THE EFFECTS OF WHOLE FOODS AND DIETARY SUPPLEMENTS ON DIGESTIVE HEALTH

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Abstract

Digestive conditions are prevalent and dietary change is a common strategy for relieving symptoms. Fiber, probiotics, anti-inflammatory compounds, and analgesic compounds may relieve some gastrointestinal symptoms.

In the first study, a literature review on foods and dietary supplements as treatments for digestive disorders was conducted. PubMed was used to search prunes, kiwifruit, kefir, aloe vera, and peppermint for the treatment of constipation, diarrhea, IBS, GERD, and ulcers. In general, the evidence was mixed and it highlighted the need for more rigorous research.

The second study investigated if two weeks of oatmeal consumption could improve digestive health in children ages seven to twelve. No differences were observed for stool frequency or stool consistency; however, fiber intake was increased and some reports of gastrointestinal symptoms improved from baseline.

The results of the review paper and oatmeal study suggest that foods and supplements may alter digestion; however, determining efficacy requires additional research.

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CHAPTER ONE: Food and supplement aids for digestive health

Introduction

Definition of digestive health

According to the American Gastroenterological Association (AGA), digestive health is defined by the presence of characteristics like "appropriate nutrient absorption, intestinal motility, immune function, and a balanced microbiota" with the absence of symptoms like "heartburn, rumbling, nausea, bloating, excessive flatulence, constipation, diarrhea, or abdominal pain and discomfort".[1] According to the AGA, disturbances in digestive health include conditions and diseases of esophagus like gastroesophageal reflux disease (GERD), diseases of the pancreas and colon, irritable bowel syndrome (IBS), constipation, and diarrhea.[2] This paper will focus on how particular whole foods and dietary supplements may alleviate disruptions in digestive health, specifically, constipation, diarrhea, IBS, GERD, and peptic ulcers.

Why do we care about digestive health?

Digestive health, according to the AGA definition, suggests freedom from conditions like IBS, constipation, and GERD while also being free of gastrointestinal (GI) irritations like stomach pain, bloating, and gas.[1] However, the presence of digestive disorders is high. A meta-analysis of eighty IBS populations estimates the global prevalence of IBS to be 11.2%.[3] A study of GERD symptom prevalence in the U.S. found over 20% of participants experienced GERD symptoms at least weekly.[4] Estimates for constipation and diarrhea vary; however, a meta-analysis of chronic constipation found a pooled prevalence of 14% worldwide[5] and a survey of U.S. self- reported bowel habits estimates diarrhea prevalence at 3.6% in men and 4.8% in women.[6]

Not only are digestive disorders common, but they are also a significant burden to sufferers both economically and in quality of life. For IBS patients, it is estimated that they spend 51% more on health care costs over a year compared to individuals without IBS.[8] Besides dealing with greater health care expenses, people suffering from digestive conditions experience a lower quality of life and productivity. People with IBS score significantly lower on surveys of health-related quality of life and are estimated to have a 15% reduction in work productivity compared to employees without IBS.[9] Constipation is also associated with lower quality of life scores.[10]

With the high prevalence, high costs, and lower quality of life associated with poor digestive health, finding treatments to prevent or alleviate these conditions is of interest. Medications exist to treat many digestive conditions; however, diet may often be the first-line recommendation for symptom alleviation.[11] For example, a common recommendation for constipation treatment is increased intake of dietary or supplemental fiber.[12] This paper will focus specifically on individual foods and supplements believed to help treat symptoms of digestive disorders. It will present research on prune, kiwifruit, kefir, aloe vera, and peppermint consumption and their impacts on digestive diseases or symptoms. Low FODMAP diets for the treatment of IBS will additionally be discussed.

Search Methods for Identifying Research on Digestive Health Benefits of Specific Foods

A literature search was conducted to investigate research on specific foods as treatment for digestive conditions. The PubMed database was used to search for relevant articles. The food search words used were “prunus domestica”, “prunes”, “prune juice”,

"actinidia" (kiwi), "kefir", "aloe", and "mentha piperita" (peppermint). These foods were specifically chosen since they are foods or supplements that are believed to have benefits for digestive health. We avoided products and supplements that were a combination of foods or spices. The digestive health search terms used were "digestive health", "gastrointestinal health", "constipation", "diarrhea", "irritable bowel syndrome", "gastroesophageal reflux", and "peptic ulcer". The last five terms are digestive conditions and were chosen since they are some of the most common GI conditions.[6,13]

A study was included if it was a randomized controlled trial, crossover trial, non-controlled trial, or cohort study. Some recent literature reviews and meta-analyses were included as well. Studies were only included if they were conducted in human subjects, were published in English, and were published within the last thirty years, since 1987. We included studies that investigated the foods of interest as whole foods, juices, syrups or gels, or as an extract in a tablet or capsule. Studies were excluded if the food of interest was combined with something else, for example, prunes in a yogurt product. Studies were also excluded if researchers did not measure GI health outcomes such as stool characteristics or reports of symptom severity.

Prunes

Prunes are long believed to have digestive health benefits, especially alleviation of constipation.[14] The improvement in constipation may be due to the high fiber and sorbitol content of prunes.[15] Prunes are produced by drying specific varieties of plums and are consumed in several forms including as prune juices, prune purees, and whole dried plums.[14]

A systematic review by Lever et al examined four randomized, controlled trials which investigated prune consumption on either improving constipation or increasing stool frequency.[16] The first study tested an intervention of 100 g of prunes per day for four weeks on the cholesterol levels and fecal output of forty-one men with mild hypercholesterolemia and no known GI disorders.[17] Stool weight measured from fecal samples was significantly higher following the prune intervention compared to after the crossover intervention of four weeks of 360 ml of grape juice per day.[17] A study by Lucas et al also used an intervention of 100 g of prunes; however, the subjects were fifty-eight postmenopausal women without GI conditions who were either assigned prunes or a treatment of 75 g of dried apples.[18] After the three month intervention period, validated bowel movement questionnaires revealed no statistical differences between prune and dried apple treatments in any outcomes including stool frequency, consistency, and bulk.[18]

The third study in the review was Howarth et al, who investigated the effect of healthy snack selection in twenty-nine women using a crossover design with two weeks of 200 calories of prunes per day and two weeks of 200 calories of low-fat cookies per day with a two-week washout period.[19] Significantly softer stools were reported by participants following the prune intervention compared to the low-fat cookie and baseline responses.[19] However, no differences in self-reports of stool frequency, straining, or feelings of constipation were observed between the treatments or from baseline using a bowel habit questionnaire.[19]

