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Dietary Fiber Supplementation for Fecal Incontinence: A Randomized Clinical Trial

Donna Z. Bliss,
School of Nursing, University of Minnesota, 5-140 Weaver-Densford Hall, 308 Harvard St. SE, 5545

Kay Savik,
School of Nursing, University of Minnesota

Hans-Joachim G. Jung,
US Department of Agriculture, Department of Agronomy and Plant Genetics, University of Minnesota

Robin Whitebird,
School of Medicine, University of Minnesota

Ann Lowry, and
Colon and Rectal Surgery Associates, Minneapolis, MN, HealthPartners Education and Research Institute, Bloomington, MN

Xioayan Sheng
School of Nursing, University of Minnesota

Donna Z. Bliss: bliss@umn.edu

Abstract

Dietary fiber supplements are used to manage fecal incontinence (FI), but little is known about the fiber type to recommend or the level of effectiveness of such supplements, which appear related to the fermentability of the fiber. The aim of this single-blind, randomized controlled trial was to compare the effects of three dietary fiber supplements (carboxymethylcellulose [CMC], gum arabic [GA], or psyllium) with differing levels of fermentability to a placebo in community-living individuals incontinent of loose/liquid feces. The primary outcome was FI frequency; secondary outcomes included FI amount and consistency, supplement intolerance, and quality of life (QoL). Possible mechanisms underlying supplement effects were also examined. After a 14-day baseline, 189 subjects consumed a placebo or 16g total fiber/day of one of the fiber supplements for 32 days. FI frequency significantly decreased after psyllium supplementation versus placebo, in both intent-to-treat and per-protocol mixed model analyses. CMC increased FI frequency. In intent-to-treat analysis, the number of FI episodes/week after supplementation was estimated to be 5.5 for Placebo, 2.5 for Psyllium, 4.3 for GA, and 6.2 for CMC. Only psyllium consumption resulted in a gel in feces. Supplement intolerance was low. QoL scores did not differ among groups. Patients with FI may experience a reduction in FI frequency after psyllium supplementation, and decreased FI frequency has been shown to be an important personal goal of treatment for patients with FI. Formation of a gel in feces appears to be a mechanism by which residual psyllium improved FI.

Keywords

incontinence; bowel; fecal incontinence; dietary fiber; fiber supplement; randomized clinical trial

Fecal incontinence (FI) afflicts approximately 10% of adults in the community and lowers quality of life (Bliss et al., 2013; Rockwood et al., 2000; Shamliyan, Wyman, Bliss, Kane, & Wilt, 2007). Conservative management of FI includes soluble dietary fiber supplementation, but the optimal type of fiber and its mechanism of action remain poorly understood.

The mechanism by which dietary fiber might lessen FI appears related to the extent to which the fiber withstands fermentation by colonic bacteria as well as the fiber's solubility and degradation. Dietary fiber that is not completely degraded and fermented by colonic bacteria increases bulking (Armstrong, Eastwood, & Brydon, 1993; Marlett, Kajs, & Fischer, 2000), water-holding (Armstrong et al., 1993; Wenzl, Fine, Schiller, & Fordtran, 1995), and gelling (Marlett et al., 2000) of feces, while fibers that are metabolized to short chain fatty acids (SCFAs) promote colonic water absorption and support the energy metabolism and health of colon cells (Andoh, Tsujikawa, & Fujiyama, 2003). Consequently, fiber supplementation might lessen FI by increasing rectal distension and improving sensory awareness of the need to defecate (Hoffmann et al., 1995) reducing the liquidity of feces (Bliss et al., 2001), or promoting more complete elimination of feces, leaving less in the rectum to leak. Increasing intake of dietary fiber, however, may result in uncomfortable symptoms, mediating its benefits.

Gum arabic (GA) has a high level of fermentation (and hence SCFA production) and low level of residual fecal fiber. Psyllium has a moderate level of fermentation and moderate level of residual fecal fiber. Sodium carboxymethylcellulose (CMC) fiber has a low level of fermentation and low residual fecal dietary fiber content. While CMC is extensively degraded to monosaccharides by bacteria, those glucose units that have carboxymethyl substitutions are not subsequently fermentable by bacteria (Bliss, Weimer, Jung, & Savik, 2013).

The few previous investigations of the effects of supplementation with dietary fiber on FI have been studies of dietary fiber alone (Bliss et al., 2001), as an adjuvant to antimotility medication and diet (Lauti, Scott, & Thompson-Fawcett, 2008), and as part of a staged intervention including antimotility medications (Sze & Hobbs, 2009) or rectal irrigation (van der Hagen, Soeters, Baeten, & van Gemert, 2011). The methods and results of these studies differed, and none had adequate statistical power.

The primary aim of this study was to compare the effects on FI frequency of supplementation with one of three dietary fibers (carboxymethylcellulose, gum arabic, or psyllium) versus a placebo, in community-living individuals who had incontinence of loose or liquid feces. Outcomes of secondary interest were the effects of fiber supplementation versus a placebo on FI amount and consistency, overall FI severity score, supplement intolerance, and quality of life. Our main hypothesis was that supplementation with psyllium, which is moderately degraded and fermented, would result in the lowest frequency of incontinence episodes. Secondary hypotheses were that psyllium supplementation would

result in the lowest (firmest) fecal consistency score and highest quality of life score. In addition, we explored the possible mechanism(s) underlying a fiber's efficacy (i.e., water-holding capacity, gel formation, and extent of fiber fermentation).

Methods

Study Design

The design was a parallel groups, placebo-controlled, single-blind randomized clinical trial. The design of the protocol was informed by a pilot study (Bliss et al., 2001), the investigators' expertise, and review of the literature. The 52-day protocol had a 14-day run-in baseline period, after which eligible subjects were randomly assigned to one of the four supplements by research staff uninvolved in enrollment. Randomization was accomplished using computer-generated numbers in blocks of eight concealed in sequentially numbered opaque envelopes created and monitored by the statistician. After randomization, fiber amounts were increased by one-third every 2 days during a 6-day incremental dosing period and then maintained during a 32-day steady amount period. During the final 14 days of the steady amount period (steady amount period 2), subjects collected similar types of data as during the 14-day baseline period, with the addition of reporting supplement intake. (A figure of the study design is available from the corresponding author for one year after this publication). Subjects and the study team staff who recruited, enrolled, or trained subjects, delivered supplements, or collected data were blinded to the fiber content of the supplements.

