Validation of a Questionnaire for Digestion-Associated Well-Being in Healthy Undergraduate Students

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Fiber may affect general well-being positively or negatively, but this has not been assessed in healthy adults. This study validates a questionnaire designed to capture changes in digestion-associated well-being when participants increase their fiber intake. Healthy individuals, ages 18-25 (n=22), were recruited for a 3-week study. After completing a 1-week baseline period, participants consumed 1 cup of high fiber cereal (39 g dietary fiber) for 1 week followed by a 1-week washout period. Daily and weekly questionnaires captured changes in total fiber intake, gastrointestinal function, and digestion-associated well-being. The digestion-associated well-being questionnaire consisted of 20 questions rating well-being from strongly disagree to strongly agree. Following the intervention, self-selected participants joined a focus group to evaluate the relevance of the digestion-associated well-being questionairre. Total intake of dietary fiber and weekly bowel movements increased (15.3 ±1.5 g [mean ± SEM] to 53.4±1.7 g of fiber [$P<0.05$]; and 17.0 ±1.0 to 22.3 ±2.0 stools per week [$P=0.01$]) with the fiber intervention. However, responses to 11 of the questions in the digestion-associated well-being questionairre did not change (i.e., ≥80% of responses were strongly disagree or disagree for all 3 study weeks). Focus group input suggested the wording of the digestion-associated well-being questionairre was too strong. Further modifications are required in wording and response anchors.

INTRODUCTION

Typically, Americans do not consume enough fiber in their diets, which may affect their digestion-associated general well-being. Increasing fiber in the diet has been shown to have beneficial gastrointestinal effects such as aiding in digestive health, increasing fecal bulking, delaying gastric emptying, and accelerating bowel transit (Lattimer et al., 2010). However, too much dietary fiber can cause bloating and intestinal gas, which may also affect general well-being (Eswaran et al., 2013). The effects of changing an inadequate fiber diet to a more than adequate fiber diet in healthy individuals on general well-being have not been explored.

General well-being, and more specifically digestion-associated well-being, is related to subjective feelings associated with nutrition in healthy individuals. The concept of well-being was derived from the multidisciplinary idea of quality of life. Quality of life is a broad concept including subjective evaluations of both positive and negative aspects of life (WHOQOL Group, 1998). It is important to measure quality of life/well-being to gain insight on the effects of a treatment on an individual.

All Bran Buds® cereal is an excellent source of dietary fiber containing 39 g of fiber per 1 cup and. As there is no upper limit determined for fiber, this increase of fiber is acceptable. All Bran Buds® contains wheat bran. Wheat bran makes up the outer layer of the whole grain kernel and is a concentrated source of insoluble fiber (Stevenson et al., 2012). Wheat bran also contains manganese, magnesium, phosphorous, vitamin B6, thiamin, folate, vitamin E, and antioxidants (Self-Nutrition Data, 2014). As a source of dietary fiber, wheat bran aids in digestive health: dietary fibers are associated with fecal bulking, and delayed gastric emptying (McIntyre et al., 1997). Chen and colleagues showed consuming 30 g of wheat bran per day was associated with an increase in mean stool wet weight (Stevenson et al., 2012). Insoluble fiber, such as wheat bran, can provide a significant regularity benefit (laxative effect) by stimulating secretion of water and mucous in the large bowel (McRorie Jr et al., 2016). However, too much dietary fiber can cause bloating and intestinal gas, which may also affect digestion-associated well-being.

Many studies have shown diets higher in fiber have health benefits such as decreasing obesity, reducing the risk of cardiovascular disease, and protecting against colon cancer. Despite the known physiological benefits of increasing fiber in the diet, there is limited insight on the effect of a high-fiber diet on digestion-associated well-being in healthy individuals. According to one study conducted in 2013, after 14 days of consuming at least 5.4 grams of fiber from a fiber cereal, significant improvements in subjective perception of bowel function and digestive feelings were found (Lawton et al., 2013). This indicates increasing usual fiber intake may have a noticeable impact on general well-being in healthy individuals.

