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Evaluation of the Gastrointestinal Tolerability of Fibersmart®, a Novel Dietary Fiber, Using a Randomized Controlled Trial in Healthy Men and Women

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Abstract

Dietary fiber is integral to a healthful diet and the promotion of dietary fiber remains a key global health priority. Despite these efforts, most of the global population do not meet the dietary fiber intake recommendations. FiberSmart® is a type of resistant starch which may be added to food products to increase their dietary fiber content. The purpose of this randomized controlled trial was to determine the gastrointestinal (GI) tolerability of FiberSMART® consumption in generally healthy study volunteers. Forty generally healthy adults were randomized and allocated into either the intervention (n = 20; 27.8 ± 8.0 years; BMI: 26.6 ± 4.4; female: 8) or control (n = 20; 28.4 ± 11.4 years; BMI: 24.5 ± 4.6; female: 7) condition. Each group completed three phases of seven days each, separated by a 21-day wash-out. Participants in the intervention condition received an escalating dose of 10 g/day, 30 g/day and 50 g/day of FiberSMART® consumed in a single dose on each day, while those in the control condition received placebo (flavored drink without addition of FiberSMART®) on each day. Thirty-eight participants completed the trial (n = 19 in each condition). There were no significant between-group differences (p = .376) in the GI composite score over the three phases, and the reported symptoms were mild overall. Additionally, GI symptoms did not appear to increase across the escalating doses, which was supported by additional measures of GI tolerability including stool characteristics and self-reported quality of life. A dietary fiber supplement with good tolerability, as demonstrated in these studies of FiberSMART® in generally healthy adults, is of relevance to public health strategies aiming to increase global dietary fiber content.

Keywords: *Dietary Fiber; Dietary Fibre; Health; Controlled Trial; RCT*

Introduction

Dietary fiber is predominantly obtained from plant-derived foods such as fruits, vegetables, whole grains and legumes [1]. The health benefits of dietary fiber have long been acknowledged [2-6], where increased dietary fiber intake has been shown to lower rates of cardiovascular disease (CVD) [1], type 2 diabetes (T2D) [7] and has demonstrated an inverse association with some cancers [8]. Dietary fiber is therefore integral to a healthful diet and the promotion of dietary fiber remains a key health priority in many national dietary recommendations and guidelines [9-11]. Despite these health benefits of fiber, data from the Australian population suggests less than 20% of adults meet the suggested dietary target (28g for women, 38g for men) to reduce the risk of chronic disease [12], while only 57% of children met the levels of dietary fiber deemed adequate (Adequate Intake; AI). Levels of dietary fiber intake are even lower in US adults and children [13-15] with less than 1 in 10 Americans of all ages meeting recommendations and the majority consuming less than half of the recommended intake. Trends indicate that levels of dietary fiber have not changed in the last 10 years despite consistent health-messaging to increase dietary fiber, suggesting that underconsumption of dietary fiber will likely continue [16].

While increased consumption of fiber-rich foods, such as vegetables and legumes remain critical, an alternate strategy is to increase the nutrient content of foods via addition of novel dietary fibers. There are multiple forms of dietary fiber which may be used to enrich foods. These can broadly be classified as soluble, insoluble or resistant starch [17]. FiberSmart® is a type of resistant starch, composed of at least three glucose molecules which are linked together in a way which makes them resistant to enzymatic cleavage. The polymer bonds of FiberSMART® resistant dextrin are composed of alpha 1,2 / alpha1,3 / and some beta linkages and has a caloric value of approximately 1.4 - 2.0 kcal/g. FiberSmart® is neutral in flavour, with a relative sweetness to sugar of ~20 - 30%. The benefits of resistant starches such as FiberSMART®, are that they exhibit fermentability and increased absorption of minerals. As such, the FDA recognizes resistant dextran/ starch as a functional soluble fiber [18].

Despite dietary fiber having been linked with multiple health benefits, increased levels of fiber in the diet may also be associated with increased gastrointestinal (GI) symptoms such as bloating, flatulence and diarrhea. The magnitude and severity of these GI symptoms depend on the physiochemical properties of the fiber. It is therefore important to assess GI tolerability of specific types of fiber.

Purpose of the Study

Therefore, the primary purpose of the current study was to assess GI tolerability following consumption of dextran-resistance starch, FiberSmart®. We hypothesised that FiberSMART® would be well-tolerated with nominal GI tolerance issues up to 50 g/day provided in a single dose.

