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Title: ***Liquid Fiber Dietary Supplement Use in the Long Term Care Resident: A Study of Bowel Regulation through Pharmaceutical Laxative Replacement Therapy***

Graduate Degree/ Major: **MS Food and Nutritional Sciences**

Research Advisor: **Carol Seaborn, Ph.D., RD, CD, CFCS**

Submission Term/Year: **Spring, 2013**

Number of Pages: **55**

Style Manual Used: American Psychological Association, 6th edition

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Abstract

Chronic constipation affects as much as 50% of the institutionalized elderly (Gallagher, et al., 2008). The most common treatment for the condition is a pharmaceutical laxative regiment. Habitual laxative use, however, may have adverse consequences such as bowel dependency, electrolyte imbalances, and contribution to polypharmacy. Non-pharmaceutical approaches (e.g., dietary interventions) offer a potential alternative to constipation treatment without the multitude of side effects.

This study evaluated the efficacy of liquid fiber supplementation as a replacement to drug-based constipation medications in the long-term care resident. During the three week study, bowel movement statistics (frequency, size, and condition) were measured and analyzed. Results indicated no statistically significant difference between bowel movement data collected pre and post intervention. Thus, the study results provide evidence for further study of liquid fiber supplementation as a viable bowel management option.

Acknowledgments

I would like thank my thesis advisor, Dr. Carol Seaborn, for the constant encouragement, expertise, and guidance. If not for this source of support, this research project could not have been completed. Secondly, I would like to express sincere gratitude to those individuals at the research site who assisted in data collection, consent acquisition, staff training, and scheduling of resources. Finally, I would like to acknowledge those who agreed to partake in this study. Your participation was crucial to this project, and I trust that your efforts will yield future benefits.

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Chapter I: Introduction

The position paper of the Academy of Nutrition and Dietetics (AND), formerly the American Dietetic Association (ADA), recommends that the daily fiber intakes are 25 grams for women (age 18-50) and 38 grams for men (age 18-50) (Slavin, 2008). Proven benefits of adequate fiber intake include managing constipation (difficult and infrequent defecation) and diverticular disease (a condition where undesired intestinal pouches can lead to inflammation and infection) (Marlett, McBurney, & Slavin, 2002). Other suspected health benefits of fiber consumption include a reduced risk of coronary heart disease, hypertension, and cancer (especially colon) as well as improved blood glucose control. Unfortunately, typical American fiber intake averages 15 grams per day, which is well below the AND guidelines (Slavin, 2008).

One area of health related to fiber, defecation, is especially relevant in the elderly. Experts estimate that constipation, a common defecation disorder, affects up to 26 percent of elderly men and 34 percent of elderly women (Schaefer & Cheskin, 1998). In professional practice, physicians define constipation as having fewer than three bowel movements per week. Consequences of untreated constipation may include impaction, perforation, or even death (Tariq, 2007). Chronic constipation in which symptoms persist for several months or even years, affects as much as 50% of the institutionalized elderly (Gallagher, O'Mahoney, & Quigley, 2008).

Some common factors contributing to chronic constipation in the long-term care resident include low fiber intake, inadequate hydration, reduced mobility, and polypharmacy interactions (Leung, Riutta, Kotecha, & Rosser, 2011). Management of the condition is complex and often an area of debate among health care professionals. Both pharmacological and non-pharmacological treatments are currently used in practice, sometimes concurrently.

Advocates of drug free interventions to treat constipation, such as registered dietitians, often propose increasing both fiber (from whole foods) and fluid intake, as well as following a routine of daily exercise. The long-term care resident, however, often suffers from poor dentition, immobility, dysphagia, and a reduced appetite (Thomas, Ashmen, Morley, & Evans, 2000). Another common nutritional barrier found in this population is dementia, a syndrome presenting with symptoms of cognition decline (e.g. memory, understanding, and/or judgment). It has been estimated that dementia affects 14% of Americans over age 70 (Plassman et al., 2007). As a result of these factors, achieving adequate intake of fiber from whole food sources to treat the condition becomes impractical.

Physicians most often prescribe medicinal laxatives for bowel management in the aged. In fact approximately 50% of hospitalized elderly and nursing home residents report daily laxative use. Over $400 million is spent yearly on laxatives in the United States alone (Pekmezaris, Aversa, Wolf-Klein, Cedarbaum, & Reid-Durant, 2002). Chronic laxative use, however, can have negative physiological consequences such as intestinal paralysis, vitamin and mineral depletion, polypharmacy, and an increased risk of kidney failure (Hsieh, 2005).

The use of concentrated fiber supplements in bowel regulation in the elderly has been studied and has shown promising results (Petticrew, Watt, & Sheldon, 1997). This treatment option may help reduce or eliminate laxative use as well as provide a significant cost savings to health care providers and their recipients. Unfortunately, these over-the-counter products have historically been powder-based and have often introduced undesirable taste and texture changes when added to beverages and foods. In addition, powder-based supplements typically offer an average of 2-4 grams of fiber per serving. Considering the American dietary average of 15 grams of fiber daily, achieving AND recommendations of 25-38 grams would require an unreasonable amount of such products. Concentrated liquid fiber supplements (10-15 grams of

fiber per serving) propose to offer the same benefits of powder-based supplements without the aforementioned drawbacks.