The primary objective of this study to identifying changes in responses in the DAWBQ to be compared with changes in the Gastrointestinal Symptoms Response Scale (GSRS) scores with the addition of a high-fiber cereal to the diets of individuals who typically consume inadequate

amounts of fiber. Secondary objectives include identifying changes in self-reported stool frequency and self-reported stool consistency (Bristol Stool Scale score).

MATERIALS AND METHODS

Digestion-Associated Well-Being Questionnaire

This study is designed to evaluate whether a questionnaire developed and piloted in a previous study (IRB201501168) will be able to capture changes in digestion-associated well-being in participants who change their fiber intake from an inadequate to a more than adequate intake.

The Digestion-Associated Well-Being Questionnaire (DAWBQ) was previously developed using pre-existing quality of life questionnaires as guidelines (unpublished data). Most quality of life questionnaires that are typically studied are targeted towards capturing how interventions affect gastrointestinal function in diseased states rather thanin healthy individuals. The DAWBQ was created by consolidating themes from quality of life questionnaires and applying them to healthy individuals. These themes included activities, worries/concerns, emotional well-being, perceived health, social interaction, and body image. Studying healthy individuals with this framework will help provide insight on the benefits of fiber on dietary-associated well-being in healthy people, since limited information is available on this topic.

In order to improve the clarity and language of the DAWBQ, the questionnaire was pilot tested in a cohort of males and females who typically consume an adequate fiber diet, prebiotic, or probiotic supplements. The participants were asked to take the questionnaire followed by a 30-minute scripted interview, where participants commented on the relevance and clarity of each question. The interviews were transcribed and extensively reviewed and the comments were used to revise the DAWBQ. The questionnaire was then evaluated for its ability to capture effects of fiber on aspects of day-to-day life such as daily activities, body image, leisure, and worries/concerns.

Participants

This study was approved by the University of Florida IRB. Participants (n=22, Figure 1) were recruited on the University of Florida campus. It was required that participants be male or female undergraduate students at the University of Florida ages 18-25 years old. After consenting, the participants included in the study were further screened according to their usual fiber intakes. Males who had a usual fiber intake of ≤20 g/d and females who had a usual fiber intake of ≤16 g/d were included in the study (measured by the NutritionQuest Fruit/Vegetable/Fiber Screener). These participants were required to be willing to consume the study cereal for 7 days and answer daily and weekly questionnaires during the duration of the study. Additionally, participants were asked to discontinue consuming prebiotic, fiber, or probiotic supplements or foods containing probiotics. All questionnaires were administered online via Qualtrics.com and thus required participants to have internet access during the duration of the protocol.

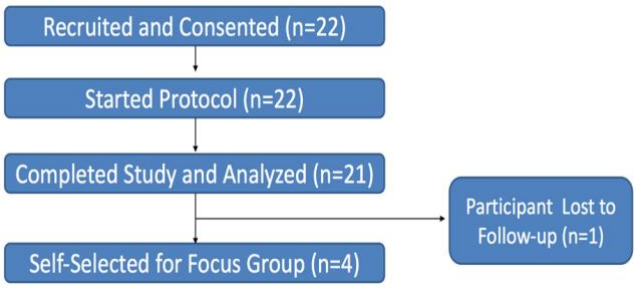

Figure 1. Participant Flow

Study participants who consumed vegan/vegetarian diets, were heavy drinkers, participated in purposeful strenuous exercise of >300 minutes per week on average, were currently being treated for a physician-diagnosed gastrointestinal disease or condition (such as ulcerative colitis, Crohn's disease, gastroparesis, cancer, peptic ulcer disease, Celiac disease, short bowel disease, ileostomy, colostomy) other than Gastroesophageal Reflux Disease (GERD) or diverticular disease, were lactating or pregnant, or had an allergy or intolerance to any of the ingredients in the study cereal were excluded from the study.