The final study in the review was a crossover trial in forty subjects with chronic constipation and used an intervention of 100 g of prunes per day for three weeks compared to 22 g of psyllium, a soluble fiber and bulking agent commonly recommended for constipation treatment.[20] The prune treatment increased the average number of complete spontaneous bowel movements and significantly improved stool consistency ratings from baseline compared to the psyllium treatment from baseline.[20]

The review by Lever et al concluded that the results from the four studies were too difficult to compare due to differences in the populations studied and the control food used.[16] They expressed concerns about the rigor of the studies with one crossover study failing to use a washout period[17] and, while participants were unblinded to the intervention in all four studies, only two mentioned accounting for this in their analyses.[17,20] The authors also questioned the use of dried apples as a control for prunes by Lucas et al as apples also contain both fiber and sorbitol.[16] Lever et al overall recommended that future studies use stronger designs to determine a recommended dose of prunes for digestive health.[16]

Research has been also been conducted in prune juices as a treatment for constipation. Piirainen et al used a single arm intervention to test two weeks of 250 ml of prune juice in fifty-four subjects with mild GI symptoms; however, the study failed to address what these GI symptoms were.[21] They found a significant reduction in ratings of difficulty with defecation during the two weeks of prune juice consumption compared to baseline, but no significant differences in stool frequency or consistency were observed.[21] Cheskin et al examined two weeks of eight ounces of plum juice compared to both apple

juice and apple juice with psyllium added on thirty-nine adults with constipation in a crossover design.[22] While there was no statistical difference in stool frequency or reported immediate relief of constipation, plum juice consumption was associated with significantly softer stools compared to apple juice and apple juice with psyllium.[22] Both studies in juice had promising results; however, neither used the validated Bristol stool scale[23] to assess stool consistency but rather had participants self-report consistency using scales with words like loose, soft, hard, and very hard.[21,22]

Overall, prunes and prune juice appear to improve some constipation outcomes. Only Lucas et al found no improvements in any constipation symptoms; however, the use of dried apples as a control in the study may not have been well-founded.[16,18] The exact GI outcomes that showed significant improvements were not consistent from study to study and prunes often did not improve every outcome measured in the trials[16,18] which suggests that prunes may only provide limited relief from constipation symptoms.

Kiwifruit

Kiwifruit is another whole food believed to have a positive impact on constipation. The "Hayward" kiwifruit is the green-flesh variety that is the most common commercially and is the variety most familiar to people as kiwifruit.[24] In 2000, the "Gold Kiwifruit", which has a yellow-colored flesh, entered the market.[24] The few human studies of kiwifruit and digestive health mainly suggest its use as a laxative to treat constipation in specific populations.[25–27]

A crossover study conducted by Rush et al examined the effect of three weeks of kiwifruit consumption at a dose of 100 g of kiwi per 30 kg of weight in an elderly

population of healthy adults over the age of sixty compared to a three week period where participants abstained from kiwifruit consumption.[25] They found significant increases in stool frequency, softness of bowel movements, and bulk of stools during the period of kiwifruit consumption; however, the Bristol stool scale was not used to assess consistency and stool bulk was self-estimated by participants rather than measured by weight.[25] A later study in China by Chan et al recruited thirty-three constipated adults and twenty healthy adults for a four week treatment of two kiwifruits per day.[26] They found a significant increase in spontaneous bowel movements, significant decreases in both laxative use and self-reported difficultly with constipation, and significant decrease in colonic transit time following the treatment period in constipated participants.[26] No significant differences in constipation outcomes were observed in healthy participants.[26]

Another study of kiwifruit and digestive health examined a treatment with two kiwifruit per day for four weeks in forty-five IBS patients with constipation and sixteen healthy participants compared to a group of fifteen IBS patients taking placebo glucose capsules.[27] The IBS participants in the treatment group experienced significant increases in bowel movement frequency over time; however, they still had fewer bowel movements after treatment compared to the healthy participants.[27] Colonic transit time, measured using radiopaque markers, was also significantly decreased in the IBS treatment group; however, no significant differences in fecal bulk were found.[27] These three studies suggest that in specific populations, regular kiwi consumption may improve constipation symptoms.

Two recent studies have examined supplements of kiwifruit for constipation and stool frequency.[28,29] Ansell et al used a randomized, double-blind, crossover study to test supplements derived from green and gold kiwifruit prepared by removing the seeds and skin of the fruit and processing the flesh into a powder.[28] Nineteen healthy participants and nine participants with functional constipation completed each of the four interventions of 2400 mg of a Gold supplement (gold kiwifruit), 2400 mg of Actazin (green kiwifruit), 600 mg of Actazin, or a placebo for twenty-eight days each with a two week washout period in between each intervention.[28] The 2400 mg dose of Actazin and Gold supplement caused significant increases in average daily bowel movements compared to the washout period in the healthy participants but not in the group with constipation.[28] Stool consistency as measured by the Bristol Stool scale was not significantly different for each of the treatments compared to the washout period for either the healthy or constipated cohort.[28]

Kindleysides et al conducted a randomized, double-blind, crossover trial testing 1 g of green kiwifruit extract in a capsule for three weeks in thirty-two adults reporting three or fewer bowel movements per day compared to a placebo.[29] No significant differences in bowel movement frequency, stool consistency, or reported GI symptoms were observed between the kiwifruit extract and the placebo.[29] With the exception of Kindleysides et al, promising improvements in constipation symptoms are seen in studies of kiwifruit; however, more research needs to be conducted to investigate whole kiwifruit and kiwi extract in other populations and using validated tools for measuring stool bulk and consistency.

Kefir

Kefir is a fermented beverage believed to act as a probiotic and have positive health effects due to the bacterial species it contains.[30] Kefir is a product made from kefir grains added to milk and allowed to ferment.[31] These grains contain bacteria that continue to thrive in the final milk product.[31] Little research has been conducted on kefir and digestive issues; however, a few emerging studies suggest kefir may be effective for some conditions including diarrhea, constipation, and *Helicobacter pylori* infection.[32–34]

Kefir has been studied for the treatment of both diarrhea and constipation. A randomized, double-blind, control study in 125 children under five years old taking antibiotics found no statistical difference in diarrhea occurrence with treatment of 150 ml of kefir for ten days during antibiotic treatment compared to a heat-killed control drink.[32] Since the children enrolled in the study were free from diagnosed diarrhea, they may have been too healthy to see differences in diarrhea occurrence between the kefir and control drink.[32] When investigating constipation, a pilot study using a single arm intervention in twenty adult participants with functional constipation found that 500 ml of kefir per day for four weeks significantly improved self-reported stool frequency, consistency, and self-rated bowel satisfaction while significantly lowering use of laxatives compared to baseline responses.[33] As both studies were the first to examine kefir and diarrhea and constipation accordingly, more research needs to be done to follow-up with these findings.