Sample Size

Power analysis for sample size was based on frequency of FI episodes/day, our main outcome, and the desire to detect a medium effect size ($f = 0.25$), which translates to a difference of 0.5 FI episodes/day between groups, using an analysis of covariance (ANCOVA). The increase in power due to multiple repeated measures over time enabled a detectable difference smaller than 0.5 FI episodes/day. Based on standard deviations and correlations from our previous research (Bliss et al., 2001), a sample size of 160 (40 subjects in each of the four groups) was determined to result in power of 80% to detect a medium effect size with alpha set at .05. In addition, a subsample of 13 subjects from each group ($n = 52$) were randomly identified at study start to collect a stool that was left unfrozen and analyzed for possible mechanisms of fiber effects.

Eligibility

Subjects were recruited in 2004–2007 from a health maintenance organization and a university-affiliated colon and rectal surgery practice in MN (Whitebird, Bliss, Savik, Lowry, & Jung, 2010). Inclusion criteria were age ≥18 years, living in the community (not a nursing home or assisted living facility), having FI of loose or liquid consistency at least twice in a two-week period, toileting independently, and ability to read and write English. Persons who regularly performed pelvic floor muscle exercises and/or biofeedback on a maintenance regimen for at least 20 weeks or took a steady dose of anti-motility medication on a regular schedule and still met the FI criteria were also eligible.

Individuals were excluded if they had difficulty swallowing, gastrointestinal (GI) tract altered by surgery, malabsorption disorder, inflammatory bowel disease, GI cancer in active treatment, allergy to the fibers, regularly used a laxative or enema, were tube-fed, or were unwilling to discontinue taking periodic self-prescribed fiber supplements or anti-diarrheal medications. Those enrolled who scored ≤ 24 on the Mini Mental State Examination (Folstein, Folstein, & McHugh, 1975), reported fewer than two episodes of FI, or were incapable of performing study procedures during the run-in period were ineligible to be randomized. Eligibility evaluation and recruitment have been reported elsewhere (Whitebird et al., 2010). The ethical review boards at the institutions of the investigators approved the study.

Dietary Fibers and Supplements

Use of gum arabic (Nutriloid arabic spray powder, TIC Gums, Inc., Belcamp, MD) and psyllium (Gallipot, Inc., St. Paul, MN) fibers enabled comparison of the effects of fibers of high and moderate levels of fermentation (and hence SCFA production) and low and moderate levels of residual fecal fiber, respectively. Use of sodium CMC fiber (Gallipot, Inc.) allowed assessment of the impact of a low level of fermentation when residual fecal dietary fiber content was also low.

GA and CMC have GRAS (generally regarded as safe) status (US Federal Register, 2012; 2011). Although psyllium is not yet affirmed as GRAS, there is evidence showing that consumption up to 25 grams/day of psyllium in various food types is safe (Life Sciences Research Office Federation of American Societies for Experimental Biology, 1993). The Food and Drug Administration recognized the evidence for psyllium's safety in its preliminary review of a petition for its GRAS status and when approving a petition to claim benefit from cardiovascular disease from psyllium consumption (US Federal Register, 1998).

The measured composition of the fiber supplement sources was reported elsewhere (Bliss, Weimer et al., 2013). On average, 16.6 grams/day, 14.6 grams/day, and 16.2 grams/day of dietary fiber from GA, psyllium, and CMC, respectively, were provided to subjects. The measured percentage of soluble fiber was 88% of the GA source, 36% of CMC, and 7% of psyllium. GA was primarily pectic polysaccharides based on the high concentrations of arabinose, galactose, and uronic acid residues. Psyllium was predominantly a xylan type of hemicellulose. CMC was rich in glucose residues as expected; however, the total amount of glucose measured was low because the Uppsala Dietary Fiber method (Theander et al., 1995) cannot measure carboxymethyl-substituted glucose residues. Therefore, the remaining dry matter of CMC not accounted for by sodium must have consisted of substituted glucose residues. Substituted CMC is highly soluble (Barba, Montane, Rinaudo, & Farriol, 2002).

From preliminary analyses of fiber sources, we estimated fiber supplements to provide 16 grams of total dietary fiber/day. Supplements were prepared as two fruit juice mixtures, each 270 ml, providing 7 grams total fiber/day, and two small muffins providing 9 grams total fiber/day. Frozen juice concentrates were diluted to half-strength with water. The placebo supplements contained the diluted juice or basic muffin recipe ingredients only and resembled the GA supplements. Using nutrition charts, we estimated that the juice alone or

basic muffin recipe provided 70 and 260 kcals and 0 grams and 3 grams of fat daily, respectively. From each supplement order, one additional juice mixture and one additional muffin were made, frozen, composited into eight batches over the course of the study, and analyzed for total fiber (Theander, Aman, Westerlund, Andersson, & Pettersson, 1995).

Subjects ingested one muffin, a juice mixture, and at least 150 ml of other fluids of choice at the morning and evening meals each day of the supplement period. During the baseline period, they were instructed to drink a minimum of 840 ml of fluid/day, which equaled the fluid provided in the juice supplements and the additional fluid intake required with the supplements, and to report the fraction of the required fluid that they drank daily. Subjects were instructed to maintain all other usual diet and activity. During the baseline period and steady amount period 2, subjects were provided and wore an incontinence absorbent product of their choice (an incontinence pantiliner, pad, or brief [Kimberly Clark, Irving, TX]). The same type of product was worn in both periods.

To enable monitoring of intervention fidelity, subjects were asked to swallow an opaque dark blue gelatin capsule (size 4) daily with the morning juice supplement. The capsule contained a decoy amount (1 mg) of food dye (FD & C blue No. 1 [Gallipot, Inc., St. Paul, MN]) except on study days 25 and 35, when a marker amount (90 mg) that colored feces green/blue was clandestinely administered. During the dosing period, subjects were trained to recognize color change of their feces and then reported fecal color daily during the steady amount periods.

Dietary and fiber intake was estimated by analyzing a daily diet record completed during the last seven days of the baseline period and of steady amount period 2 using Nutritionist Pro software (Axxya Systems, Stafford, TX). Subjects' height and weight were measured at study start. Study staff made 27 in-person visits to each subject for training, data collection, and review of forms.