Recruiting and Consenting

A recruiting plan and standard operating protocol was devised before recruitment began. Study Coordinators were instructed to flier in popular areas on University of Florida campus such as Turlington Plaza and Plaza of the Americas. They were scheduled during and between class periods to hand out fliers and go to undergraduate buildings to hang up fliers on public bulletin boards. Further, emails and phone calls were made/received to give more information on the study and to schedule consenting appointments. Institutional Review Board (IRB) approved telephone and email scripts were available for study coordinators. Recruitment took approximately 2 weeks.

Consenting appointments gave the potential participant time to review the informed consent form, the study calendar, the fiber screener (to ensure they still qualified) and related materials. If recruits were still interested in participating, a study coordinator went through the informed consent form with the potential participant. After all questions were answered, two informed consent forms were signed (one for the participant's records and one for the researcher's records).

Study Design

After providing informed consent, the participant took the fiber screener to ensure they still qualified for the study. If they qualified, study participants were assigned a number in the order of when they came for their consenting appointment. This number identified participants on daily and weekly questionnaires. Once study participants met the initial inclusion criteria, they completed a demographic questionnaire and began a 7-day ± 1 day baseline period where they completed online daily and weekly questionnaires. All questionnaires were emailed through Qualtrics.com. The daily questionnaires continued throughout the study and included questions related to cereal consumption (intervention period only), stool frequency, and the Bristol stool scale (a scale to measure intestinal transit time via stool consistency from the previous day). The weekly questionnaires were also completed throughout the study and included the DAWBQ and the GSRS. The DAWBQ asked questions related to aspects of day-to-day life such as daily activities, body image, leisure, and worries/concerns. The GSRS included questions on how bothered the participant was in the past week due to 15 gastrointestinal symptoms (the major categories being: reflux, diarrhea, constipation, indigestion, and abdominal pain). On day 8 ± 1 day of the study, participants began consuming 1 cup of fiber cereal for breakfast every day for 7 days of the intervention. Participants completed an Automated Self-Administered 24-hour dietary recall (ASA-24) on days 3 ± 1 day and 12 ± 1 day, reporting dietary intake from the previous day. The ASA-24 data was collected to see exactly how much dietary fiber one consumed in a typical day on their normal diet, and compare that to their dietary fiber intake during the cereal intervention.

During the washout period, participants did not consume any fiber cereal but did continue completing the questionnaires until Day 22 ± 1 day of the study. Participants were asked to return remaining study cereal to the Food Science and Human Nutrition Department upon receiving payment (Figure 2).

The DAWBQ was administered twice each week (total of 6 times) to test the degree to which the test results were consistent over time. The test-retest questionnaire was sent out the day after participants received their weekly questionnaire (GSRS and DAWB)

Intervention

The study cereal, All-Bran buds, was store-bought and supplied to the participants in prepackaged boxes. Participants were instructed to consume 1 cup (dietary fiber 39 g; soluble fiber 9 g; insoluble fiber 27 g) a day at breakfast. Study instructions were included on 2 cereal boxes, including a 'Foods to Avoid' card (reminding participants which foods to discontinue during the protocol), that was given to the participant during their consenting appointment. Measuring cups were provided. Participants consumed the cup of cereal daily for 7 days. On day 15 of the study, the participant stopped consuming the cereal and began the washout period where they continued their daily and weekly questionnaires until the end of the study (Day 22, see Figure 2).

Statistical Analyses

The primary outcome was to compare changes in the DAWBQ to changes in GSRS; however, there was no observed effect of the fiber intervention on GSRS for any of the five syndromes (i.e., diarrhea, abdominal pain, constipation, reflux, indigestion) as analyzed with a repeated measures analysis of variance (ANOVA) or a Friedman Repeated Measures Analysis of Variance on Ranks as appropriate. Therefore, descriptive statistics were used to report data on the DAWBQ. A paired t test was used to compare mean intake of dietary fiber during baseline and