Kefir has also been investigated as an addition to regimens for eradicating *H. pylori*, which is an infection that can cause gastric and duodenal ulcers.[34] In a

randomized, double-blind study of eighty-two patients with *H. pylori*, Bekar et al found 500 ml of kefir daily along with triple antibiotic therapy, which is standard treatment for *H. pylori,* for two weeks significantly improved the rate of eradication of the infection compared to a group receiving the tripe antibiotic therapy and a placebo.[34] Patients receiving the kefir treatment regimen also reported significantly milder symptoms of diarrhea, headaches, nausea, and abdominal pain compared to the control.[34] This study is encouraging but much more research needs to be done in *H. pylori* to confirm if kefir is an effective aid for eradicating this infection.

Aloe vera

Aloe vera is a botanical plant believed to have medicinal properties including use as a functional food to improve digestive health, especially IBS.[35] A few studies in humans have examined intake of aloe vera in patients with IBS[36–38] while one study has investigated aloe vera as treatment for GERD.[39] In a randomized, double-blind study by Davis et al, fifty-four participants with IBS were assigned to either ingest a 200 mL dose of flavored aloe vera gel or a flavored placebo syrup per day for one month.[36] IBS symptoms were measured with a validated questionnaire that assessed the overall state of IBS, as well as stomach pain, distention, and satisfaction with bowel movements.[36] No statistically significant differences were found in IBS symptoms between participants taking the aloe vera treatment compared to the control.[36]

Another randomized, double-blinded study in forty-seven IBS patients utilized a crossover design to examine the effects of 120 mL of aloe vera drink taken daily for five months on reported IBS symptoms compared to a placebo drink.[37] Similar to Davis et al,

no significant differences were found between the aloe vera treatment and placebo for improvement of IBS symptoms or quality of life as reported in validated questionnaires.[37] However, while the study enrolled 110 participants, only forty-seven completed the entire study which the authors suggested may have been due to the long duration of the study which included two five-month interventions separated by a two-week washout period.[37]

A recent randomized, double-blind trial by Storsrud et al included sixty-eight IBS patients assigned to either consume tablets containing 500 mg of aloe vera extract per day or a placebo dissolved in water for four weeks.[38] The primary outcome measured was the number of "responders", people who had either improved symptoms by at least fifty points on an IBS questionnaire or reported relief from symptoms for at least half of the weeks of the trial.[38] While no significant differences were found between the number of "responders" in the aloe vera treatment group and the placebo group, there was a significant reduction in reported bloating, frequency of pain, and severity of pain in the aloe vera group at the end of the treatment compared to the baseline values.[38]

From the three studies presented here, the results overall suggest aloe vera may not be an effective treatment for IBS. However, Storsrud et al observed aloe vera provided some symptom relief to IBS patients and further research may be warranted to investigate if aloe vera supplementation can alleviate IBS symptoms to some degree.[38] Storsrud et al, for example, suggested a larger sample size might have enabled them to detect differences between aloe vera and the placebo group.[38]

Aloe vera has also been studied as a treatment for GERD. Panahi et al conducted a randomized, positive-controlled trial in seventy-nine participants with diagnosed

GERD.[39] Participants either received 10 mL of aloe vera syrup per day for four weeks or one of two medications used to treat GERD, either 20 mg of omeprazole or a 300 mg of ranitidine daily.[39] GERD symptoms were assessed with a validated questionnaire completed at baseline, week two, and week four of treatment.[39] Panahi et al found aloe vera reduced the frequency of GERD symptoms like regurgitation, dysphagia, and vomiting comparably to both omeprazole and ranitidine; although, it less effectively reduced symptoms of heartburn, flatulence, and belching.[39] The authors concluded aloe vera had a similar ability to treat GERD symptoms as the two medications tested.[39] As this was a pilot study, more research is needed to support aloe vera's efficacy for GERD treatment.

Peppermint

Peppermint is a plant from the mint family and the oil extracted from the peppermint plant is believed to have medicinal properties including treating IBS, headaches, and dyspepsia.[40] Most research has examined its use as an IBS treatment.[41,42] Pittler and Ernst published a review and meta-analysis of eight RCTs testing peppermint oil as a treatment for IBS.[41] While a meta-analysis of five of the studies showed a significant improvement in overall IBS symptoms ($p < .001$), the authors were quick to point out that one of the studies excluded from analysis was the only study of the eight that used validated criteria to diagnose IBS.[41,43] Additionally, the authors scored the studies on a 1 to 5 scale based on quality of methods.[41] Two of the eight studies scored the highest at a 4; however, both of these studies found negative results for the use of peppermint oil for IBS.[41,43,44] Pittler and Ernst ultimately concluded that there was not

enough evidence to conclusively determine if peppermint oil is effective for IBS and called for better designs in future studies, specifically noting that only one crossover study utilized washout periods between treatments[45] and a majority of studies failed to use a validated definition for IBS.[41] They additionally expressed concern about the duration of treatment in the trials which they said for IBS patients should last two to three months due to the nature of IBS.[41]

A more recent review by Grigoleit and Grigoleit included sixteen clinical trials examining peppermint oil as IBS treatment.[42] The authors calculated the average success rate in the peppermint oil groups across the studies was 58% compared to an average of 29% success in the placebo groups.[42] Grigoleit and Grigoleit concluded from the trials that peppermint oil was effective for IBS treatment at a dose of 180 mg - 200 mg for two to four weeks duration.[42] However, an average success rate of 58% from the peppermint oil studies suggests that not everyone will see relief from IBS using peppermint. Overall, research of peppermint oil for treating IBS shows some promising results; however, future research needs stronger study designs that use a validated definition of IBS for the inclusion criteria, increase the duration of treatment, and include washout periods in crossover studies.[41]