Collection of Feces

On each of the last 7 days of the baseline period and steady amount period 2, subjects collected all their feces in a plastic bag that was placed into a portable cooler containing dry ice to minimize bacterial degradation of fiber and odor. One subject with reduced sensation for defecation wore a perianal pouch (Hollister, Inc., Libertyville, IL) to collect feces, which was handled similarly to the plastic bag. Study staff collected frozen feces daily and in a few instances every other day. For the subgroup of 52 subjects who collected feces that were not frozen, the samples were analyzed within 12 hours of collection.

Outcome Measures

Fecal incontinence—For the primary outcome of FI frequency, subjects recorded in a diary the date and time of every FI episode on each of the 14 days of the baseline period and of the steady amount period 2. A FI episode was a diary report of "incontinent," which was defined for the subjects as the involuntary or accidental leakage of feces from the rectum. FI frequency was measured as the number of FI episodes/day.

For the secondary outcome of consistency of incontinent feces, subjects used a 4-level classification (*hard and formed*, *soft but formed*, *loose and unformed*, and *liquid*) shown to have good face and content validity, criterion validity (≥ 80% agreement with experts for 75% of stools tested) and reliability (inter-rater reliability weighted kappa = 0.84 [$p < .001$]; Bliss et al., 1999; Bliss et al., 2001; Bliss, Dhamani, Savik, & Kirk, 2003). These ratings were then averaged over each day.

The secondary outcome of amount of FI had six levels (*none*, *leakage between buttocks*, *on an incontinence absorbent product*, *on underwear*, *on outerwear*, or *on shoes/the floor*) and again was averaged over each day. Subjects reported the largest amount leaked for each FI episode (e.g., *leakage on underwear* meant that this had occurred in addition to leakage on the incontinence absorbent product).

Overall FI severity was calculated as (number of FI episodes/day) * (consistency of the FI episodes/day) * (amount of the FI episodes/day) for each day of the baseline period and steady dose period 2.

Supplement intolerance and quality of life—Subjects reported supplement intake as the fraction of the placebo or fiber supplement consumed (i.e., *all*, *¾*, *½*, *¼*, or *none*) daily and returned unconsumed portions. After an initial report of supplement intolerance, a one-time reduction in fiber amount to 10 grams total fiber/day was permitted. Supplement intolerance was assessed by several measures: the percentage of subjects who reduced their amount of supplemented fiber or withdrew from the study after random assignment, the proportion of a supplement that was unconsumed, and the reported number and severity of adverse GI symptoms. Five adverse GI symptoms (belching, bloating, flatus, fullness, abdominal) and two obfuscating symptoms (headache and sleepiness) were logged daily using a modified instrument (Zumarraga, Levitt, & Suarez, 1997) with a 5-point scale (0 = *none*, 1 = *minimal*, 2 = *small*, 3 = *medium*, and 4 = *large*).

Quality of life was measured at study start and end using the Fecal Incontinence Quality of Life (FIQL) questionnaire, all of whose subscales have shown discriminant validity vs. controls at $p < .01$ by ANOVA; convergent validity with SF-36, $r = 28–.55$, $p < .05$; test-retest reliability $p > .05$ per *t*-test; Cronbach alpha for internal consistency ≥ 0.80 (Rockwood et al., 2000).

Analyses of Feces

All laboratory analyses were conducted in duplicate. Frozen feces from each individual collection were combined into a composite using an amount from each bag reflecting that bag's proportion of the total wet weight of all feces collected in that period. Feces from days of incomplete collections or those left unfrozen were not included in the composites.

Wet and dry weights and the percentage of water were measured in individually collected and composited feces per methods previously reported (Bliss et al., 2001). The Uppsala Dietary Fiber method (Theander et al., 1995) was used to quantify the total fiber content in composites of feces. The formation of a gel (Marlett et al., 2000) and water-holding capacity

(WHC) (Armstrong et al., 1993) were measured in the non-frozen feces collected from the subset of 52 subjects using established methods.

Statistical Analyses

For each outcome of interest, the analysis included the effect of fiber group and period and their interaction. The interval-level parametric measures collected once per period were analyzed using ANOVA or ANCOVA, with post hoc comparisons using Tukey's LSD (least significant difference). Measures of FI collected daily during the baseline period and steady amount period 2 and summarized by day were analyzed using mixed model analysis. The autoregressive and random effects covariance structure was chosen for the mixed models based on the correlation of outcomes over time. Aikake's information criterion and the Bayesian information criterion were used as measures of fit. Non-parametric measures were analyzed using a Kruskal-Wallis ANOVA, and post hoc comparisons made using pairwise Mann-Whitney U or chi-square tests, with Bonferroni adjustment. The percentage of water in collected feces was correlated with subjects' self-rating of the consistency of their feces using Spearman's rho.

For the primary aim, intent-to-treat analysis (ITTA) was conducted using mixed models and generalized estimating equations (GEE) methods as appropriate for each outcome. For the mixed model ITTA (n = 206), all available data on any study day was included in the analysis. Per-protocol analysis (PPA; n = 189) was conducted for those who finished both data collection periods.

For the outcome of FI amount, a preliminary analysis was performed to assess whether the type of incontinence absorbent product used by subjects affected the amount of FI reported. Overall, 90% of the subjects in the ITTA wore an incontinence pantiliner, which was larger and thicker than those typically used for menstruation. No difference was found in the amount of FI among the various incontinence absorbent products ($p > .05$); therefore, the analyses of FI amount and of the composite score of FI severity (which included amount) combined users of all absorbent products.

For symptom amount, multinomial logistic regression was used, treating level of symptoms (none to large) as ordinal. Multinomial logistic regression is a classification method that generalizes logistic regression to multiclass problems, i.e., those with more than two possible discrete outcomes. The analysis results in odds ratios of advancing from one symptom level to the next (Fitzmaurice, Davidan, Verbeke, & Molenberghs, 2009).

To aid in clinical interpretation, estimations of daily FI frequency were converted to weekly by multiplying them by 7 days/week. Statistical analyses were performed using SPSS v.17 and SAS v. 9.2. Final parameter estimates were considered significant at $p < .05$.

Results

Randomization of the 206 subjects resulted in assignment of 49 to placebo, 53 to CMC, 50 to GA, and 54 to psyllium. In the PPA, there were 47 subjects in the placebo group, 47 in the CMC group, 49 in the GA group, and 46 in the psyllium group. The number and

demographic characteristics of subjects in each group did not differ significantly (Table 1). A majority of subjects in each group was female and white, and they were middle-aged on average.