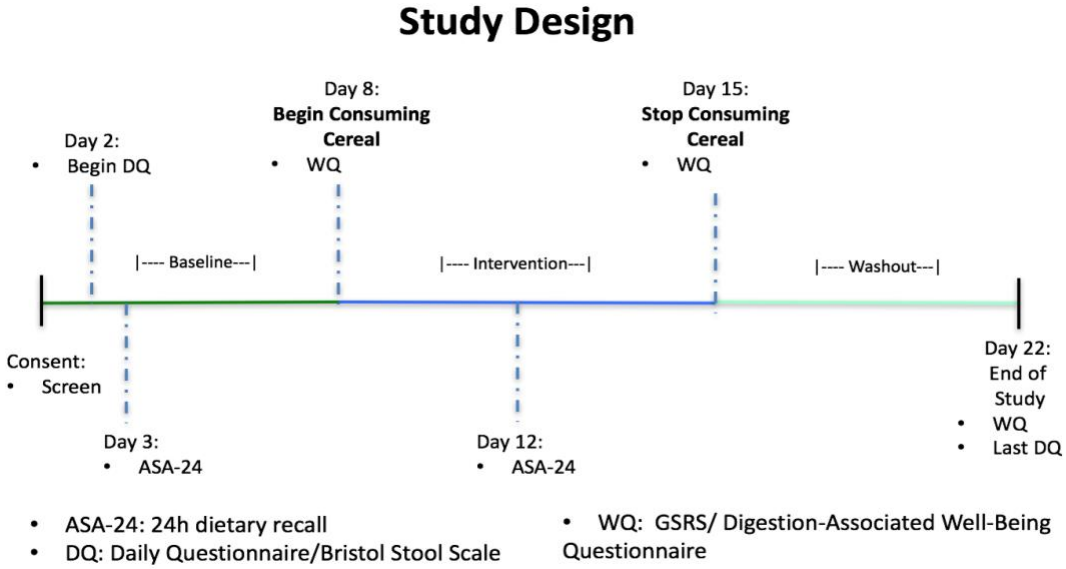

Figure 2. Study Design

treatment weeks. The average weekly bowel movements were compared using a repeated measures ANOVA. Data analysis were performed using the computer software program Sigma Plot (SysStat Software Inc., version 12.5). The alpha criteria were set at a P-value less than 0.05.

RESULTS

The majority of participants were non-Hispanic white females (Table 1). Dietary fiber intake increased with the consumption of the high fiber cereal (Figure 3). With the high fiber cereal, participants went from an inadequate diet (≤ 16g/d for females and ≤ 20g/d for males) to a more than adequate fiber diet.

Table 1. Participant Chart

	n(%)
Age*	20.3 ± 0.3
Sex	
Males	9(45)
Females	11(55)
Race	
Black or African American	2(10)
White	18(90)
Ethnicity	
Hispanic or Latino	3(15)
Non Hispanic or Latino	17(85)

[1] Data not available (n=1). *Mean ± SEM

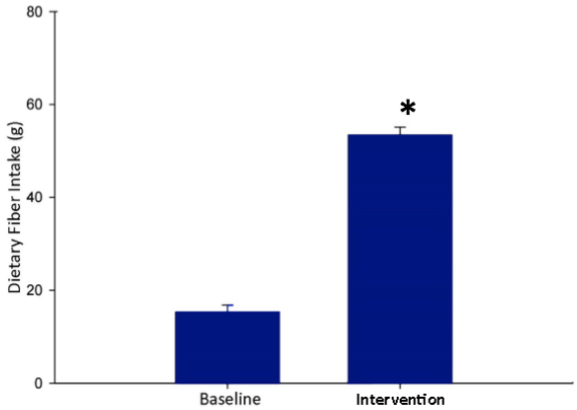

Figure 3. Average dietary figer intake on days 3 and 12

Dietary fiber intake increased during the intervention when participants were asked to consume 1 cup of high fiber cereal (*P<0.05). Dietary intake was assessed using the Automated Self-Assessment 24-hour Recall. Changes were observed in average weekly bowel movements (Figure 4) where weekly bowel movements were greater with the intervention versus baseline but not different from the washout period. According to the focus groups interviews, more frequent emptying was related to "feeling lighter and healthier." An increase was seen with the fiber intervention versus the baseline intervention (*P=0.01). No change was observed from intervention to washout.