Statement of the Problem

The problem to be investigated is the following question: "Is the use of liquid fiber supplementation in the long-term care resident (senior adult) physiologically efficacious for the regulation of bowel function?"

Purpose of the Study

The purpose of the study is to determine the efficacy of the use of a liquid fiber supplementation in place of a pharmaceutical laxative regiment for bowel regulation. All subjects were long-term care residents using at least one pharmaceutical laxative daily. Success will be measured using a proprietary survey tool to gather data both preceding and following dietary intervention. Specifically, detailed data regarding resident bowel patterns (frequency, size, and quality) will be gathered and analyzed to determine effectiveness of the study treatment.

Assumptions of the Study

Assumptions of this study include that research site staff completed the surveys honestly, accurately, and as completely as possible. Additionally, it is assumed that the research site staff understood the proper use of the survey tool and the data collection design (schedule). Finally, it is assumed that study participants complied with all steps of data collection.

Definition of Terms

Alimentary. Related to nutrition or digestion.

Carbohydrate. An organic compound consisting of only carbon, hydrogen, and oxygen found in both plants and animals. Some forms may or may not be digestible in humans.

Dietary fiber. Non-digestible carbohydrate and lignin portions of plant food (Institute of Medicine, 2001).

Dysphagia. Medical term for the symptom of difficulty in swallowing.

Laxation. Referring to the occurrence of a bowel movement.

Lignin. The main non-carbohydrate constituent of plant cell walls, providing strength and structure.

Odds ratio. A method of expressing probability of an event occurring in an exposed vs. unexposed group related to a treatment.

Polypharmacy. The use of more medication than is clinically indicated or warranted, most often observed in the elderly. Adverse health effects and non-compliance can result.

Limitations of the Study

The study was limited to one long-term care facility in mid-western Wisconsin. There was minimal racial diversity possible when selecting a sample from the population. This lack of diversity limited the ability to infer conclusions regarding findings to all cultures. Data collection required cross-disciplinary coordination as opposed to one researcher/research team, potentially introducing error. In addition, data were partially collected using second hand information. Those subjects who were able to self-toilet verbalized answers to nursing staff who in turn transferred the information to the data collection form. Another limitation was the lack of a comprehensive dietary analysis for each subject to measure daily dietary fiber intake. Ultimately, this was not feasible due to resource constraints.

Methodology

Study participants (or legal representatives) provided informed consent through a signed form adopted from the UW-Stout Human Consent Form template and mailed to the appropriate party. The study site assisted in preparation of these letters. Once consent was obtained, site nursing staff was trained in the use of the survey tool and the research schedule. Baseline data were collected by authorized nursing staff for one week. Treatments were then administered (and appropriate data collected) according to the study design.

Chapter II: Literature Review

Information presented in this chapter pertains to fiber and its associated health benefits as well as constipation as it relates to the long-term care resident. Definitions and sources of fiber, fiber intake recommendations, and the use of fiber in bowel health are discussed. Next, the clinical definition of constipation, prevalence in the elderly, traditional treatment options in long-term care facilities, and the risks of chronic laxative use are addressed.

Fiber and Associated Health Benefits

Dietary fiber has demonstrated benefits for both health maintenance and disease prevention (Slavin, 2008). A diet rich in fiber is typically lower in calories, higher in essential micronutrients, and lower in total fat content, all of which provide beneficial health effects including improved weight control and bowel movement regulation. Fiber-rich diets have also been used in the prevention (and/or treatment) of cardiovascular disease, type 2 diabetes, and hypercholesterolemia. In addition, some research studies have suggested that dietary fiber may reduce the risk of bowel cancer, especially colorectal cancer (Slavin, 2008).

Definitions of dietary fiber. A variety of definitions of fiber exist worldwide (Institute of Medicine, 2001). Some definitions are based on how fiber is isolated chemically while others are based on physiological effects in the body. The lack of a standardized definition ultimately led to the Institute of Medicine's Food and Nutrition Board to form a Panel on the Definition of Dietary Fiber (Institute of Medicine, 2001). After deliberation, this body presented a definition of fiber by means of the following three terms: dietary fiber, functional fiber, and total fiber.

Dietary fiber is defined as the non-digestible carbohydrate and lignin portions of plant food (Institute of Medicine, 2001). These components are not hydrolyzed (broken down) in humans due to a lack of required alimentary enzymes (Keim, Levin, & Havel, 2006). By definition, dietary fiber is fiber that is naturally occurring and intact when consumed. A

common example is cellulose, a carbohydrate found in plant cell walls, which is considered to be dietary fiber if consumed from an unprocessed whole food source. Dietary fiber may or may not produce a physiological effect (Institute of Medicine, 2001).