Seventeen (8%) subjects withdrew after random assignment, and their demographic characteristics were similar to the 189 who completed the study: 65% were female, 82% were white, and mean age was 62 (*SD* =16). Two (4%) withdrew from the placebo group, 6 (11%) from the CMC group, 1 (2%) from the GA group, and 8 (15%) from the psyllium group. Although attrition in the psyllium and CMC supplement groups was more than twice that of the other two groups, the difference was not statistically significant. Reasons for attrition included health problems unrelated to the study (e.g., broken hip), family issues, inability to perform some study procedures, and intolerance of adverse symptoms. (An enrollment flow diagram is available from the corresponding author for up to one year after this publication).

Subjects estimated that they had FI for a median of four to five years. The placebo group reported a median of 5 (range 0–44) years of FI, the CMC group a median of 4 years (range 0–29), the GA group a median of 4 years (range 0–44), and the psyllium group a median of 4 years (range 0–44). Four (2%) subjects took a steady dose of antidiarrheal medications (2 subjects in the GA group and 2 in the psyllium group), and 28 (14%) performed maintenance pelvic floor muscle exercises and/or biofeedback (5 subjects in the placebo, 11 in the CMC, 8 in the GA, and 4 in the psyllium group).

Intervention Adherence

The self-reported proportion of supplemented fiber consumed by each group was high, averaging at least 98%. The total proportion of intake of the juice mixture in both the ITTA and PPA samples was 0.99 (*SD* 0.02) for the placebo group, 0.99 (*SD* 0.03) for the GA group, and 0.98 (*SD* 0.04) for the psyllium group. The total proportion of juice intake for the CMC group was 0.97 (*SD* 0.07) in the ITTA and 0.98 (*SD* 0.04) in the PPA. The total proportion of intake of the muffin in both the ITTA and PPA was 0.99 (*SD* 0.02) for the placebo group, 0.98 (*SD* 0.05) for the GA group, and 0.98 (*SD* 0.04) for the psyllium group. The total proportion of muffin intake for the CMC group was lower than in other groups, 0.96 (*SD* 0.06) in the ITTA and 0.96 (*SD* 0.05) in the PPA ($p < .05$ compared to the other groups).

A total of 14% (28/206) of subjects in the ITTA sample and 13% (25/189) in the PPA sample reduced the fiber amount in their supplements. Most were in the CMC group: 16 (30%) in the ITTA sample and 15 (32%) in the PPA sample, followed by the psyllium group, 11 (20%) in the ITTA sample and 9 (20%) in the PPA sample. In the GA group, 1 (2%) in both the ITTA and PPA samples reduced fiber amount, and none in the placebo group did so in either analysis sample.

All but 19 subjects saw a color change of feces after swallowing the dye marker. One subject was never able to recognize a color change. Nine subjects (5%, 9/189) were unable to recognize a color change during training but did recognize it at one or both times when the marker dye was administered. Nine other subjects (5%) recognized a color change

during training but not at one or both time points later. First appearance of the dye color in feces after being swallowed ranged from < 1 to 6 days, with no difference among the groups.

Adherence to data collection procedures was high in all groups. Only one subject in the GA group and one in the CMC group missed completing a diet record. Only 2.5% of stools were not collected, which did not differ by group ($p = .49$). Intake of macronutrients (protein, carbohydrate, and total, soluble, and insoluble fat), kilocalories, alcohol, and dietary fiber from usual diets did not differ significantly among groups in either the baseline or supplement periods ($p > .05$). All groups showed minor variations in diet intake between study periods. (A table of the results of the diet analysis by group is available for up to one year after this publication from the corresponding author).

Fecal Incontinence Frequency

Estimated values for each FI outcome in the ITTA or PPA analysis based on the betas generated from least squared means analysis are provided in Tables 2–4. FI frequency, our main outcome, did not differ among the supplement groups in the baseline period (Table 2). Estimated weekly FI frequency in the baseline period was 6.2 FI episodes/week in the placebo group, 4.7 in the CMC group, 5.3 in the GA group and 5.0 in the psyllium group.

During supplementation, compared to the placebo group, FI frequency in the psyllium group significantly decreased, whereas in the CMC group it significantly increased during supplementation in both the ITTA and PPA. FI frequency in the GA group in the supplement period was not statistically different from the placebo group in either ITTA or PPA.

In the supplement period, FI frequency was estimated to be 5.5 FI episodes/week for the placebo group, 6.2 for the CMC group, 4.3 for the GA group, and 2.5 for the psyllium group. An example calculation of these weekly estimates in the supplement period in the ITTA using the values in Table 2 is given for the psyllium group: ([0.88 – [0.16* 7 days/week, the estimated FI frequency/week for psyllium group in the baseline period] + [−0.10 * 7 days/week, the change in FI frequency/week seen in placebo group in the supplement period] + [−0.27 * 7 days/week, the change in FI frequency specific to psyllium group]) = 2.5 episodes FI/week.

The psyllium group had the greatest percent change in FI frequency, a decrease of 51%, compared to the other groups. FI frequency decreased 20% in the GA group and 11% in the placebo group, and it increased 32% in the CMC group.

Secondary Outcomes

Other characteristics of FI, such as consistency and amount, did not differ among the groups during the baseline or supplementation periods in the ITTA or PPA (Table 3). The consistency score of episodes of FI ranged from 1 (*hard and formed*) to 4 (*liquid*) in all groups. Estimated scores for FI consistency/day per group showed that the placebo and GA groups had soft but formed consistency in the baseline and supplement periods on average, and the CMC group had loose and unformed consistency in both study periods. FI

consistency in the psyllium group was loose and unformed on average in the baseline period and soft but formed in the supplement period. The average daily amount of FI was enough to soil an incontinence absorbent product (Table 3) in both study periods in three of the groups, whereas in the GA group, FI amount decreased from soiling an incontinence absorbent product at baseline to soiling just between the buttocks in the supplement period.

The composite score of all characteristics of FI severity (frequency, consistency, and amount) did not differ among supplement groups in the baseline period (Table 4). Estimated FI severity scores ranged from 2.2 (CMC group) to 2.7 (placebo group). Compared to the placebo reference group, the psyllium group had a significant improvement (decrease of 54% overall) in the FI severity score in the supplement period, whereas the CMC group had significant worsening (increase of 44%) in FI severity. There was no significant change in the FI severity score of the GA group.