The low FODMAP diet

A diet low in fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPs) is another potential dietary treatment for some digestive issues. While the bulk of this paper has focused on single foods or dietary supplements, the low FODMAP diet requires the avoidance of many food items that may cause GI pain or

discomfort.[46] FODMAPS include fructose, lactose, fructans, galactans, and polyols like sorbitol.[46] Some examples of high FODMAP foods are dairy milk, unless it's lactose free; fruits with high fructose content like apples, pears, and mangoes; fruits high in fructans or galactans like cherries, apricots, and peaches; and vegetables, cereals, and legumes high in polyols like broccoli, wheat, rye, and chickpeas.[46] FODMAPs may create discomfort for some people since they are not well absorbed by the small intestine, affect osmolality in the GI tract, and are rapidly fermented in the large intestine.[46] The low FODMAP diet involves eliminating high FODMAP foods for around six weeks and then slowly introducing the foods back into the diet to determine which are problematic to the individual.[47] The diet has been evaluated and determined effective in IBS patients[46,48,49] even being including in the dietetic guidelines for IBS treatment in the UK.[50] Some considerations when implementing the low FODMAP diet are that the diet is only recommended under the close supervision of a registered dietitian and the patient should have a definitive diagnosis of IBS before beginning the diet to avoid masking other GI disorders such as Celiac's disease.[47] Also, ideally, it is recommended that a breath hydrogen test be performed before starting the diet to assess for malabsorption of lactose and fructose to determine if elimination of these sugars is necessary.[46] The low FODMAP diet is not recommended for healthy or asymptomatic populations as the low FODMAP diet may alter gut microbiota unfavorably.[51] While this paper has focused primarily on foods that may improve GI health, the low FODMAP diet is based on eliminating high FODMAP foods that may cause abdominal pain and discomfort. However, both the

foods presented and the low FODMAP diet are natural dietary treatments for GI disorders.

Summary

This paper specifically examined research on prunes, kiwifruit, kefir, aloe vera, and peppermint oil as treatment for digestive conditions or their symptoms. The literature overall suggested that prunes may effectively improve some symptoms of constipation like stool consistency[19,20,22] and fecal bulk[17]; however, these symptoms did not consistently see improvement in all studies[18]. Kiwifruit consumption has shown positive results for constipation and stool frequency in limited populations like IBS patients and elderly adults[25,27]; however, more research in both the whole fruit and kiwi extract are needed and in more diverse populations. Kefir has been studied limitedly as a treatment for diarrhea, constipation, and *H. pylori* infections[33,34]. The promising results of the preliminary studies in constipation and *H. pylori* suggest that future research in these areas is warranted. Aloe vera's efficacy as an IBS treatment is not strongly supported by the limited research presented here[36,37]. However, Storsrud et al. observed improvements in some IBS symptoms[38] suggesting that aloe may provide some relief and should be examined further. Peppermint oil's use as an IBS treatment also produced mixed results[41,42] with few studies having strong designs and few using the correct IBS diagnosis.[41] However, its potential to alleviate IBS symptoms warrants further research using more rigorous methodology. Finally, this paper discusses briefly the use of the low FODMAP diet as a treatment for IBS. Overall, many of these foods and dietary supplements have produced promising results for digestive health; however, many have

been studied very limitedly or the studies failed to use validated definitions for the digestive conditions or validated measuring tools. Since food and diet are often an approach for alleviating GI symptoms, stronger studies of foods and digestive outcomes can help us determine if these foods or supplements can be recommended to promote digestive health.

CHAPTER TWO: Oatmeal consumption in children increases fiber intake and alleviates some difficulties with defecation

Introduction

Constipation is a prevalent digestive issue in children affecting an estimated 12% of the childhood population worldwide.[52] Several symptoms can contribute to a diagnosis of constipation including hard stool consistency, straining while defecating, incomplete evacuation of a bowel movement, and experiencing fewer than three bowel movements per week.[11] Constipation can create substantial difficulties for children and their caregivers. For example, children who chronically experience constipation report a lower quality of life compared to their healthy counterparts in the Pediatric Quality of Life Inventory that includes domains in physical, social, and emotional well-being.[10] Besides impacts on health and wellbeing, constipation can be a significant financial burden for families. Money spent on health-related services is significantly higher for children with constipation compared to children without constipation.[53] In the U.S., this totals an additional 3.9 billion dollars spent on health services for children with constipation per year compared to families with healthy children.[53]

One factor that could contribute to the prevalence of constipation in children is a low intake of fiber. Fiber is believed to improve bowel movements by increasing fecal bulk and slowing transit time, allowing more water to be retained in stool causing a softer stool consistency.[54] According to NHANES data collected between 2013-2014, children ages six to eleven consume about 14 – 15 g of fiber per day[55] while the Daily Reference Intakes recommend fiber intakes of 25 g for children four to eight years old and 26 g and 31 g of fiber for female and male children respectively ages nine to thirteen.[56]

A review paper of whole grains, fiber, and constipation in children saw an overall

association between high fiber diets in children and a lower incidence of constipation.[57] However, they concluded that current research of fiber interventions in children with constipation, either dietary or supplemental, is inconclusive with some studies supporting the use of dietary or supplemental fiber and others finding no effects at all.[57]

Oatmeal is a whole grain food high in the soluble fiber, beta-glucan.[58] Soluble fiber is believed to allow stool to absorb more water and soften the consistency which may help people experiencing hard stools.[54] Since little research has been done on specific high-fiber foods, like oatmeal, and digestive health in children, we wanted to examine if oatmeal intake would ease symptoms of constipation in children. Our aim was to examine if two weeks of oatmeal consumption improved stool frequency, consistency, and other GI symptoms in children who experience difficulty with defecation.

Methods

Participants

We recruited forty children to achieve 80% power to identify a mean change of 0.65 SD in defecation frequency; however, a total of thirty-three children, eighteen males and fifteen females, completed the study. Thirty-three participants gave us 80% power to detect a mean change of 0.72 SD. Participants were recruited by flyers posted around the University of Minnesota campus including student family housing complexes and campus daycare centers. Recruitment was also conducted by emails to Minneapolis neighborhood groups. To determine eligibility, participants completed an online screening questionnaire. Children were included if they were between the ages of seven and twelve, experienced five or fewer stools a week, and if they were low fiber

consumers, defined as fewer than fourteen grams of fiber per day. Children were excluded if they used laxatives, had been on antibiotics in the last month, used fiber supplements, or were not habitual breakfast eaters. The recruitment methods and study design was approved by the University of Minnesota International Review Board (IRB approval 1604S86583). Written informed consent was obtained from all the children participants and their parent or guardian. The participants additionally signed assent forms confirming they could leave the study at any time without consequence.