Functional fiber is defined as any isolated non-digestible carbohydrate found to have a beneficial health effect in humans (Institute of Medicine, 2001). Unlike dietary fiber, functional fiber is extracted from a food source though processing and is then consumed either alone or in food as an additive. Therefore, cellulose can instead be considered functional fiber as long as the form used is obtained through artificial extraction. Cellulose, in a chemically altered form called methylcellulose, meets the other criteria of a functional fiber in that it has been found to be an effective and safe treatment for constipation (Hsieh, 2005).

Total fiber is defined as the sum of both dietary and functional fiber. This term is often used when assessing an individual's fiber intake or when determining fiber content in food for labeling purposes (Institute of Medicine, 2001).

Other classification systems of fiber still exist, however, complicating the definitions of fiber (Slavin, 2008). Fiber is also often categorized as either soluble or insoluble. While both of these are fermented to some degree by bacteria in the gastrointestinal tract, soluble fiber is more readily fermentable due to its higher viscosity and ability to dissolve in water. Insoluble fiber is metabolically inactive and absorbs water throughout gastrointestinal transit (Keim, Levin, & Havel, 2006). The solubility of fiber was initially thought to predict physiological effects. However, further research has provided inconsistent results (Slavin, 2008). These terms are still used by health care professionals in patient education and by the Food and Drug Administration (FDA) in nutrition labeling (Higdon, 2005).

Sources of dietary and functional fiber. Chemically, fiber found in foods is either considered non-starch polysaccharides or lignin (Lupton & Trumbo, 2006). Non-starch

polysaccharides are categorized further into cellulose, beta-glucans, hemicelluloses, pectins, and gums. While these sub-types differ in solubility and viscosity, all are complex carbohydrates. As previously mentioned, lignin is the plant component providing structural support. Lignin is not carbohydrate based, but instead is a phenylpropane polymer (alcohol and acid).

Fiber is found in both the skin and flesh of plant foods. While fiber is almost exclusively plant based, a few sources are animal based (Keim, Levin, & Havel, 2006). Some common sources of fiber in the American diet are listed in Table 1.

Table 1

Common Sources of Dietary and Functional Fiber

Insoluble fiber		
Cellulose	Hemicellulose	Lignin
Whole wheat flour	Bran	Mature vegetables
Bran	Whole grains	Wheat
Most immature vegetables		Fruits and edible seeds
Soluble fiber		
Gums	Pectin	Chitin/chitosan
Oats	Apples/citrus fruits	Crabs (shell)
Legumes (beans)	Carrots	Lobster (shell)
Barley	Bananas	Shrimp (shell)

Fiber intake recommendations. According to the position paper of the Academy of Nutrition and Dietetics (AND), formerly the American Dietetic Association (ADA), recommendations for fiber intake differ throughout the life cycle (Slavin, 2008). Men and

women aged 18-50 should consume 25 and 38 grams of total fiber per day, respectively. The fiber recommendations for adults over 50 are 21 grams for women and 30 grams for men. This decrease in fiber needs for older adults comes from a decrease in their overall dietary energy needs (Slavin, 2008).

The fiber intake recommendations are based on an Adequate Intake (AI) reference value determined by the Institute of Medicine in 2001. Adequate Intake (AI) is used for a nutrient when there is insufficient scientific data to establish an Estimated Average Requirement (EAR). Requirements for determining an EAR reference value is more stringent, and stipulate that a nutrient's amount present in the body must be measurable (Slavin, 2008).

Since fiber is not absorbed, neither blood nor tissue fiber levels can be measured. Instead, the AI for fiber was determined by the Institute of Medicine based on the results of numerous epidemiological studies whose results indicated a positive relationship between dietary fiber intake and a reduction in the risk for developing coronary heart disease (CHD). These findings led to intake recommendations for individuals using the criteria of age and gender. The formula used to calculate these recommendations is 14 grams of total fiber per 1000 kcal (Calories) consumed (Institute of Medicine, 2001). Table 2 summarizes these fiber recommendations based on age and gender (Lupton & Trumbo, 2006).

Table 2

Adequate Intake by Gender and Age for Total Fiber (g/day)

Age	Males	Females
1-3 y	19	19
4-8 y	25	25
9-13 y	31	26
14-18 y	38	26
19-50 y	38	25
>50 y	30	21
Pregnant women	---	28
Lactating women	---	29

Note: AI for 0-12 months not determined. (Lupton & Trumbo, 2006)

Use of fiber in bowel health and disease prevention. Scientists have long hypothesized that dietary fiber intake is related to a reduction in risk of bowel cancers (Park et al., 2005). The mechanisms suggested include: fecal dilution of carcinogens and pre-carcinogens aided by fiber bulking, fiber-induced production of short chain fatty acids which have an anti-carcinogenic effect, and the binding of carcinogenic bile acids by fiber during digestion. While numerous studies have been conducted to validate these hypotheses, the results have produced conflicting results (Park et al., 2005).