Methods

An independent randomised controlled trial (RCT) was conducted through Murdoch University, Australia, and sponsored by Anderson Advanced Ingredients. The study adopted a single blind (participant) RCT design wherein participants were allocated to either the fiber (FiberSMART®; INT) or control (CONT) condition. Allocation was performed after obtaining informed written consent and following the initial screening process. Allocation was completed in a blinded fashion using a numbered list consisting of 1's and 2's in randomly permutated blocks (each block n = 2-6) from a computer-generated list (http://www.randomisation.com). Each block consisted of a balanced treatment allocation ratio (1:1 in each block). Blinding was achieved by sending only study IDs and gender to an investigator (TF) not involved in the assessments, who assigned each ID to the predetermined conditions. Males and females were counterbalanced across conditions by generating two separate lists (one for males and one for females). The study was approved by Murdoch University Human Research Ethics Committee, Western Australia, and written informed consent was obtained from all participants prior to commencement of the study. All investigations were conducted according to the principles expressed in the Declaration of Helsinki.

Study participants

The study recruited both men and women between the ages of 18 and 75 years. Participants were not eligible for this study if they: i) had constipation (defined as 0 - 3 stools per week over a 6-week period); ii) were currently taking prescribed medication for digestive symptoms (e.g. anti-spasmodic, laxatives and anti-diarrheic drugs); iii) had a history of any medical disorder or were consuming dietary supplements that could potential interfere with study outcomes; iv) were vegetarians or vegans and; v) were on antibiotics or had consumed laxatives in the 4-weeks prior to the screening visit. Using a medium effect size (f = 0.25), a sample size of 30 participants was deemed sufficient to provide 80 power to detect (α-error probability value set at .05) within-between interactions (Two conditions: INT and CON) using measures taken at three different time-points. To account for possible attrition, we increased the target sample size to forty participants. Participants were recruited via public advertisements at Murdoch University and in the local community and enrolled between March 2020 and March 2021, with final follow-up assessments completed July 2021.

Experimental procedure

Participants attended the Murdoch University Exercise Physiology laboratory to complete their preliminary assessment (Baseline: Week 0) which included body anthropometrics (height, weight, and waist circumference), vital signs (blood pressure and heart rate), and a health questionnaire (SF-36). Upon completion of all preliminary assessments, participants were then randomly assigned into their respective conditions (INT and CON) as described earlier.

Over a 12-week period, participants in the INT condition consumed either 10 g/day, 30 g/day or 50 g/day of FiberSMART® soluble fiber for 7-consecutive days, with a 21-day washout period between each of the doses. The fiber was consumed in a single serving, by addition of the fiber to a commercially available apple juice beverages (250 ml, Pop Tops®; 273 kJ, total carbohydrate 15.3g, sugars 15.0g). The fiber was presented in a dose-escalating manner as presented in figure 1. Participants in the CON condition consumed the same apple fruit drink, without addition of the FiberSMART®. In Week 13, participants completed their post-intervention assessments, which were identical to the baseline assessments, at least 24h after the last day of the wash-out period, but no more than 96 h after the last day of the wash-out period.