Oatmeal

The oatmeal was packaged in pouches each containing a one ounce serving of dry, instant oatmeal and came in two different flavors, Maple Brown Sugar and Cinnamon Spice. Each pouch contained 3g of fiber. Participants were instructed to prepare the oatmeal packets with either water or milk of any type in the microwave. Participants were allowed to include additives to their oatmeal such as honey, sugar, maple sugar, and spices; however, they were instructed not to add any high fiber foods such as fruit, other grains, or fiber supplements.

Measurements

Subjects were required to keep bowel movement diaries where they recorded the date and time of each bowel movement during the seven days of the baseline week and during all fourteen days of the oatmeal intervention. Physical activity diaries were also kept and the type of exercise and the number of minutes of exercise were recorded both for the seven days of baseline and the fourteen days of oatmeal consumption. Food diaries were kept during certain days of the study where participants recorded everything

they ate and drank for three days at a time. Subjects were instructed to measure food portions using measurements like cups, tablespoons, teaspoons, etc. Subjects were also given a Nutritional Data System for Research (NDSR) food portion visual poster to help estimate food consumed. The information from the food diaries was analyzed for total calories, carbohydrate, fat, protein, and fiber consumed using NDSR 2014 software. To assess gastrointestinal symptoms, children filled out two validated questionnaires, the Child Regularity Questionnaire[59] and the GI Tolerance Questionnaire.[60] Participants or their parents were also required to take photos of the child's stool for three days during the study. The stool was to be photographed in the toilet with no tissue paper obstructing the view. Most parents used a cell phone camera to capture the photographs and were instructed to avoid taking blurry photos. The stool photos were emailed to the study staff and the staff assigned a Bristol stool score to each photo depending on the consistency of the stool.

Study Design

Subjects were required to attend a pre-study visit at the University of Minnesota along with a parent or guardian to review the study protocol, sign assent and consent forms, and to receive instructions on how to prepare oatmeal packets and take stool photographs. The questionnaires, diaries, and oatmeal packets were dispensed at this time. During the first week of the study, days 1-7, subjects consumed their normal diet with no oatmeal and baseline measurements were taken. The measurements included filling out the bowel movement and physical activity diaries the entire week. On days 5-7, a food diary of the child's diet for the entire three days was recorded. Finally, on the

last day of the week, day 7, participants filled out the GI Tolerance Questionnaire and the Child Regularity Questionnaire. Day 7 is also when the first stool picture was taken, though we accepted any stool photos taken during this week if a bowel movement did not happen on day 7.

Days 8-13 were a washout period where no information was recorded. Day 14 started the two weeks of oatmeal consumption. Two packets of instant oatmeal were consumed each day for the two-week period. For the entire two-week period, days 14-27, a bowel movement diary and physical activity diary were recorded. At the end of the first week of oatmeal consumption, day 20, the GI Tolerance Questionnaire, Child Regularity Questionnaire, and stool photograph were completed. As with day 7, a stool photo from another day that week was also acceptable. A food diary was completed for the last three days of the oatmeal intervention, days 25-27. Also on the final day of oatmeal consumption, day 27, the GI Tolerance Questionnaire, Child Regularity questionnaire, and the third stool photo were completed.

Participants were provided with a calendar and checklist that listed all the questionnaires and diaries and when each had to be completed. Participants or their parents were also sent emails as an additional reminder for each day paperwork was due or a photo had to be taken. At the end of the study, once all materials were completed, participants returned to the University of Minnesota to drop off the questionnaires, diaries, and empty or unused oatmeal packets. Stool photos were emailed to the study staff and the staff assigned a score from the Bristol stool scale to each photo based on stool consistency. The food diaries were analyzed using NDSR software. Figure 2-1

displays the study timeline and indicates when each diary, questionnaire, and stool photo was to be completed by the participants.

Statistical Analyses

Descriptive statistics were calculated and presented using means and standard deviations for continuous outcomes and frequencies and percentages for categorical outcomes. Linear mixed models were used to evaluate change from baseline to week one and week two. Models included a fixed effect of time and a random intercept to account for repeated measures within subject. Models were conducted for males and females combined, and also separately by males and females.

Analysis was performed using Statistical Analysis Software (version 9.3, SAS Institute Inc., Cary, NC). A two-sided P value < 0.05 was considered statistically significant.

Results

Stool Frequency and Consistency

The average number of bowel movements recorded in the Bowel Movement diaries for the baseline week, week one, and week two are shown in Table 2-1. No statistical differences were observed for stool frequency when comparing baseline to week one, baseline to week two, and between week one to week two ($p = 0.58$, $p = 0.24$, and $p = 0.52$ respectively). When the analysis was divided by gender, there were still no differences in stool frequency between each week. Table 2-2 shows stool consistency scores according to the Bristol stool scale for each stool photo. No significant differences were seen in the Bristol stool score between the three photos from day 7 to day 20, day 7

to day 27, or day 20 to day 27 ($p = 0.85$, $p = 0.62$, and $p = 0.50$ respectively). Again, when analysis of stool consistency was separated by gender, the differences were not statistically significant.

Child Regularity Questionnaire

The mean responses from the Child Regularity Questionnaire are included in Table 2-3. For all participants, significant decreases were seen in self-reported scores of straining and gas from baseline compared to week one of oatmeal consumption ($p = 0.05$ and $p = 0.04$). A significant decrease in reports of incomplete evacuations of bowel movements was seen in the second week of oatmeal consumption compared to the baseline ($p = 0.01$). Self-reported stool frequency was significantly increased from baseline to both week one and two of oatmeal consumption ($p = 0.02$ and $p = 0.007$). No significant differences were seen in any symptoms when comparing week one and two of oatmeal consumption. Table 2-4 shows the average responses from the Child Regularity Questionnaire for females. When females were analyzed separately, significant differences were seen only in flatulence symptoms between the baseline week and both weeks one and two of oatmeal consumption ($p = 0.02$ and $p = 0.04$). Table 2-5 shows the average responses for males of the Child Regularity Questionnaire. In males, significant differences were seen between baseline and week two for both complete evacuation of stool and ratings of abdominal discomfort ($p = 0.03$ and $p = 0.04$). Self-reports of stool frequency were also significantly greater from baseline to week one and week two of oatmeal consumption ($p = 0.003$ and $p = 0.02$). In both males and females, no significant differences were seen between week one and week two of oatmeal consumption.