In 2003, the results from an observational study of 519,978 individuals, aged 25-70, were released as a part of a larger cohort study called the European Prospective Investigation into Cancer and Nutrition (EPIC) (Bingham, et al., 2003). The study was coordinated by health professionals from 10 different European countries. This diverse study allowed for comparisons between regions with differing rates of cancer occurrence, food habits, and cultural lifestyles.

Study participants completed dietary and lifestyle questionnaires bi-yearly from 1992-1998. Anthropometric measurements and previous medical history were collected at the time of enrollment. Participant follow-up concluded in June 2002. Cancer incidence was collected by using national cancer registry data.

For data analysis, gender-specific quintiles of total dietary fiber intake were established to determine a hazard ratio (and in turn a relative risk) for developing colorectal cancer. The results indicated an inverse relationship between dietary fiber intake and incidence of colorectal cancer (adjusted relative risk of 0.75 [95% CI, 0.59-0.95] for the highest versus lowest quintile of fiber intake). Also, the trend in hazard ratio across quintiles was significant (p=0.005). The regression coefficient (β=0.80) predicted an 8% reduction in risk for each quintile increase in dietary fiber. In total, the study's findings showed a 40% risk of colorectal cancer when average dietary fiber intakes increased from the lowest quintile to the highest (Bingham, et al., 2003).

A more recent epidemiological study, however, did not find a protective effect of dietary fiber intake on colorectal cancer (Uchida et al., 2010). Using a case-control study design, the Fukuoka Colorectal Cancer Study in Japan examined dietary fiber intake in 1631 subjects. Comprising the subject pool were 816 incident cases of colorectal cancer and 815 community controls. Using a computer-assisted interview process, consumption frequencies and portion sizes of 148 food/beverage items were collected. Analysis of the data, using odds ratios (OR) as a clinical measurement, indicated that dietary fiber consumption was not associated with a decreased risk of colorectal cancer. Instead, an association was found between white rice, which has little to no fiber content, and a decreased risk of distal colorectal cancer (Uchida et al., 2010).

Another area of bowel health that has long been associated with fiber intake is diverticular disease, which includes both diverticulosis (colonic pouches) and diverticulitis (inflamed or infected colonic pouches). Diverticulosis, a typically asymptomatic condition,

affects up to two-thirds of people over the age of 80 (Stollman & Raskin, 2004). Epidemiologists label diverticulosis a "Western" disease due to the highest concentration of cases in North America and Europe. While the exact etiology remains unclear, researchers often attribute this to a diet low in fiber, stemming from the urbanization of societies (Stollman & Raskin, 2004).

Evidence reviewed by the Food and Nutrition Board of the Institute of Medicine overwhelmingly indicated a relationship between fiber intake and diverticular disease (Institute of Medicine, 2001). It was summarized that numerous case control studies have shown that individuals with diverticula have diets lower in dietary fiber diets than individuals without the disease. In addition, the prospective Health Professionals Follow-up Study (HPFS) gave evidence of a protective property of dietary fiber against diverticular disease (Institute of Medicine, 2001).

Constipation and the Long-term Care Resident

Constipation is one of the most common gastrointestinal complaints. According to a recent systematic review of the epidemiology of constipation, the condition affects approximately 15% of adults in North America (Higgins & Johanson, 2004). Prevalence increases with age, especially in those over age 65. Residents in long-term care facilities are at an even higher risk for developing constipation due to factors such as decreased mobility, adverse medication affects, and inadequate fluid intake (Tariq, 2007). The costs to those afflicted are observed not just financially but also in terms of an overall decreased quality of life.

Definitions of constipation. Before considering treatment for an individual with constipation, it is necessary to understand the complexities of the condition. Patients often describe constipation as straining during defecation and the presence of hard stools. Most physicians, however, describe constipation as having fewer than three bowel movements per

week (Tariq, 2007). Constipation can also be described as either acute or chronic. In addition, sub-classifications based on etiology are often used when diagnosing constipation clinically.

Constipation, in general, is categorized as either primary or secondary. In primary constipation, also known as idiopathic constipation, the condition stems from no known external cause (Gallagher, et al., 2008). Further sub-categories include normal transit, slow transit, and outlet constipation. Normal transit, the most common type of constipation, is observed when stool transit time is within normal ranges, but the patient still has reported difficulty defecating and/or the presence of hard stools. Slow transit constipation is similar except that transit time is slower than normal. Outlet constipation involves insufficient colon or anal sphincter muscle activity to produce timely, comfortable bowel movements (Gallagher, et al., 2008).

In secondary constipation, an external cause has been identified and the pathology is known. The cause may be gastrointestinal (colorectal tumor, irritable bowel syndrome), neurological (Parkinson's disease, multiple sclerosis), metabolic (diabetes mellitus, dehydration, insufficient dietary fiber), psychological (anxiety, depression), or pharmacological (use of diuretics/antidepressants/antacids). Since the cause(s) is/are known in secondary constipation, a management strategy can more easily be formulated (Gallagher, et al., 2008).