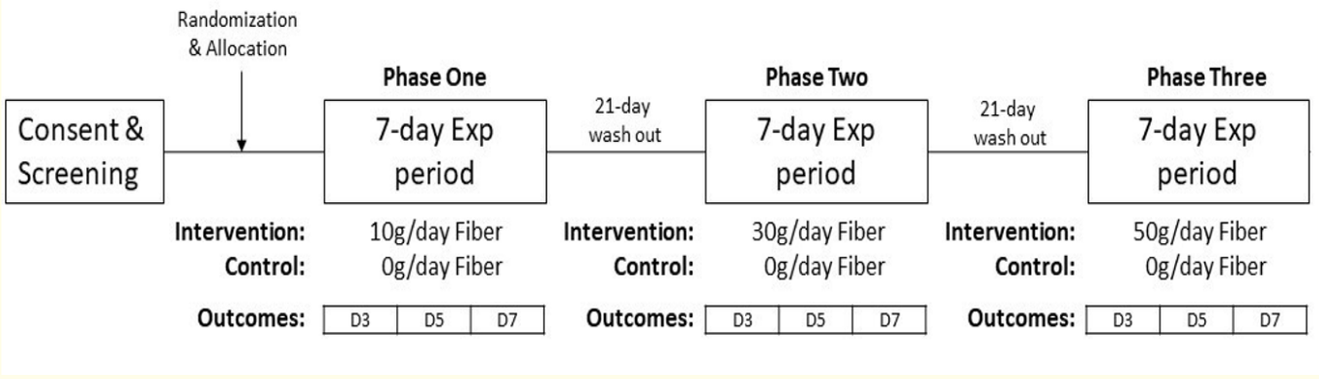

Figure 1: *Study design.*

Outcome measures

The primary outcome measure for this study was the change in gastrointestinal symptoms and stool characteristics between conditions across the three phases (condition by time interaction). Secondary measures included changes in body anthropometrics (height, weight, body mass index, waist and hip circumference and waist-to-height ratio) and vital signs (blood pressure and heart rate).

Gastrointestinal symptoms and stool characteristics

Gastrointestinal (GI) symptoms were recorded on day 3, day 5 and day 7 of each phase via the use of a GI symptom diary based on previously described questionnaires [19,20]. Symptoms included commonly reported GI symptoms associated with the oral intake of dietary fiber supplementation including nausea and vomiting (i.e. Have you felt any nausea (wanting to vomit) today?), heartburn (i.e. Have you had heartburn (burning in the chest) today?), abdominal pain (i.e. Have you had abdominal pain today?), diarrhoea (i.e. Have you had diarrhoea today?) and constipation (i.e. Have you had constipation today?). The presence of these were reported as did not experience, no more than usual, somewhat more than usual, much more than usual, while the severity of the GI symptom was collected using a 4-point scale (Absent, mild, moderate, severe). When present, the duration (time, min) and frequency (number of occurrences) of nausea and abdominal pain recorded.

Stool characteristics were recorded on days 3, 5 and 7 of each phase via a diary and recorded over the intervention period. Participants were asked to record frequency and consistency of bowel movements based on the Bristol Stool Form Scale (BSFS). The BSFS is a validated 7-point scale that has been used extensively (e.g. [20]) in clinical practice and research for stool form measurement.

Body anthropometrics

Body mass was calculated using a calibrated electronic digital while height (m) was measured using a wall-mounted stadiometer. Body mass index (BMI) was then calculated by dividing body mass by the height measured in metres-squared ($kg.m^{-2}$). Waist circumference was measured on a horizontal plane at the narrowest point between the lower costal border (10^{th} rib) and the uppermost lateral border of the iliac crest while hip circumference was measured at the largest circumference of the buttocks. Waist-to-hip ratio (WHR) was calculated by dividing the waist circumference measurement by the hip circumference measurement.

Health-related quality of life

Participant's health-related quality of life outcomes were measured at baseline and at post-intervention via the 36-item short form survey (SF-36). The SF-36 [21-23] comprises of 36 questions that cover eight domains of health. Upon completion of the questionnaire,

scores for the different domains are converted and pooled using a scoring key, for a total score indicating a range of low to high quality of life. For the purpose of this study, the domains of Pain, General Health and Health Change were regarded as most relevant and reported.

Safety assessments

Adverse events (AEs) were captured using open-ended question (Did you have any significant medical problem since the last study visit?) at each visit to the laboratory. Assessment of adverse events (AEs) were evaluated per the US Food and Drug Administration standard categorization with respect to their severity (mild, moderate, severe) and potential of relationship to the dietary supplement (not related, unlikely, possibly, probably, definitely). Given the nature of the current study, being a dose-escalating tolerance study of dietary fiber, GI symptoms were an expected outcome and as such were recorded as study outcomes and not an AE.