Self-ratings of the consistency of feces were strongly correlated with the percentage of water in the 6,863 duplicate samples of individually collected feces (Spearman's rho = .69, $p < .001$). The correlation between the percentage of water for individually collected and composited feces was also strong (rho = .75, $p < .001$). Mean percentage of water content differed significantly in each self-rated category of stool consistency: *hard and formed* = 71.7% (*SD* 4.3), *soft but formed* = 75.9% (*SD* 3.8), *loose and unformed* = 81.2% (*SD* 3.6), and *liquid* = 85.5% (*SD* 3.7; $p < .001$ overall and for each pairwise comparison).

Characteristics of Feces

There were no significant differences in characteristics of the composites of feces among the groups in the baseline period (Table 5). In the supplement period, the wet weight of the fecal composites of the psyllium group was greater than that of the placebo and GA groups. The water content of the composites of the psyllium group was 3–4% higher than that of all other groups. A gel developed only in the feces of the psyllium group. The CMC group's wet and dry weights of fecal composites were greater than those of the placebo group.

Although the acidic uronic acids were lower in the feces of the psyllium group compared to the placebo and GA groups (Table 6), total fecal dietary fiber concentration of the psyllium group was greater than in other groups (Table 5). Psyllium was the only supplement with a significant increase in fiber content of feces from baseline (Table 5).

The psyllium group had a greater concentration of total neutral sugars (Table 6) and of arabinose and xylose residues, whereas glucose residues were more abundant in the CMC group compared to all other groups (both $p < .001$, Table 6). It should be noted that because carboxymethyl-substituted glucose units could not be quantified using the Uppsala method, total fecal fiber and sugar estimates of the CMC group are artificially low (Theander et al., 1995).

Supplement Intolerance and Quality of Life

For most days, symptoms were absent or amounts were fairly small. The amount of flatus had the highest average daily scores (between 1.5, *small*, and 2.5, *medium*). Symptom amount did not differ significantly among the groups in the baseline period. In the

supplement period, the probability of greater symptom amounts differed among the groups, and most symptom increases were seen in the CMC group, which when compared to the placebo group reported a greater likelihood of a larger amount of flatus (OR= 1.9, CI 1.3–2.7, p <.001), nausea (OR= 2.4, CI 1.1–5.4, p = .03), abdominal cramping (OR= 1.7, CI 1.04–2.8, p =.03), fullness (OR=2.0, CI 1.2–3.4, p = .007), and bloating (OR= 2.2, CI 1.3–3.8, p = .003). Compared to GA supplementation, CMC supplementation was associated with a greater likelihood of more abdominal cramping (OR=1.6, CI1.0– 2.6, p = .049) and fullness (OR=1.9, CI 1.1–3.0, p = .01). The psyllium group had a greater likelihood of a larger amount of abdominal cramping compared to GA supplementation (OR=1.7, CI 1.04–2.7, p = .03) and placebo (OR=1.7, 1.0–2.7, p = .03). Other symptom amounts did not differ significantly among the groups in the supplement period.

Symptom amount differences were not considered clinically significant, however, because the level to which the symptom increased was rarely above small. As an example, the average percentage of days when the amount of abdominal cramping was small was 5% of days in both the baseline and supplement periods in the placebo group, 8% and 11% of days in the CMC group, 9% and 7% of days in the GA group, and 6% and 9% of days in the psyllium group.

There were no significant differences in FIQL, including lifestyle, coping, depression, and embarrassment scores, among the groups in the baseline or supplement periods, per the ITTA or the PPA. (A table of the FIQL results is available for up to one year after publication of this manuscript by request to the corresponding author.)

Discussion

Dietary supplementation with psyllium reduced the frequency of FI episodes more than placebo, in both the ITTA and PPA. On average, psyllium supplementation of approximately 15 grams total fiber/day reduced FI incontinence frequency in half. In contrast, supplementation with GA did not significantly change FI frequency, and CMC resulted in an increase in FI. The amount of dietary fiber provided in this study raised subjects' intake to near recommended levels (25–30 grams/day; Slavin, 2008). With the exception of the CMC group, the additional fiber seemed to be tolerated fairly well, based on the few reported symptoms and low rates of attrition (8%) and fiber reduction (14%) overall.

Our hypothesis that psyllium supplementation would have the greatest clinical effect was based in part on the assumption that psyllium would be less degradable than GA. The psyllium group had the highest total fiber content in fecal composites, suggesting the presence of residual dietary fiber that was not degraded by colonic bacteria. Unlike the other supplements, psyllium increased the fiber content of feces when compared to the baseline period. Concentrations of the two major psyllium fiber monosaccharide components (arabinose and xylose) increased in feces of this group, reflecting the composition of sugars in psyllium fiber and suggesting that the residual non-degraded fiber in the fecal composite was psyllium. Because cellulose is slowly degraded, the higher glucose concentration in CMC-supplemented subjects might be expected. However, CMC supplementation did not

improve FI outcomes. The lack of increase in fiber residues in the feces of GA-supplemented subjects was expected because GA is a more highly degradable fiber source than the others used in this study, as demonstrated by GA's high in vitro degradability using feces as a bacterial inoculum (Bliss, Weimer et al., 2013).

Our findings provide preliminary evidence of a possible mechanism for psyllium's reduction in FI frequency due to the formation of a gel by unfermented psyllium and fecal water. A gel was found only in the feces of subjects in the psyllium group. Results agree with findings by Marlett et al. (2000), who reported that after psyllium supplements were given to subjects without bowel irregularity or constipation, fecal gel was not fermented by colonic bacteria (Marlett & Fischer, 2003). In our previous work (Bliss et al., 2001), we suggested that dietary fiber supplementation reduced FI by firming consistency of incontinent feces. Although a smaller amount of psyllium and a larger amount of GA were administered in that earlier study than in the present study, the consistency of incontinent feces from subjects consuming either fiber supplement was firmer compared to placebo, and no difference in total wet weight of feces among groups was found. In the present study, the psyllium group had no difference from the placebo group in reported consistency of incontinent feces, yet the total wet weight of feces of the psyllium group was greater than that of the other groups. The increase in the total wet weight of feces after ingestion of psyllium but not after GA is consistent with findings of other studies (Eastwood, Robertson, Brydon, & MacDonald, 1983; Marlett & Fischer, 2003; Wenzl et al., 1995).