A health care provider (e.g. physician) uses a combination of techniques to clinically diagnose constipation. Medical history, dietary history, physical examination, patient interviews, and the results of specific diagnostic tests (blood/stool/colonoscopy/sigmoidoscopy) may all be used. Although an individual's self-described symptoms play a role, many clinicians still tend to initially define constipation quantitatively (< 3 bowel movements per week) (Hsieh, 2005).

Along with a classification of primary or secondary, a diagnosis of constipation usually carries the distinction of being acute or chronic (Tack, et al., 2011). Acute constipation is considered transient, lasting 1-3 days and usually resolving on its own or with the use of over-

the-counter medications (e.g. laxatives). Some cases of acute constipation, however, require immediate medical attention (e.g., surgery to resolve an intestinal blockage).

Chronic constipation is not as easily defined. Historically, clinicians have often disagreed on what amount of time justifies the use of the word 'chronic', as well as which specific symptoms must be present. This has led to inconsistencies in treatment when comparing both domestic and international approaches (Ginsberg, et al., 2007).

In response to a lack of consensus in defining gastrointestinal disorders, including chronic constipation, the Rome criteria were developed by a group of international physicians in 1990. An initial revision, known as Rome II was published in 1999, followed by the second and most current revision known as Rome III in 2006 (Gallagher, et al., 2008). Table 3 summarizes the Rome III criteria used to define chronic constipation (Longstreth et al., 2006).

Table 3

Rome III Criteria for Chronic Constipation

Presence of two or more of the following for at least 3 months with onset of symptoms ≥ 6 months prior to diagnosis:
Straining during ≥ 25% of defecations
Lumpy or hard stools in ≥ 25% of defecations
Sensations of incomplete evacuation for ≥ 25% of defecations
Sensations of anorectal obstruction/blockage for ≥ 25% of defecations
Manual maneuvers to facilitate ≥ 25% of defecations
Fewer than three evacuations per week
Loose stools are rarely present without the use of laxatives

(Longstreth et al., 2006)

Prevalence in the elderly. The relationship between constipation and age prevalence has been analyzed in a number of studies. One study estimated that constipation affects up to 26 percent of elderly men and 34 percent of elderly women in the U.S. (Schaefer & Cheskin, 1998). Another study estimated that constipation prevalence is approximately 24% of independent older people (>65) in Minnesota (Tariq, 2007). In addition, it has been estimated that up to 75% of the institutionalized elderly rely on laxatives, at least intermittently, to manage constipation (Schaefer & Cheskin, 1998). These reported rates are considerably higher than the national average of 12-19% prevalence across all age ranges, indicating that constipation prevalence appears to increase with age, especially after age 65 (Higgins & Johanson, 2004). It should be noted, however, that most of the studies reviewed relied exclusively on self-reported data.

Elderly individuals residing in a long-term care setting appear to be at particular risk for developing constipation. Some common factors associated with the development of the condition in this population include; dietary deficiencies (insufficient fiber and fluid intake), medication side effects (especially those associated with diuretics and antidepressants), and certain medical conditions both acute and chronic (e.g. pneumonia, congestive heart failure, Parkinson's disease) (Vasanwala, 2009). If recent census results are an accurate indication of the age demographic shift in the United States, an alarming trend is developing. Specifically, "as the U.S. population becomes more elderly, more likely to be living with chronic neurological disease, and more likely to reside in nursing homes, the prevalence of constipation is expected to increase dramatically" (Higgins & Johanson, 2004, p. 758).

Traditional treatment options in long-term care facilities. Most constipation treatments can be categorized as either pharmacological or non-pharmacological (Tariq, 2007). The pharmacological agents most often utilized include: osmotic laxatives, stimulant laxatives, stool softeners, and rectal suppositories/enemas.

Osmotic laxatives cause secretion of water into the intestine (via chemically induced osmosis), softening and lubricating the stool and thus making it easier to pass. Some common examples of osmotic laxatives are polyethylene glycol (e.g. Miralax), magnesium hydroxide (e.g. Milk of Magnesia), magnesium citrate, lactulose, and sorbitol (Hsieh, 2005).

Stimulant laxatives cause an increase in intestinal motility and secretions, stimulating peristalsis (wave-like contractions) of the bowel. Some common examples of stimulant laxatives are bisacodyl (e.g. Dulolax), senna, (Senokot), and castor oil (Tariq, 2007).

Stool softeners act as surfactants (reducing surface tension) by incorporating both water and fat to the stool for lubrication. Some common examples of stool softeners are docusate sodium (Colace) and docusate calcium (Surfak) (Heieh, 2005).