GI Tolerance Questionnaire

The responses from the GI Tolerance Questionnaire are displayed in Figure 2-2. No differences were seen in the number of participants reporting any of the gastrointestinal symptoms when comparing the baseline week, week one of oatmeal, and week two of oatmeal. Additionally, no differences were observed in the total number of GI symptoms participants reported between each week. When analysis was split between males and females, no differences were observed in number of gastrointestinal symptoms.

Food Diaries

The average intakes of calories, carbohydrate, fat, protein, and fiber from the food diaries are shown in Table 2-6. Overall, an increase in total grams of carbohydrates and fiber consumed was observed between the baseline food diaries, days 5-7, and the food diaries collected during the oatmeal intervention, days 25-27 ($p = 0.0008$ and $p = 0.008$). In males, differences were also seen in total carbohydrates and fiber intake ($p = 0.0014$ and $p = 0.005$) as well as an increase in total calories ($p = 0.04$) between the first food diary and the second. When females were analyzed separately, no differences were seen in any nutrient from the pre-oatmeal food diary to the oatmeal intervention diary.

Discussion

We did not see a change in stool frequency or consistency with two weeks of oatmeal consumption in our population of children. Several factors in our study may have impacted these results. Since this is a pilot study, there is not a standardized dose of oatmeal to treat problems with defecation. Perhaps a greater amount of oatmeal per day would result in greater changes in stool frequency and consistency. Additionally, the

population of children we recruited had only mild constipation symptoms, which we defined as five or fewer bowel movements a week to try to recruit "healthy" children with some problems with defecation. A true diagnosis of constipation would require fewer than three bowel movements per week.[11] We intentionally did not recruit children from clinics or doctor's offices to avoid children with diagnosed constipation; however, perhaps different results would be obtained in a truly constipated population.

We did see a significant increase in fiber intake during the two weeks of oatmeal consumption compared to the baseline week. This suggests that oatmeal may be a vehicle to introduce more fiber into the diets of children. We know from NHANES data that children in this age group do not get enough fiber[55] so oatmeal may be one way to address low fiber consumption.

In males, we saw an increase in total calories with the oatmeal intervention; however, this was likely due to the inclusion of a male child who reported during one of the baseline days that he consumed under 400 calories. We believe that this day may be an incomplete report of food intake. However, analysis of total calories between the baseline week compared to week 1 without the outlier gave a p-value of 0.06 which was close to significance.

A promising result we found from the Child Regularity Questionnaire is that self-reports of gas frequency decreased significantly after a week of oatmeal consumption compared to baseline. We hypothesize that one fear associated with increased intake of fiber is unwanted GI responses like flatulence. Our results; however, suggest that gas occurrence does not increase with oatmeal intake, but may actually decrease. There were

also decreases in reports of straining during defecation and decreases in incomplete evacuations of stool during a bowel movement. This suggests some relief from difficulties with defecation following oatmeal intake.

Something that is interesting to note is that children reported in the Child Regularity Questionnaire a significantly higher stool frequency following oatmeal consumption compared to baseline; however, this increase in stool frequency was not reflected in the Bowel Movement diaries. Children believed they were defecating more after oatmeal treatment; however, according to their diaries, stool frequency was not significantly increased. It appears that children believed they had more bowel movements during oatmeal consumption even when stool frequency did not increase. It is also possible that the oatmeal intervention created a placebo-effect that made children think they were defecating more often even when that was not the case.

It is also interesting to note the differences in responses to the Child Regularity Questionnaire between males and females. The only significant change in symptoms in females was decrease in reported gas. Males reported no significant difference in gas but in stool frequency, abdominal pain, and straining.

Overall, while we did not see changes in stool frequency or stool consistency, we observed increases in fiber intake and reduction in some GI symptoms. Our research suggests that two packets of instant oatmeal per day effectively increases fiber intake in children who are low fiber consumers. The changes in self-reported symptoms like gas, incomplete evacuation, and straining suggest that some constipation symptoms may be attenuated by regular oatmeal consumption. Future studies should perhaps focus on

clinically constipated populations and more research into the ideal amount of oatmeal needed to produce beneficial digestive outcomes should be investigated.

Future directions

The information obtained studying oatmeal consumption in children with difficulty defecating will be useful when organizing future research. Recruiting children who fit our specific criteria was difficult. We were not seeking children that were clinically constipated or completely healthy; rather, we sought kids who defecated five or fewer times per week. The specificity of this criterion made recruiting difficult as we had to exclude many children who defecated too frequently. This also prevented us from using hospitals or clinics to recruit as we were avoiding a true diagnosis of constipation. In the future, deciding either to study a healthy child population with no defecation problems or a population of children with diagnosed constipation would likely streamline the recruitment process. Additionally, it could provide insight as to whether oatmeal is effective at increasing stool frequency in constipated children compared to children who defecate regularly.

A second obstacle we faced was participant burden. Many participants did not reside in Minneapolis or St. Paul, but rather in the surrounding suburban areas and had to travel thirty minutes or more to reach the University of Minnesota for their pre-study visit and to drop off study materials. Some expressed concerns about finding time to make these trips and some sent their materials back by mail to avoid a trip to the University. They additionally had a significant amount of paperwork to fill out throughout the month of the study. Perhaps, future studies could employ an online system for all the

questionnaires so they could be completed online either on a computer or smartphone and sent to the study staff electronically. This would eliminate the need to return to our laboratory to drop off paperwork. Additionally, the online system could also be set up to provide email or text reminders to study participants on days when paperwork or photos needed to be completed. Finally, since this trial was the first to look at a specific food item, oatmeal, and digestive health in children, it would be interesting to examine other high fiber food items like granola, whole grain breads, or fruit on defecation patterns in children. It may also be worthwhile to study products with oatmeal such as oatmeal bars or cookies since they may be more palatable to children than oatmeal itself.