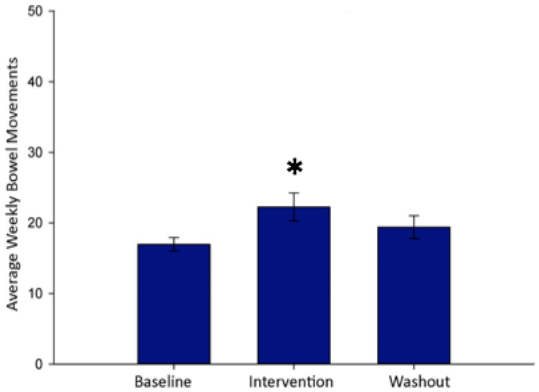

Figure 4. Average weekly bowel movements increassed with the fiber intervention

The Bristol Stool Scale captured whether the fiber intervention had any effect on stool consistency (Type 1= Separate hard lumps, like nuts, to Type 7= Watery, no solid pieces.). However, stool consistency did not change during the study (data not shown).

GSRS data were also evaluated to see whether digestive symptoms were occurring in the study population with the fiber intervention. Scores were not different across the three study periods (Table 2).The DAWBQ data were analyzed based on percentage of participants who responded strongly disagree or disagree as a measure of variability in participant responses (see Table 3). For example, if 90-100% of participant responses were strongly disagree or disagree then this indicates that the question is not very applicable to the participant population. A greater range of responses (1= strongly disagree to 7= strongly agree) indicates that the question is more applicable and may be more sensitive to changes in well-being in healthy people. For the questions relating to satisfaction with regularity and satisfaction with bowel movements (Table 3, questions 19 and 20) 22.2% and 15.9% answered either strongly disagree or disagree to each of the questions; whereas, 49.2% and 44.4% answered agree or strongly agree to each of the questions. The greater variability in responses showed that these were better questions; this was also supported by focus group data (Table 4). Self-selected focus group participants (n=4) commented, "I was really happy with the results of the intervention. It improved my well-being and I was very satisfied," and "It [high fiber cereal] increased the frequency and volume of my bowel movements and I feel healthier and lighter." Even though variability was seen in questions 19 and 20, after running a Friedman Repeated Measures Analysis of Variance on Ranks Test, the differences in the mean values among the treatment groups were not great enough to exclude the possibility that the difference was due to random sampling variability (no significant difference, P=0.329 and P=0.294, respectively).

Table 2.: Gastrointestinal Symptom Rating Scale scores for each of the symptom subscores[1]

	Baseline median (25th, 75th)	Intervention median (25th, 75th)	Washout median (25th, 75th)	P-value[2]
Reflux	1 (1, 1)	1 (1, 1.5)	1 (1, 1)	0.289
Indigestion	1.5 (1.25, 1.75)	1.5 (1.25, 1.75)	1.25 (1.19, 1.5)	0.425
Abdominal Pain	1.67 (1.33, 2)	1.33 (1, 1.67)	1.33 (1, 1.67)	0.652
Constipation	1.33 (1, 2)	1.33 (1, 1.67)	1.16 (1, 1.83)	0.816
Diarrhea	1 (1, 1.67)	1.5 (1, 2)	1 (1, 1.67)	0.660

Note. [1]Symptom scores represent the average response to two to four questions related to each symptom. Responses to questions were scored from 1 = no discomfort to 7 = severe discomfort.
[2]Data were analyzed using a One-Way Repeated Measures Analysis of Variance or Friedman Repeated Measures Analysis of Variance where appropriate.

Table 3. Digestion-Associated Well-Being Questionnaire data.