Rectal suppositories and enemas induce bowel movements by distending the colon and rectum. Suppositories are solid (or semi-solid) plugs comprised of medication, whereas enemas are liquid solutions. Both are inserted or injected rectally to produce a laxative effect (Vasanwala, 2009).

The non-pharmacological approaches most often utilized include; use of bulking agents, adequate fiber and fluid intake, and exercise regiments.

Bulking agents increase stool weight and size, which in turn stimulates gastrointestinal motility. This occurs in two ways. Firstly, bulking agents incorporate both soluble and insoluble components that attract water due to their hydrophilic properties, thus increasing stool weight. Secondly, the non-digestible constituents of bulking agents remain in the colon (large intestine) as stool is formed, adding to its weight and size. Some common examples of bulking agents are psyllium (Metamucil), methylcellulose (Citrucel), and polycarbophil (Fibercon) (Hsieh, 2005).

Adequate dietary fiber intake, as discussed earlier in this chapter, acts to increase stool size and increase gastrointestinal motility much in that same way manufactured bulking agents

do. Again, dietary fiber intake may either be from food or from supplements. It should be noted that data regarding long-term benefits of fiber preparations to treat constipation is limited (Hsieh, 2005). Even less data exists on the utilization of liquid fiber supplementation to treat constipation.

Adequate fluid intake contributes to fecal lubrication in the colon, easing the passing of bowel movements. Certain fluids, however, possess diuretic properties and should be decreased or avoided when symptoms of constipation are present. These fluids include coffee, tea, and alcohol (Vasanwala, 2009).

Adequate exercise is important to bowel health due to its ability to increase overall circulation, including gastrointestinal circulation. Certain abdominal and pelvic floor muscle exercises may assist in defecation efforts. Prolonged immobility has been associated with complaints of constipation in the elderly, hence the argument for the potential of exercise in a constipation treatment plan (Tariq, 2007).

Risks of chronic laxative use. With the convenience of pharmaceutical approaches to bowel management, comes the potential for adverse side effects from long-term laxative use. Stimulant laxatives have been associated with numerous adverse side effects including hypokalemia (low potassium), protein losing enteropathy (net loss of protein via the gastrointestinal tract), and hypernatremia (increased water and sodium retention) (Vasanwala, 2009).

Unrecognized and untreated hypokalemia can contribute to existing hypertension and increase the risk for cardiac (ventricular) arrhythmias. Often in the elderly, protein losing enteropathy places the afflicted at risk for serious infections due to an already compromised immune system. Like hypokalemia, hypernatremia increases blood pressure, only more significantly. Individuals with hypernatremia are often asymptomatic. Chronic use of stimulant

laxatives may also cause a dependency effect, manifesting in reduced gastrointestinal peristalsis. In addition, cathartic inertia, a condition where prolonged neuromuscular damage results in an unresponsive colon, has been reported in patients using stimulant laxatives (Gallagher, et al., 2008).

Osmotic laxative use has been associated with numerous electrolyte imbalances including hypermagnesemia, hyperphosphatemia, hypercalcamia, hyponatrmia, and hypokalemia (Gallagher, et al., 2008). Use of osmotic laxatives is therefore contraindicated for those with congestive heart failure or chronic renal insufficiency (Hsieh, 2005).

Chronic laxative use, regardless of the pharmaceutical type, also often contributes to polypharmacy, which translated literally means 'many medications'. While the term is generally used to describe the adverse phenomena occurring when an individual is prescribed multiple medications, differing definitions of polypharmacy exist. European studies generally use a definition based on the number of medications taken (usually 8 or more). Studies conducted in the United States defined polypharmacy as the unnecessary use of medications when they are not clinically indicated (Fulton & Allen, 2004).

The genesis of polypharmacy often occurs from an expectation by both care providers and patients of a pharmaceutical solution to a medical complaint or condition. Non-pharmaceutical approaches, such as dietary interventions, are frequently not perceived by patients (and even some clinicians) as being therapeutic forms of treatment. Complicating this problem for the elderly is the recent trending towards specialty medical practice, where patients have multiple providers prescribing medication without coordination between them (Fulton & Allen, 2004).

Consequences of polypharmacy may include adverse drug-drug interactions, disease-drug interactions, food-drug interactions, and undue financial burdens. Evidence to support this is

limited however, relying primarily on observational studies. More data are required to fully investigate these claims and to improve the clinical definition of polypharmacy (Hilmer & Gnjidic, 2008).

The pharmaceutical laxative regiment commonly used for the treatment of chronic constipation may have adverse consequences such as bowel dependency, electrolyte imbalances, and contribution to polypharmacy. Non-pharmaceutical approaches offer a potential alternative to constipation treatment without the multitude of side effects. Chapter 3 outlines the methodology utilized to determine if a liquid fiber supplement could replace prescribed bowel management medication in the long-term care resident.

Chapter III: Methodology

Included in this chapter are explanations of both the procedures for selection of subjects used and the methods used in the application of study treatments. In addition, data collection methods and data analysis processes are described. The chapter concludes with the discussion of the limitations of the study.