Figure 2-1. Study Timeline

Table 2-1. Number of bowel movements recorded in bowel movement diaries

	Baseline (Days 1-7)	Week 1 (Day 14-20)	Week 2 (Day 21-27)	*p* value Baseline vs. Week 1	*p* value Baseline vs. Week 2	*p* value Week 1 vs. Week 2
Number of Bowel Movements	5.6 $\pm$ 2.7	5.4 $\pm$ 2.6	5.2 $\pm$ 2.1	0.58	0.24	0.52

Table 2-2. Stool consistency scores from stool photos

	Baseline Photo (Day 7)	Week 1 Photo (Days 20)	Week 2 Photo (Days 27)	*p* value Baseline vs. Week 1	*p* value Baseline vs. Week 2	*p* value Week 1 vs. Week 2
Bristol Score	3.9 $\pm$ 1.3	3.8 $\pm$ 1.3	4.1 $\pm$ 1.4	0.85	0.62	0.50

Table 2-3. Summary of results from the child regularity questionnaire overall

Overall	Baseline	Week 1	Week 2	*p* value baseline vs. week 1	*p* value baseline vs. week 2	*p* value week 1 vs. week 2
Puffiness	1.6 ± 0.8	1.6 ± 0.8	1.4 ± 0.5	0.79	0.11	0.06
Straining	2.1 ± 0.9	1.7 ± 0.8	1.8 ± 1.0	**0.05**	0.14	0.57
Incomplete evacuation	2.0 ± 0.8	1.8 ± 0.9	1.7 ± 0.9	0.14	**0.01**	0.25
Gas	2.7 ± 0.9	2.3 ± 0.9	2.4 ± 0.9	**0.04**	0.08	0.78
Abdominal discomfort	1.6 ± 0.9	1.6 ± 0.7	1.3 ± 0.6	0.79	0.09	0.14
Stool frequency	3.1 ± 0.8	3.4 ± 0.9	3.5 ± 0.7	**0.02**	**0.007**	0.57
Bristol scale	3.0 ± 0.8	3.0 ± 1.0	3.1 ± 0.9	0.75	0.79	0.55
Never missed school or activities	31 (97%)	32 (97%)	31 (100%)	-	-	-
Stool size	2.3 ± 0.8	2.3 ± 0.8	2.3 ± 0.9	0.55	0.57	1
Significant p-values and symptoms are bolded.						
The first six responses were ranked on a scale of 1 to 5. "Bristol scale" was a list of options 1 to 8. "Never missed school or activities" is listed in the table not as an average of the ratings reported but as number of participants who reported no school or activities missed during the study. "Stool size" was on a scale of 1 to 4. A copy of the questionnaire can be found in the appendix 1.						

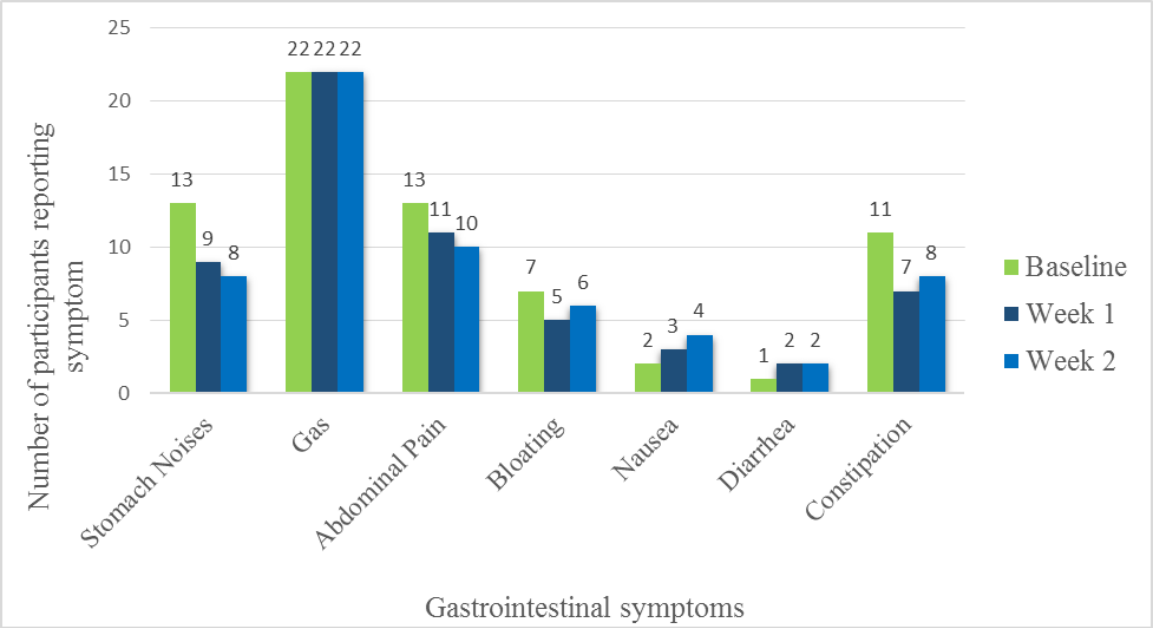
Table 2-4. Summary of results from the child regularity questionnaire for females

Female	Baseline	Week 1	Week 2	*p* value baseline vs. week 1	*p* value baseline vs. week 2	*p* value week 1 vs. week 2
Puffiness	1.5 ± 0.9	1.6 ± 0.9	1.4 ± 0.5	0.73	0.59	0.39
Straining	1.9 ± 0.8	1.6 ± 0.7	1.7 ± 0.8	0.2	0.34	0.75
Incomplete evacuation	2.1 ± 0.7	1.8 ± 1.0	1.9 ± 1.1	0.08	0.16	0.72
Gas	3.1 ± 0.8	2.5 ± 0.9	2.6 ± 0.9	**0.02**	**0.04**	0.69
Abdominal discomfort	1.4 ± 0.8	1.6 ± 0.9	1.3 ± 0.6	0.32	0.77	0.2
Stool frequency	3.4 ± 1.0	3.4 ± 1.0	3.6 ± 0.9	0.83	0.09	0.13
Bristol scale	2.8 ± 1.0	2.9 ± 1.0	3.0 ± 1.0	0.61	0.65	0.97
Never missed school or activities	14 (93%)	15 (100%)	14 (100%)	-	-	-
Stool size	2.1 ± 0.9	2.1 ± 0.7	2.0 ± 0.7	0.67	0.82	0.51
Significant p-values and symptoms are bolded.						
The first six responses were ranked on a scale of 1 to 5. “Bristol scale” was a list of options 1 to 8. “Never missed school or activities” is listed in the table not as an average of the ratings reported but as number of participants who reported no school or activities missed during the study. “Stool size” was on a scale of 1 to 4. A copy of the questionnaire can be found in the appendix 1.						