	Participants who selected Strongly Disagree/Disagree Responses (%)	Change in Response	
		Intervention - Baseline Med(25th,75th)	Washout - Intervention Med(25th,75th)
Q1: Sleep interruption	90.5%	0 (-1,0)	0 (0,0)
Q2: Embarrassed in public	95.2%	0 (0,0)	0 (0,0)
Q3: Insecure about clothing	98.4%	0 (0,0)	0 (0,0)
Q4: Interference with personal down time	87.3%	0 (0,0)	0 (0,0)
Q5: More than usual restroom use	68.3%	1 (0,2)	0 (-3,0)
Q6: Interference with physical activities	88.9%	0 (0,0)	0 (0,0)
Q7: Feeling irritable	81.0%	0 (0,0)	0 (0,2)
Q8: Made changes to clothing choices	93.7%	0 (0,0)	0 (0,0)
Q9: Attention to eating/drinking	41.3%	0 (-1,1)	0 (0,1)
Q10: Eating less	77.8%	0 (-1,0)	0 (0,0)
Q11: Uncomfortable with appearance	81.0%	0 (0,0)	0 (0,0)
Q12: Uncomfortable with sitting down	92.1%	0 (0,0)	0 (0,1)
Q13: Less self-confident	87.3%	0 (0,0)	0 (0,0)
Q14: Interference with social activities	88.9%	0 (0,0)	0 (0,0)
Q15: Change in usual appetite	79.4%	0 (0,2)	0 (-1,1)
Q16: Changes in mood	84.1%	0 (0,1)	0 (0,1)
Q17: Affect concentration	77.8%	0 (0,0)	0 (0,1)
Q18: Inconvenienced	65.1%	0 (-1,0)	0 (0,1)
Q19: Satisfaction with regularity	22.2%	0 (-2,1)	0 (-1,0)
Q:20 Satisfaction with bowel movements	15.9%	0 (-1,2)	-1 (-1,0)

Note. The Percentage of participants who selected Strongly Disagree/Disagree Responses reflects the average across all three interventions. Change in response is shown as intervention minus baseline and washout minus intervention. (1=Strongly disagree, 2=Disagree, 3=Somewhat disagree, 4= Neither agree or disagree, 5=Somewhat agree, 6=Agree, 7=Strongly agree). The green highlight represents the questions with variance in responses. All questions relate to digestive symptoms.

Table 4. Focus Group Responses

	Responses
Q1	"I have never experienced issues with sleep." "I'll go before bed or after but it won't interrupt my sleep." "Disturbed is maybe better than interrupted."
Q2	"The fiber actually regulated my BMs so the fiber made me feel less digestively uncomfortable." "Embarrassed might not be the right word-Uncomfortable or self-conscious?"
Q3	"I didn't feel discomfort- No bloating. I actually felt less bloated than normal." "More of a girl thing."
Q4	"I pooped more but that didn't really affect anything, I wasn't in the bathroom for longer." "I don't consider using the restroom during personal down time an interference. It's just a part of your life."
Q5	"My digestive symptoms weren't bad symptoms it was a positive effect." Question suggestive of negative impact
Q6	"I'm a pretty active person. It [digestive symptoms] didn't affect me during the study but it has happened before." "Relevant question."
Q7	"Digestive symptoms would not affect mood." Suggested to make that question a yes or no question and then to have the SP type in what type of change they experienced. Better to capture a positive or negative mood change
Q8	"This question is similar to question 3. I prefer question 8 wording." "This is something you would see more commonly in women."
Q9	"During the post I realized the changes that the fiber made in my diet. So I was looking more closely at what I was eating and choosing more green leafy vegetables and that kind of thing." "I've been trying to eat more fiber in my diet because I like having healthy bowel movements." -Good wording/ relevant question
Q10	Female: My eating habits changed. Male: Didn't eat less. Differences in AI between males and females?
Q11	"I was happier with my appearance on the fiber." "Digestive symptoms have nothing to do with my appearance."

Further changes in responses in the DAWBQ (Table 4) between the interventions were evaluated. The baseline responses were subtracted from the intervention responses [(Intervention (-) Baseline): median, 25th, and 75th percentiles]. A negative change indicated the participant went from more DAWB symptoms during the baseline period (their normal diet) to fewer DAWB symptoms during the intervention with the high fiber cereal. This is acknowledged as an improvement in DAWB. A positive change indicated that the participant when from fewer DAWB symptoms during their normal diet to more during the treatment. According to Table 3, there were very few changes observed between the interventions as can be seen by the many zeros. No significant changes were seen in self-reported gastrointestinal discomfort, stool consistency, and ease of passage.