These results suggest that the gel that formed in feces after psyllium supplementation bound additional water while maintaining usual fecal consistency. Increased water-holding of fecal solids may explain firming of loose/liquid feces (Bliss et al., 2001). However, neither the dry weight nor the water-holding content of fecal solids of the group that consumed psyllium was greater than those of the other groups.

The other proposed mechanism underlying a benefit of dietary fiber on FI is based on production of SCFAs promoting water absorption. In an in vitro dietary fiber degradability experiment, we found that while psyllium was highly degradable, its degradability was less than the almost complete degradation of GA (Bliss, Weimer et al., 2013). When psyllium was added to a human fecal inoculum in vitro, rates and amounts of SCFAs and gas produced fell between the amounts produced by GA and CMC fermentation (Bliss, Weimer et al., 2013). Because CMC is highly degradable but poorly fermented, it would not be expected to improve FI symptoms by either the residual fiber/gel or SCFA mechanisms.

In our earlier study (Bliss et al., 2001), we did not find increased fecal fiber concentrations after either GA or psyllium supplementation, but severity of FI symptoms was reduced by both treatments. In that study the amount of GA was ~50% greater than in the current study. These observations suggest that, in the earlier study, greater total SCFA production from GA was likely responsible for the improvement in symptom severity, whereas in the current study insufficient GA was provided to generate a SCFA-mediated response for FI. The smaller amount of psyllium in the earlier study was completely degraded, so the FI improvement in that study after psyllium supplementation must have been due to SCFAs rather than residual dietary fiber. These findings in total suggest that individuals with FI

benefit from both production of SCFAs and the presence of unfermented fiber, such as from moderately fermented psyllium fiber, but that fiber amount administered likely affects the response.

Our findings differ from those of Lauti et al. (2008), who reported no difference in anal incontinence score change between groups who consumed psyllium or a placebo, in addition to an uncontrolled amount of anti-diarrheal medication and in some instances anti-constipation medication. One reason may be the difference in their measure of anal incontinence, which also included flatus severity. Their study had few controls over possible confounding variables and lacked monitoring of intervention fidelity. Controlled studies are needed to assess whether fiber supplementation adds to the benefit of other therapies, such as anti-diarrheal medications or biofeedback training, and vice versa.

Quality of life associated with fecal incontinence did not improve in any group after supplementation. The lasting anxiety and emotional impact of past and current FI episodes on perceived quality of life is known (Peden-McAlpine, Bliss, & Hill, 2008); therefore, the duration of FI improvement in this study may have been too short to assure subjects that improvement would persist. The ability of the FIQL instrument to detect changes in in a relatively short time has not been tested. In a recent review of qualitative research about quality of life related to FI, recommendations included considering a patient's personal goals as an important part of a conservative treatment plan for FI (Bliss, Mellgren et al., 2013). A decrease in the frequency of incontinence, a finding of the current study, is one of the most common and most important personal goals of individuals with FI if complete cure is not possible (Manthey, Bliss, Savik, Lowry, & Whitebird, 2010). The small increases in total frequency of stool that resulted from supplementation of GA and psyllium did not differ from that seen in the placebo group; supplementation with CMC, however, increased frequency of FI and total bowel habits.

Limitations of this study included inability to administer the dye marker in the supplement because the amount needed to see a fecal color change stained the oral mucosa unless mixed in dense muffins with poor palatability. Allowing usual dietary intake likely increased the variability in fecal fiber content but provided a more realistic context, increasing generalizability of findings. Supplements were prepared for the study and likely require additional development for commercial use. Generalizability of findings is limited to community-living individuals whose incontinence includes loose/liquid stools. The composite FI severity score used in this study had not previously been tested. Other severity indices have been developed for anal incontinence (including incontinence of flatus) but not specifically fecal incontinence, were not appropriate for our measures, or had not been validated. Reliability and validity of the FI incident diary and self-report of FI amount was not established and is needed. Follow-up studies of the secondary or exploratory measures in this study with appropriate power and rigor are recommended.

In conclusion, psyllium supplementation may reduce FI frequency in community-living individuals by as much as half. Formation of a gel in feces appears to be a mechanism by which residual psyllium in feces improved FI. Dietary fiber supplements seem fairly well tolerated overall. Because a decrease in FI frequency is an important goal of patients with FI

when a complete cure is not possible (Manthey et al., 2010), psyllium supplementation appears appropriate as part of conservative treatment.

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Table 1

Demographics of Subjects by Supplement Group

	Placebo				CMC				Gum Arabic				Psyllium			
	ITTA (n=49)		PPA (n=47)		ITTA (n=53)		PPA (n=47)		ITTA (n=50)		PPA (n=49)		ITTA (n=54)		PPA (n=46)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Age (years)	59	14	60	14	60	13	59	13	55	14	55	15	59	15	60	14
Body mass index	29	6	29	6	31	7	31	6	29	8	29	7	30	8	30	8
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Female	32	65	31	66	39	74	35	75	37	77	38	79	44	85	41	89
Race[a] and Ethnicity																
White	44	90	42	89	48	91	42	89	47	94	47	96	49	91	43	94
Black	2	4	2	4	2	4	2	4	2	4	2	4	2	4	1	2
American Indian	0	0	0	0	1	2	1	2	0	0	0	0	1	2	0	0
Asian	1	2	1	4	0	0	0	0	1	2	0	0	1	2	1	2
More than 1 race	2	4	2	4	2	4	2	4	0	0	0	0	1	2	1	2
Hispanic	0	0	0	0	1	2	1	2	1	2	1	2	1	2	1	2
Married/Partnered [b]			30	64			34	72			38	78			26	57
Employed[b]			25	53			27	57			33	67			24	52
Education - highest level[b]																
Less than high school			1	2			0	0			2	4			1	2
High School graduate/some college			22	47			29	63			19	23			23	51
College graduate			24	51			17	37			27	56			21	47

Note. CMC = carboxymethylcellulose. ITTA= intent to treat analysis. PPA = per-protocol analysis. Age and body mass index are compared between groups using an analysis of variance; all categorical variables are compared using a chi-square test of association. All group comparisons > .05.

[a] Race groups are mutually exclusive; some cells had too few observations for analysis.

[b] PPA only.