Subject Selection Procedures

Before data collection began, approval from the UW-Stout Institutional Review Board was sought and received (Appendix A). This study was performed at a long-term care and rehabilitation center in west-central Wisconsin. Initial approval was sought and received from the site administrator to perform subject selection, including review of current resident medical charts and related historical data.

Subjects were selected by determining those residents who fit the following criteria: (1) currently taking a prescribed bowel regulation medication (both oral and/or suppository forms) at least once (1x) per day as treatment for constipation, and (2) currently receiving all nourishment by mouth (no enteral or parenteral feeding). After medical charts were reviewed, it was determined that due to the small population size, all residents meeting these criteria would be considered for the study. In addition, written approval was then sought and received from both the study site's medical director as well as from all attending physicians of potential subjects Appendices B and C show the physician consent letter and the study overview sent with letter.

Informed Consent Procedures

Informed consent for study participation was sought from all potential subjects. Consent letters were sent either directly to a potential subject (Appendix D) or to a potential subject's medical power of attorney (Appendix E). The appropriate party for consent was determined using a medical power of attorney status (active/inactive) as determined by site social work

department staff. All consent letters were sent on the same date. Approximately four weeks later, a follow-up phone call was used to confirm receipt of the consent letter and/or to address any concerns for those who had given no initial response.

Additional Site Specific Preparatory Procedures

For each subject (or legal representative) that provided informed consent to participate in the study, a physician's order was obtained for use by site nursing staff in administration of the treatment. This physician's order was placed in each subject's medical chart for the duration of the study. The treatment procedures were detailed for both the Director and Assistant Director of Nursing, who in turn disseminated the information to all other nursing staff at a site in-service.

The commercial product used as the study treatment was chosen by a panel of study site staff including representatives from nursing and dietary departments. The panel used both sensory analysis information (e.g. taste, smell, and appearance) and company-provided product details (e.g. grams of soluble fiber per serving) to make a selection from five potential choices. A simple majority vote was used to determine the selected product.

Finally, the researcher was required to attend five monthly quality assurance meetings at the study site from the time of study proposal to study commencement. The purpose of the meeting, from a study perspective, was for the researcher to provide the site staff with updated progress information and to address any questions or concerns. It was in one of these meetings that a review of HIPAA laws was performed to ensure subject protection.

Description and Application of Study Treatments

The three-week study was designed to provide the subjects with a pre-determined amount of liquid fiber supplement in lieu of all prescribed laxative and stool softener medications. Data regarding bowel movement frequency and quality as well as daily fluid intake measurements were collected to evaluate the effectiveness of the supplement. The design of the treatment

application was modeled after implementation suggestions provided by the product manufacturer. The specific methodology used was as follows:

Week 1. Baseline data were collected for all subjects regarding daily bowel movements by authorized site nursing staff using the proprietary data collection form provided by the researcher. Daily fluid intake was collected using an existing site computer program. All laxatives and stool softeners were taken as currently prescribed.

Week 2. Subjects received 30 mL (1 fl oz) of liquid fiber supplement 1x/day for seven days. This amount of liquid fiber (30 mL) provided 11 g of soluble fiber daily. All laxatives and stool softeners were taken as currently prescribed. All powdered psyllium fiber products and fiber juice products were discontinued per physician's order. Administration was performed by authorized site nursing staff and given during a scheduled medication pass. The purpose of this week was to acclimate the subject to the fiber supplement, while discontinuing any over-the-counter (non-prescription) bowel regulation medications.

Week 3. Subjects were given 30 mL (1 fl oz) of liquid fiber supplement 2x/day for seven days. This amount of liquid fiber (60 mL) provided 22 g of soluble fiber daily. All prescribed laxatives, stool softeners, powdered psyllium fiber products, and fiber juice products were discontinued per physician's order. Data were collected for all subjects regarding daily bowel movements by authorized site nursing staff using the proprietary data collection form provided by the researcher. Daily fluid intake was collected using an existing site computer program.

The amount of daily liquid fiber administered during week 3 (full dose) was 60 mL (2 fl oz) providing a total of 22 g of soluble fiber. The Academy of Nutrition and Dietetics recommendations for adults over 50 were used as a basis for determining this amount (21 grams per day for women and 30 grams per day for men). Since a comprehensive dietary analysis was not feasible at this site, an average daily fiber intake of 10-15 grams was used (provided by the

site dietitian). In addition, the amount of treatment provided (60 mL) was the same, regardless of the subject's gender, to minimize errors in the provision of the treatment.

Data Collection Form

The data collection form (Appendix F) contained all bowel movement related questions. The questions (with potential responses) were: bowel movement status (yes/no), bowel movement size (small/medium/large), bowel movement condition (hard/soft/watery), total number of bowel movements passed (0-9+), bowel aid use status (yes/no), and any abnormal bowel events (free form description).