Statistical analysis

All statistical analyses were conducted using IBM® SPSS® Statistics (version 24). Descriptive statistics are presented as means ± standard deviations (SD). Differences in baseline characteristics between the two conditions were assessed using an independent samples t-test. The primary outcome (GI composite score) was calculated as the sum of the individual severity scores for nausea, vomiting, abdominal pain, diarrhea and constipation. Effects of FiberSMART® consumption were estimated using random-intercept linear mixed models (LMM) to assess changes across time (sequential phases: phase 1: 10 g/day; phase 2: 30 g/day; phase 3: 50 g/day) in the primary (GI composite score) and secondary outcomes (intensity of GI symptoms; duration of GI symptoms; frequency of GI symptoms; fecal consistency; fecal frequency) between the two conditions (INT; CONT). Time (phases) and condition were modelled as fixed effects while participants were treated as random effects (with random intercept) to account for differences at baseline. The primary hypothesis of interest was the condition by time (phase) interaction which was examined with pairwise comparisons of the estimated marginal means. All data was retained for analysis of the primary and secondary outcomes in accordance with intention-to-treat analysis. Tests of significance were performed at alpha equal to 0.05, two-sided.

Results

Forty participants were randomized and allocated to one of the two study conditions. Descriptive data of participants are presented in table 1. One participant was lost to follow-up after completion of the first phase (10 g/day) in the INT condition, while one participant was lost to follow-up after completion of the first phase (0 g/day) from the CONT condition (reason stated: lack of time).

Condition	**Intervention Condition (n = 20; Females: 8)**						**Control Condition (n = 20; Females: 7)**					
	Pre		**Post**		**Change**		**Pre**		**Post**		**Change**	
Measures	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age (y)	27.8	8.0					28.4	11.4				
Height (m)	1.8	0.1					1.7	0.1				
Weight (kg)	82.3	15.8	82.4	15.0	-3.4	16.9	74.4	16.8	74.2	16.3	-1.0	2.5
BMI	26.6	4.4	25.4	7.4	-1.1	5.6	24.5	4.6	24.3	4.6	-0.3	0.7
WC (cm)	83.4	11.1	82.9	12.2	-4.4	18.9	79.8	11.6	78.8	11.2	-158.0	2.2
HC (cm)	103.8	11.0	104.2	10.6	-0.1	1.3	99.8	8.6	98.5	8.3	-1.4	2.4
WHR	0.8	0.1	0.8	0.1	0.0	0.0	0.8	0.1	0.8	0.1	0.0	0.0
WHtR	0.48	0.06	0.45	0.12	-0.03	0.11	0.46	0.06	0.45	0.06	-0.01	0.01
SBP (mmHg)	128	9	126	5	-3	6	132	12	131	10	-1	7
DBP (mmHg)	69	8	72	10	4	5	75	11	74	6	0	6
RHR (bpm)	65	8	62	8	-2	5	75*	11	71*	12	-4	4
SF36: Pain	88.8	11.8	87.4	15.9	-2.4	12.8	87.8	17.9	92.6	11.7	3.29	19.8
SF36: GH	72.3	16.2	71.1	17.8	-1.1	12.2	78.8	15.3	83.4	13.5	4.2	14.5
SF36: HC	52.5	20.8	55.3	17.4	1.3	23.6	53.8	14.3	61.8	12.5	9.2	16.6

Table 1: *Participant descriptive characteristics at the pre- and post-intervention time points and stratified by condition allocation. Significant differences (p ≥ .05) are indicated in bold with asterisk.*
y: Years; m: Meters; WC: Waist Circumference; HC: Hip Circumference: WHR: Waist to Hip Ratio; WHtR: Waist to Height Ratio; SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure; RHR: Resting Heart Rate.

Changes in gastrointestinal symptoms and stool characteristics

Data for gastrointestinal symptoms are presented in table 2 and 3. There was no condition x time interaction (p = .376) in the GI composite score, although significant main effect of condition was identified (p = .004). Mean differences [95% CI] between INT and CONT were 0.04 [-0.03, 0.12] during phase one, 0.10 [0.03, 0.18] during phase two and 0.10 [0.02, 0.17] during phase three. This represents a difference of between 0.04 to 0.10 across the six individual questions when consuming either 10 g/day, 30 g/day or 50 g/day of FiberSMART® relative to the control condition (no fiber).

