴ Mean absolute values of visual analog scales during 6-week fiber randomization period (weeks 5–10 of CR)

⁵ Approached significance, *p*=0.08.

^{*} Groups significantly different at same time point (*p*<0.001).

Table 3

Summary of self-selected diet period (weeks 36 and 48 of CR) (means±SD).

	Use of high fiber cereal supplement ¹		
	Non-users	Users	p value
Reported Dietary Intake and % CR			
n	13	17	
Reported energy intake ² (kcal/day)	1786±544	1803±333	--
Fat (%)	30.7±4.9	30.4±4.3	--
Carbohydrate (%)	51.1±6.2	52.0±7.5	--
Protein (%)	20.2±2.7	20.5±3.3	--
Alcohol (%)	0.9±1.0	1.7±1.9	--
Total dietary fiber (g/day)	24.3±11.1	33.7±9.7	0.023
Insoluble (g/day)	15.2±6.8	24.1±8.0	0.003
Soluble (g/day)	6.8±3.6	7.0±2.1	--
Fiber from high fiber cereal (g/day)	1.5±2.2	11.5±5.9	<0.001
Insoluble (g/day)	1.4±2.0	10.7±5.5	<0.001
Soluble (g/day)	0.1±0.1	0.5±0.3	<0.001
% CR by DLW (mean of wks 36 and 48)	7.0±12.1	16.1±11.1	0.045
Diet Related Gastrointestinal Adverse Events			
Total number of symptoms reported	0	0	--
Physical Activity Level			
PAL (TEE/RMR)	1.6±0.1	1.6±0.1	--

¹ Users defined as those who reported consumption of the high fiber cereal ≥2 times/wk on average during periods when diet records were collected; Non-users defined as those who reported consumption <2 times/wk or never.

² 1 kcal=4.184 kJ.