The test-retest questionnaire was sent out the day after the main weekly questionnaire. The last two DAWBQs (from the washout period) were used to assess test-retest reliability. On average, people responded the same on both DAWBQs 60% of the time (data not shown). Sixty percent of identical responses on the DAWBQ indicates questionable reliability. A questionable reliability score could suggest the time between each questionnaire (24 hours) significantly influenced participant responses, even though they were asked to respond based on the past 7 days.

Discussion

The purpose of this study was to validate a questionnaire on DAWB in healthy undergraduates. Results indicated that a higher fiber diet is associated with an increase in bowel movement frequency. This was expected as insoluble fiber, such as wheat bran (main fiber source in All Bran Buds) is associated with an increase in fecal bulking and normalization of bowel habits (Eswaran et al., 2013).

Adequate/high fiber diets are associated with delayed gastric emptying but could also cause bloating or intestinal gas (Eswaran et al., 2013). Because of the suggested effects of high fiber diets, researchers expected to observe changes in DAWB. However, according to the DAWBQ and GSRS, no changes were observed in DAWB or gastrointestinal symptoms (Table 2) across the three study periods.

Overall, gastrointestinal function changed as measured by an increase in average bowel movements per week. The 39 g of dietary fiber (in addition to the habitual dietary fiber intake) did not illicit significant changes in gastrointestinal symptoms or well-being in the population investigated. These data indicate that perhaps, this population is not significantly affected by digestive symptoms. Such an increase in dietary fiber may cause a more noticeable effect in older individuals, who are more sensitive to gastrointestinal symptoms and have modified gastrointestinal health functions (Donini et al., 2009).

Focus group responses indicated that participants did prefer the increased bowel movements and felt "healthier and lighter". They also felt more satisfied with their stool consistency (Table 3, Question 20). Additionally, participants noted that they tried to include more fiber in their diet during the washout period because they realized the changes that the fiber made (Table 3, Question 9). This may explain why a decrease in fiber intake was not observed from the intervention to the washout period. The focus group participants often reported a question was "good" but it did not pertain to them. This could suggest the questions in the DAWBQ are too broad and need to be more specific. For example, in Question 12, participants did not like the phrase "inconvenienced while sitting down." One participant suggested, "Maybe say, 'You were uncomfortable sitting for long periods of time'… Be more specific." The feedback received from the analysis of variability in DAWBQ questions and from the focus group will allow researchers to modify the language and anchors of the questionnaire and pilot test the improved version in a new sample of healthy individuals. The future work will require data from interviews of people who have completed the questionnaire, on the language and relevance of the questionnaire.

Another interesting point of the focus group, was that timing was a significant factor when consuming the fiber and experiencing symptoms. This was also a common theme in a focus group from another study (unpublished data) where the questionnaire was piloted in individuals consuming resistant maltodextrin. Participants reported that eating the fiber in the morning resulted in more positive digestive symptoms than when they consumed later in the day. There were also some differences in how the fiber affected dietary intake between males and females based on comments in the focus groups. A female reported that her eating habits changed as a result of the fiber but a male stated that he didn't eat less during the intervention. This could be due to the fact that females received a greater amount of fiber per 1000 kcal of intake since both sexes were asked to consume 39 g/day.

Conclusions

Increasing dietary fiber intake from inadequate to more than adequate, did not have a significant impact on digestion-associated well-being in the population investigated. Although no changes were observed in self-reported stool consistency, gastrointestinal function was impacted as was seen by an increase in average bowel movements per week during the cereal intervention. One of the reasons for not observing changes in DAWB may be that the wording of the DAWBQ was too strong. Further modifications are required in wording and response anchors. Suggestions from the focus groups often supported DWAB questions where a low variability was observed in the study questions. The low variability in responses and little-to-no changes detected between interventions in GSRS and DAWBQ responses suggests the fiber intervention was not great enough to find measureable changes in digestive symptoms or well-being in young individuals. At least 12 questions in the DAWB will need to be modified and re-piloted in future studies.

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