Table 2

Frequency of Fecal Incontinence per Day by Group in Mixed Model Analysis

	Placebo[a] *n*=49[b]/47[c]	CMC *n*=53/47	GA *n*=50/49	Psyllium *n*=54/46	Overall Difference from Placebo Baseline	Additional Difference Specific to Fiber Group		
	β(seβ)[d]	β(seβ)[e]	β(seβ)[e]	β(seβ)[e]	β(seβ)[e]		β(seβ)[f]	*p*-value
Baseline	0.88 (0.10)	−0.20 (0.12)	−0.10 (0.12)	−0.14 (0.12)				
Supplement Period[b]	0.88 (0.10)	−0.21 (0.12)	−0.12 (0.12)	−0.16 (0.12)	−0.10 (0.10)	CMC	0.32 (0.13)	.020
						GA	−0.05 (0.21)	.710
						Psyllium	−0.27 (0.13)	.048
Supplement Period[c]	0.87 (.10)	−0.18 (0.13)	−0.14 (0.15)	−0.38 (0.15)	−0.17 (0.05)	CMC	0.37 (0.07)	<.001
						GA	0.01 (0.07)	.920
						Psyllium	−0.22 (0.07)	.003

Note. CMC = carboxymethylcellulose. GA = gum Arabic. FI = fecal incontinence.

[a] Placebo group was reference group.

[b] intent-to-treat analysis.

[c] per-protocol analysis.

[d] for intercept representing the average FI frequency/day of placebo group in the baseline period

[e] for difference from placebo in baseline period

[f] for additional difference specific to fiber group in supplement period

Table 3

Fecal Incontinence Consistency and Amount per Day by Group in Mixed Model Analysis

	Placebo[a] *n*=49[b]/47[c]	CMC *n*=53/47	GA *n*=50/49	Psyllium *n*=54/46	Overall Difference from Placebo Baseline	Additional Difference Specific to Fiber Group		
	β(seβ)[d]	β(seβ)[e]	β(seβ)[e]	β(seβ)[e]	β(seβ)[e]		β(seβ)[f]	*p*-value
			FI Consistency					
Baseline	2.0 (0.15)	0.12 (0.22)	0.008 (0.22)	0.25 (0.22)				
Supplement Period [b]	2.0 (0.15)	0.15 (0.20)	0.001 (0.20)	0.21 (0.20)	−0.05 (0.14)	CMC	0.13 (0.21)	.42
						GA	−0.06 (0.21)	.76
						Psyllium	−0.20 (0.24)	.52
Supplement Period [c]	2.1 (0.09)	0.003 (0.12)	−0.03 (0.12)	−0.08 (0.13)	−0.04 (0.07)	CMC	0.17 (0.09)	.08
						GA	−0.07 (0.10)	.46
						Psyllium	−0.05 (0.11)	.63
			FI Amount					
Baseline	1.6 (.07)	0.11 (0.09)	−0.04 (0.09)	0.19 (0.09)				
Supplement Period [b]	1.6 (.07)	0.21 (0.12)	−0.03 (0.11)	0.20 (0.12)	−0.04 (0.06)	CMC	−0.09 (0.08)	.28
						GA	−0.08 (0.09)	.43
						Psyllium	−0.02 (0.10)	.99
Supplement Period [c]	1.6 (.09)	0.18 (0.11)	−0.04 (0.11)	0.20 (0.12)	−0.04 (0.06)	CMC	−0.10 (0.09)	.25
						GA	−0.07 (0.09)	.40
						Psyllium	−0.02 (0.10)	.87

Note. CMC = carboxymethylcellulose. GA = gum Arabic. FI = fecal incontinence. The average FI consistency for the placebo and gum arabic groups was soft but formed in both the baseline and supplement periods; for the CMC group, FI consistency was loose and unformed in both periods, and for the psyllium group, it was loose and unformed in the baseline period and soft but formed in the supplement period. There was no statistical or clinical difference in FI amount among groups.

[a] Placebo group was reference group.

[b] intent-to-treat analysis.

[c] per-protocol analysis.

[d] for intercept representing the average FI frequency/day of placebo group in the baseline period

[e] for difference from placebo in baseline period

f for additional difference specific to fiber group in supplement period

Table 4

Fecal Incontinence Severity Score per Day by Group in Mixed Model Analysis

	Placebo[a] *n*=49[b]/47[c]	CMC *n*=53/47	GA *n*=50/49	Psyllium *n*=54/46	Overall Difference from PlaceboBaselin	Additional Difference Specific to Fiber Group		
	β(seβ)[d]	β(seβ)[e]	β(seβ)[e]	β(seβ)[e]	β(seβ)[e]		β(seβ)[f]	*p*-value
Baseline	2.7 (0.34)	−0.53 (0.47)	−0.27 (0.47)	0.04 (0.47)				
Supplement Period [b]	2.7 (0.34)	−0.55 (0.52)	−0.28 (0.53)	−0.02 (0.52)	−0.56 (0.28)	CMC	1.50 (0.39)	<.01
						GA	0.08 (0.39)	.84
						Psyllium	−0.89 (0.39)	.02
Supplement Period [c]	2.8 (0.39)	−0.61 (0.55)	−0.35 (0.54)	−0.21 (0.55)	−0.57 (0.28)	CMC	1.50 (0.39)	<.01
						GA	0.09 (0.39)	.81
						Psyllium	−0.85 (0.40)	.03

Note. CMC = carboxymethylcellulose. GA = gum Arabic. FI = fecal incontinence.

[a] Placebo group was reference group.

[b] intent-to-treat analysis.

[c] per-protocol analysis.

[d] for intercept representing the average FI frequency/day of placebo group in the baseline period