Intervention Condition (N = 20)												
	Phase One (10 g/day)				Phase Two (30 g/day)				Phase Three (50 g/day)			
Question	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
Nausea	95%	3%	2%	0%	100%	0%	0%	0%	100%	0%	0%	0%
Vomiting	100%	0%	0%	0%	100%	0%	0%	0%	100%	0%	0%	0%
Heartburn	93%	5%	2%	0%	100%	0%	0%	0%	98%	2%	0%	0%
Abdominal pain	88%	10%	2%	0%	92%	8%	0%	0%	80%	18%	2%	0%
Diarrhea	92%	3%	5%	0%	98%	2%	0%	0%	88%	7%	5%	0%
Constipation	98%	2%	0%	0%	98%	2%	0%	0%	97%	2%	2%	0%
Control Condition (n = 20)												
Question	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
Nausea	100%	0%	0%	0%	98%	0%	2%	0%	92%	8%	0%	0%
Vomiting	100%	0%	0%	0%	100%	0%	0%	0%	100%	0%	0%	0%
Heartburn	93%	7%	0%	0%	100%	0%	0%	0%	100%	0%	0%	0%
Abdominal pain	92%	3%	5%	0%	92%	5%	2%	2%	98%	2%	0%	0%
Diarrhea	100%	0%	0%	0%	100%	0%	0%	0%	100%	0%	0%	0%
Constipation	95%	5%	0%	0%	93%	7%	0%	0%	100%	0%	0%	0%

Table 2: *Prevalence (expressed as %) of answering 1 (Did not experience), 2 (no more than usual), 3 (somewhat more than usual), 4 (Much more than usual) averaged across each phase (Day 3, Day 5, Day 7 of loading period) stratified by condition allocation and study phase.*

	Intensity Mean (SD)		Duration Mean (SD)		Frequency Mean (SD)	
	INT	**CONT**	**INT**	**CONT**	**INT**	**CONT**
Phase 1	1.08 (0.15)	1.04 (0.13)	29.3 (81.5)	10.8 (33.3)	0.32 (0.78)	0.22 (0.72)
Phase 2	1.15 (0.09)	1.05 (0.12)	10.5 (25.3)	14.2 (45.5)	0.18 (0.43)	0.22 (0.61)
Phase 3	1.20 (0.13)	1.10 (0.04)	24.4 (60.7)	8.6 (24.0)	0.12 (0.22)	0.12 (0.22)

Table 3: *Condition mean and standard deviation for intensity (expressed as: 1, absent; 2, mild; 3, moderate; 4, severe), duration (minutes/day) and frequency (number of episodes) stratified by condition allocation and study phase.*

There was no condition x time interaction (p = .491) or main effect of condition (p = .377) for the duration of symptoms. Mean differences [95% CI] between INT and CONT were 18.5 [-12.8, 49.8] min during phase one, -4.7 [-36.8, 27.3] min during phase two and 14.7 [-17.3, 46.8] min per day during phase three. This represents a difference in the daily duration of symptoms associated with nausea and abdominal pain (combined) of between -4.7 min 18.5 min when consuming either 10 g/day, 30 g/day or 50 g/day of FiberSMART® relative to the control condition (no fiber).

There was no condition x time interaction (p = .790) or main effect of condition (p = .911) for the frequency of symptoms. Mean differences [95% CI] between INT and CONT were 0.1 [-0.2, 0.4] episodes during phase one, -0.0 [-0.4, 0.3] episodes during phase two and -0.0 [-0.4, 0.3] episodes per day during phase three. This represents a difference in the daily frequency of symptoms associated with nausea and abdominal pain (combined) of 0 and 0.1 episodes when consuming either 10 g/day, 30 g/day or 50 g/day of FiberSMART® relative to the control condition (no fiber).

There was no condition x time interaction (p = .140) or main effect of condition (p = .081) for stool frequency. Mean differences [95% CI] between INT and CONT were 0.3 [-0.1, 0.7] bowel movements during phase one, -0.0 [-0.4, 0.4] bowel movements during phase two and 0.4 [0.1, 0.8] bowel movements per day during phase three. This represents a difference in the daily stool frequency of 0 to 0.4 bowel movements when consuming either 10 g/day, 30 g/day or 50 g/day of FiberSMART® relative to the control condition (no fiber).

Regarding the Bristol Stool Chart, there was no condition x time interaction (p = .274) however, there was a main effect of condition (p = .023). Mean differences [95% CI] in ratings of fecal consistency between INT and CONT were 0.2 [-0.4, 0.8] during phase one, 0.7 [0.1, 1.3] during phase two and 0.7 [0.1, 1.3] during phase three. This represents a fecal consistency difference in the rating of between 0.2 to 0.7 on the Bristol Stool Chart, when consuming either 10 g/day, 30 g/day or 50 g/day of FiberSMART® relative to the control condition (no fiber).