Table 2-5. Summary of results from the child regularity questionnaire for males

Male	Baseline	Week 1	Week 2	*p* value baseline vs. week 1	*p* value baseline vs. week 2	*p* value week 1 vs. week 2
Puffiness	1.6 ± 0.7	1.7 ± 0.7	1.4 ± 0.5	0.99	0.09	0.08
Straining	2.2 ± 0.9	1.8 ± 0.8	1.9 ± 1.2	0.13	0.28	0.65
Incomplete evacuation	1.9 ± 0.9	1.8 ± 0.9	1.5 ± 0.7	0.67	**0.03**	0.07
Gas	2.2 ± 0.7	2.2 ± 0.9	2.2 ± 0.8	0.72	0.72	1
Abdominal discomfort	1.8 ± 0.9	1.5 ± 0.6	1.3 ± 0.6	0.18	**0.04**	0.41
Stool frequency	2.9 ± 0.5	3.3 ± 0.8	3.3 ± 0.5	**0.003**	**0.02**	0.47
Bristol scale	3.3 ± 0.6	3.1 ± 1.0	3.3 ± 0.9	0.37	0.9	0.42
Never missed school or activities	17 (100%)	17 (94%)	17 (100%)	-	-	-
Stool size	2.5 ± 0.7	2.4 ± 0.8	2.5 ± 0.9	0.2	0.54	0.51
Significant p-values and symptoms are bolded.						
The first six responses were ranked on a scale of 1 to 5. "Bristol scale" was a list of options 1 to 8. "Never missed school or activities" is listed in the table not as an average of the ratings reported but as number of participants who reported no school or activities missed during the study. "Stool size" was on a scale of 1 to 4. A copy of the questionnaire can be found in the appendix 1.						

Figure 2-2. Number of participants reporting GI symptoms from the GI tolerance questionnaire



The number of participants reporting each gastrointestinal symptoms on the GI

Table 2-6. Intakes of nutrients reported in the food diaries

	Baseline (Days 5-7)	During Oatmeal (Days 25-27)	*p* value
Female			
Calories	1669.7 ± 717.8	1722.3 ± 579.5	0.67
Total Fat (g)	62.5 ± 29.6	57.6 ± 29.1	0.37
Total Carb (g)	224.5 ± 107.7	254.5 ± 68.7	0.11
Total Protein (g)	59.5 ± 25.0	56.5 ± 23.0	0.46
Fiber (g)	16.4 ± 8.0	17.7 ± 5.8	0.36
Male			
Calories	1616.1 ± 468.4	1795.4 ± 680.3	**0.04**
Total Fat (g)	62.2 ± 23.4	60.8 ± 30.3	0.75
Total Carb (g)	213.5 ± 70.0	258.2 ± 92.3	**0.0014**
Total Protein (g)	58.5 ± 21.2	65.0 ± 29.5	0.10
Fiber (g)	14.9 ± 5.4	18.1 ± 7.0	**0.005**
Overall			
Calories	1640.5 ± 592.2	1762.2 ± 634.3	0.09
Total Fat (g)	62.4 ± 26.3	59.4 ± 29.6	0.38
Total Carb (g)	218.5 ± 88.8	256.5 ± 82.0	**0.0008**
Total Protein (g)	59.0 ± 22.9	61.1 ± 27.0	0.43
Fiber (g)	15.6 ± 6.7	17.9 ± 6.4	**0.008**
The significant p-values and symptoms are bolded.			

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Appendix 1: Child Regularity Questionnaire

Reference: Lewis SJ, Heaton KW: Stool form scale as a useful guide to intestinal transit time. *Scand J Gastroenterol* 1997; 32:920-924.

Please complete this questionnaire by picking the best answer for the following questions:

1. In the past week, how often did you feel puffy and uncomfortable in the belly?
   1 Never
   2 Almost Never
   3 Sometimes
   4 Often
   5 Almost Always

2. In the past week, how often did you strain or squeeze to try and pass a poop?
   1 Never
   2 Almost Never
   3 Sometimes
   4 Often
   5 Almost Always

3. In the past week, how often did you finish pooping but it still felt like there was some poop that didn't come out?
   1 Never
   2 Almost Never
   3 Sometimes
   4 Often
   5 Almost Always

4. In the past week, how often did you have gas (fart)?
   1 Never
   2 Almost Never
   3 Sometimes
   4 Often
   5 Almost Always

5. In the past week, how often did you feel discomfort or hurt in your tummy below your belly button?
   1 Never
   2 Almost Never

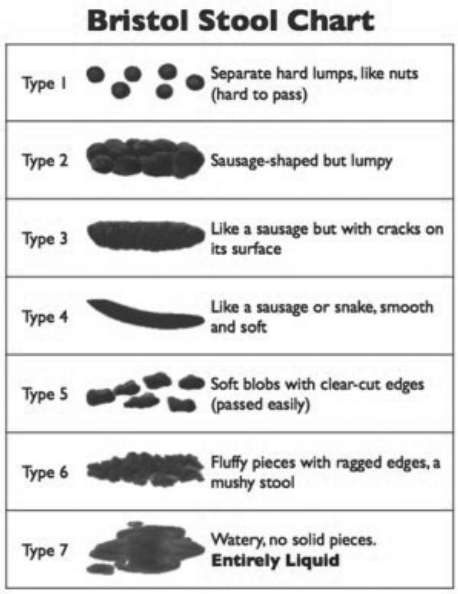
3 Sometimes
4 Often
5 Almost Always

6. In the past week, how often did you poop?
   1 Never
   2 Almost Never
   3 Sometimes
   4 Often
   5 Almost Always

Please also complete questions 7-9, by picking the best answer to the following questions:

7. If you look at the chart below, which picture resembles the poop you past this week?

1 Type 1
2 Type 2
3 Type 3
4 Type 4
5 Type 5
6 Type 6
7 Type 7
8 I did not look at my poop last week



8. Did you miss school or playtime because of problems with your tummy or wanting or needing to poop?

1 Never
2 Less than 3 times this week
3 More than 3 times this week
4 At least once a day

9. What size is your poop closest to?

1 Grape
2 Golf ball
3 Baseball
4 Softball

Appendix 2: GI Tolerance Questionnaire

Adopted From: Jacqz-Aigrain et al. Gastrointestinal tolerance of erythritol-containing beverage in young children: a double-blind, randomized controlled trial. *European Journal of Clinical Nutrition* 2015;69:746-751.

For the past week, please rate your response to each question on the following scale:

(0) None
(1) Mild, no restriction of everyday activities
(2) Average, partial limitation of everyday activities. Severe, inability to perform everyday activities

Stomach Noises
0 1 2 3

Gas
0 1 2 3

Abdominal pain
0 1 2 3

Bloating
0 1 2 3

Nausea
0 1 2 3

Diarrhea
0 1 2 3

Constipation
0 1 2 3

Please list any additional symptoms experienced and the severity of the symptoms below:

Symptom	**Severity (0-3)**
_____	_____