[e] for difference from placebo in baseline period

[f] for additional difference specific to fiber group in supplement period

Table 5

Laboratory Characteristics of Feces by Fiber Group

	Placebo (*n*=47)	CMC (*n*=47)	Gum Arabic (*n*=49)	Psyllium (*n*=46)
	***M* (*SD* or *SEM*[a])**	***M* (*SD* or *SEM*[a])**	***M* (*SD* or *SEM*[a])**	***M* (*SD* or *SEM*[a])**
Total wet weight feces (g/d)				
Baseline[a]	160.7 (66.0)	168.5 (80.7)	153.2 (62.6)	153.9 (90.5)
Supplement [b]	155.1 (11.1)^{A}	206.3 (11.1)^{BC}	167.8 (10.9)^{AB}	213.5 (11.2)^{C}
Total dry weight feces (g/d)				
Baseline	35.7 (11.5)	37.6 (15.7)	35.8 (13.2)	35.1 (19.6)
Supplement[c]	35.5 (2.2)^{A}	45.6 (2.2)^{B}	37.0 (2.2)^{AB}	41.1 (2.5)^{AB}
Total fiber (mg/g dry matter of feces)				
Baseline	296.8 (57.1)	283.6 (55.9)	281.6 (53.1)	283.9 (68.7)
Supplement[b]	282.0 (9.8)^{A}	284.2 (9.6)^{A}	301.6 (9.4)^{A}	335.6 (9.7)^{B}
Percent water in feces[d]				
Baseline	76.6 (4.9)	76.5 (5.2)	75.8 (4.4)	75.6 (5.9)
Supplement[b]	76.1 (0.6)^{A}	77.4 (0.6)^{A}	76.8 (0.6)^{A}	79.7 (0.6)^{B}
Water-holding capacity (g water /g dry weight of feces) [d]				
Baseline	3.1 (1.1)	2.8 (1.5)	3.3 (1.3)	3.0 (1.9)
Supplement	3.2 (0.3)	3.6 (0.3)	3.1 (0.3)	3.5 (0.3)
Fecal gel (mg/g dry weight of feces)[d]				
Baseline	none	none	none	none
Supplement	none	none	none	106.7 (40.9)

Note. CMC = carboxymethylcellulose. Lab analyses were done only on the per-protocol analysis sample (n = 189). All comparisons between groups were accomplished using ANOVA (baseline period) or ANCOVA (supplement period). There was no significant difference among groups at baseline; in the supplement period, the covariate of the baseline period value was significant in all analyses, $p < .001$.

[a] In baseline period, *M* (mean) (*SD* [standard deviation]), in supplement period, *M* adjusted for baseline values (*SEM*).

[b] $p < .001$ and

[c] $p = .007$ for group comparisons in the supplement period. Pairwise comparisons were adjusted for multiple comparisons using Tukey's LSD.

[d] For these analyses, *n* was 13 in each group.

[A] For pairwise comparisons, values that do not share a letter within a row differ significantly, $p < .05$.

Table 6

Dietary Fiber Sugar and Klason Lignin Composition (g/kg dry matter) of Stool Composites during Baseline and Supplement Periods

		Placebo (*n*=47)	CMC (*n*=47)	Gum Arabic (*n*=49)	Psyllium (*n*=46)
Content	**Period**	***M* (*SD* or *SEM*[a])**	***M* (*SD* or *SEM*[a])**	***M* (*SD* or *SEM*[a])**	***M* (*SD* or *SEM*[a])**
Rhamnose	Baseline	5.88 (1.64)	5.43 (1.92)	5.96 (1.59)	5.72 (1.57)
	Supplement	6.25 (0.20)^{A}	4.71 (0.20)^{B}	7.03 (0.20)^{C}	6.13 (0.20)^{A}
Fucose	Baseline	1.57 (1.06)	1.34 (0.88)	1.36 (0.63)	1.28 (0.67)
	Supplement	1.28 (0.14)	1.38 (0.13)	1.48 (0.13)	1.69 (0.14)
Arabinose	Baseline	21.05 (11.0)	17.04 (9.33)	17.17 (9.2)	17.63 (13.33)
	Supplement *b*	17.53 (2.18)^{A}	15.32 (2.14)^{A}	18.34 (2.1)^{A}	42.30 (2.17) ^{B}
Xylose	Baseline	31.1 (15.37)	26.93 (14.51)	27.64 (16.76)	27.64 (19.54)
	Supplement *b*	27.84 (4.23)^{A}	29.81 (4.17)^{A}	25.58 (4.09)^{A}	67.25 (4.22) ^{B}
Mannose	Baseline	11.68 (4.97)	10.58 (2.93)	10.54 (2.10)	10.98 (3.40)
	Supplement *b*	10.39 (0.59) ^{A}	14.07 (0.58) ^{B}	12.05 (0.57) ^{B}	12.74 (0.59)^{B}
Galactose	Baseline	14.01 (6.16)	11.53 (2.66)	12.95 (4.36)	21.78 (4.37)
	Supplement *b*	12.61 (1.25)^{A}	11.30 (1.24)^{A}	18.38 (1.20)^{B}	18.55 (1.24)^{B}
Glucose	Baseline	92.77 (30.62)	94.43 (38.06)	91.37 (39.57)	94.14 (43.21)
	Supplement *b*	91.71 (4.43)^{A}	122.56 (4.38)^{B}	100.37 (4.29)^{A}	90.08 (4.43) ^{A}
Total Neutral Sugars	Baseline	178.07 (48.75)	167.29 (54.23)	166.98 (49.0)	170.17 (64.2)
	Supplement *b*	164.73 (8.86)^{A}	200.35 (8.74)^{B}	184.26 (8.57)^{AB}	239.28 (8.83)^{C}
Uronic Acids	Baseline	18.86 (10.98)	15.72 (9.63)	17.75 (9.48)	17.21 (11.29)
	Supplement*c*	19.14 (1.38) ^{A}	14.05 (1.36) ^{B}	20.77 (1.33) ^{A}	15.76 (1.37) ^{B}
Total Sugars	Baseline	196.93 (54.41)	183.00 (59.77)	184.73 (54.27)	187.38 (71.18)
	Supplement*b*	201.59 (11.35) ^{A}	217.65 (11.67)^{A}	215.62 (11.38)^{A}	268.77 (11.66)^{B}
Klason Lignin	Baseline	99.83 (29.0)	100.60 (27.94)	96.84 (26.24)	96.47 (28.74)
	Supplement*b*	97.38 (4.26)^{A}	70.51 (4.21)^{B}	96.73(4.13)^{A}	80.39 (4.26)^{B}

Note. CMC = carboxymethylcellulose. Lab analyses were done only on the per-protocol analysis sample (*n* = 189). All comparisons between groups were accomplished using ANOVA (baseline period) or ANCOVA (supplement period).There was no significant difference among groups for any values in the baseline period.

[a]In baseline period, *M* (mean) (*SD* [standard deviation]), in supplement period, *M* adjusted for baseline values (*SEM*).

[b] $p < .001$ and

[c] $p = .002$ for among group comparisons in the supplement period. Pairwise comparisons were adjusted for multiple comparisons using Tukey's LSD.

[A] For pairwise comparisons, values that do not share a letter within a row differ significantly, $p < .05$.