Changes in body anthropometrics and health-related quality of life

Changes in body anthropometrics and health-related quality of life are presented in table 4. Resting heart rate was the only participant characteristic identified as being significantly different at baseline between INT and CONT.

	Daily bowel movements Mean (SD)		Fecal consistency scores Mean (SD)	
	INT	**CONT**	**INT**	**CONT**
Phase 1	1.7 (0.7)	1.4 (0.4)	3.6 (1.1)	3.4 (0.8)
Phase 2	1.4 (0.6)	1.4 (0.6)	4.2 (1.0)	3.5 (0.7)
Phase 3	1.7 (0.9)	1.3 (0.5)	4.3 (1.3)	3.5 (0.7)

Table 4: *Daily bowel movements and average fecal consistency scores (mean, standard deviation) for participants stratified by condition allocation and study phase.*

Safety assessment

No AEs were reported in the current study.

Discussion

The purpose of the current study was to assess GI tolerability following consumption of a novel dextran-resistance starch, FiberSmart®. The key findings of the study were: i) GI composite score did not demonstrate a condition by time interaction, however, participants in the INT group had statistically significantly higher average GI composite scores compared to the CONT group; ii) no significant differences in the frequency or duration of GI symptoms were identified between conditions; iii) fecal consistency was statistically significantly increased in the INT condition relative to the CONT condition, however stool frequency was not significantly different; iv) no AEs were reported in the current study.

GI composite scores were shown to be statistically significantly different (main effect) between conditions. However, these differences were low, ranging in magnitude from 0.04 to 0.1 across the six individual questions (4-point scale) and as shown in table 2, GI symptoms

were expressed in relatively few individuals and did not appear to increase with escalating doses. The types of reported symptoms were consistent with previous literature using different forms of dietary fiber [20] as well as polydextrose [19,24] at similar doses to the current study. While the maximum dose (50 g/day) in this study is reported as a daily dose, it is important to acknowledge that the fiber was presented as a single serve fruit drink, which was likely consumed in a single instance. The rationale for presenting this as a single serving as opposed to multiple servings was to increase adherence to consumption of the fiber.

Frequency and duration of the GI symptoms were also not significantly different between conditions. Duration of GI symptoms was characterised by substantial individual differences (as identifiable by the standard deviations), with the few individuals noting GI symptoms, reporting these for extended periods of time. However, this occurred in both conditions and there was no apparent trend or pattern indicating an association with the higher doses of the fiber supplement. Moreover, the mean intensity of these symptoms ranged from 1.08 - 1.20.

Additional GI tolerability parameters including frequency of bowel movements was also similar between conditions. Fecal consistency increased in the INT group, suggesting an increasing ease of stool passage. The range of scores for fecal consistency remained in the mid-range of the Bristol Stool Chart ratings, indicating no presence of diarrhea or of constipation. These findings are consistent with those of others adopting a similar dosing strategy [19,20] and support the GI tolerability of FiberSMART®.

There were no notable differences in the health-related parameters (Table 1). This is unsurprising given the short time-period over which the fiber intake occurred (three one-week periods). Additionally, the participants in the current study were apparently healthy (according to their BMI, blood pressure) and relatively young individuals wherein health improvements are less likely to occur.

Conclusion

Consumption of FiberSMART® dissolved within a single beverage resulted in similar GI symptoms to consumptions of the beverage without addition of fiber (i.e., negative control) and these symptoms were identified as mild overall. In support of the GI tolerability of FiberSMART®, GI symptoms did not appear to increase across the doses (10 g/day, 30 g/day, 50 g/day) and were supported by other measures of GI tolerability including stool characteristics and self-reported quality of life. A dietary fiber supplement with good tolerability, as demonstrated in these studies for FiberSMART®, is of relevance to public health strategies which aim to increase global dietary fiber content. While no direct health improvements were noted in this short-term intervention in healthy individuals, longer-term studies with clinical populations may reveal direct health benefits.

Author Contributions

All authors contributed to the design of the study. ST and TF conducted the study and performed the data analyses. All authors contributed to data interpretation and preparation of the manuscript. ST and TF had full access to the data and responsbility for the final publication.

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Conflict of Interest

The authors declare no conflict of interest.

Clinical Trial Registration

ANZCTR identifier ACTRN12620000142932.

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