Bowel movement status referred to presence of at least one bowel movement per day. Total number of bowel movements referred to a cumulative total of bowel movements per day. Bowel aid use status referred to the need of a secondary (non-scheduled) bowel aid for bowel management per day. Use of a bowel aid was employed at the discretion of authorized medical staff as needed per an established site bowel management protocol. Bowel movement status, total number of bowel movements, and bowel aid use status were recorded once daily.

Bowel movement size and bowel movement condition were evaluated using the established site bowel management protocol standards for consistency and accuracy. Abnormal bowel events referred to any unexpected bowel-related occurrence (e.g. diarrhea, constipation, and/or bloating). The purpose of the abnormal bowel event data point was to track a subject's progress in the event they withdrew from the study. Bowel movement size, bowel movement condition, and abnormal bowel events were collected per occurrence.

The data collection form was used by authorized site nursing staff per instruction provided at an employee in-service. For those subjects able to self-toilet, the information used to complete the data collection form was provided by that subject orally to nursing staff. For those

subjects unable to self-toilet, nursing staff was able to retrieve the data collection form information first-hand.

Data Analysis

Statistical analysis for this study was computed with the assistance of Susan Greene, institutional planner with the Planning, Assessment, Research and Quality department at the University of Wisconsin Stout. All data were analyzed using the Statistical Program for Social Sciences, version 17.0 (SPSS, 2008), Chicago, Illinois.

In evaluating the efficacy of replacing bowel regulation medication with a liquid fiber supplement, it was critical to compare baseline data (week 1) to 'treatment only' data (week 3). To achieve this, numerous statistical tests were executed. Due to the small sample size (7), the Wilcoxon test was employed. The Wilcoxon test is the non-parametric equivalent to the paired samples t-test, where pre and post treatment measurements are compared within each subject for differences. The measurements that were compared using the Wilcoxon test were: bowel movement status, total number of bowel movements, and bowel aid use status.

Significance testing was not able to be performed on bowel movement size or bowel movement condition data. Instead, frequency distribution tables were used to compare results from week 1 data to week 3. Descriptive statistics (mean, standard deviation, minimum and maximum values) were also run to profile all measurements.

Limitations

One major limitation was sample size. Out of approximately 65 potential subjects, only 7 provided informed consent to participate and successfully completed the study. This lack of participants required a change to the statistical test used (Wilcoxon test instead of paired t-test) where less subjects are needed in making statistical inferences.

Another limitation was the lack of a comprehensive dietary analysis to better assess current fiber intake. The study site did not have the means to measure dietary fiber content of meals served nor to track the amount of foods consumed by individuals. Performing individual three- or seven-day food records on all subjects was not feasible.

In addition, the bowel movement data collected was partially dependent on second hand information. Those subjects who were able to self-toilet verbalized answers to nursing staff who in turn transferred the information to the data collection form. This potentially introduced errors due to subject misjudgment and/or misinterpretation.

Finally, the fluid intake data collected was found to be incomplete and therefore could not be used. This data were intended to assure that adequate fluid was being consumed to reduce the risk of constipation from increasing dietary fiber. The study site, however, displayed a high sensitivity to hydration status of all residents and nursing staff was specifically informed to encourage subjects to drink more fluids during the study.

Chapter IV: Results

This chapter will present the results of the study. Initially, study demographics are shown. Secondly, a study summary is given. Finally, the remainder of this chapter summarizes the findings based on the research objective for this study.

Study Demographics

In the summer of 2012, seven participants living in a skilled nursing facility in Menomonie, Wisconsin volunteered (or were volunteered by their medical power of attorney agent) to partake in this research project. The potential number of participants from the research site was 65 and of that 10.8% (n=7) participated in the study. Of those subjects who began the study, 100% (n=7) successfully completed the study.

All participants were over 60 years of age. Based on gender, there were 14.2% (n=1) male and 85.7% (n=6) females. Of those participating in the study, 100% were Caucasian.

Study Summary

During this three-week study, participants were given a liquid fiber supplement in lieu of a prescribed bowel management medication. Week one consisted of gathering baseline bowel movement data with no medication changes. Week two consisted of providing each subject a half-dose of the treatment while discontinuing all PRN (non-scheduled) bowel management medications but with no changes to prescribed (daily) bowel management medication. Week three consisted of providing each subjects a full (therapeutic) treatment dose while discontinuing all prescribed (scheduled) and PRN bowel management medications. During week three, various bowel movement characteristics were measured. Data were collected by authorized research site staff using a proprietary survey tool (Appendix F). The purpose of the study was to evaluate the efficacy of this type of dietary intervention and its potential in reducing polypharmacy in the elderly.

Wilcoxon Test Results

The Wilcoxon test was conducted to evaluate whether certain characteristics of bowel movements were of significant difference from week one (before intervention) to week three (after intervention). The specific characteristics compared using the Wilcoxon test were: bowel movement status, total number of bowel movements, and bowel aid use status (see Chapter 3 for variable definitions). These results are summarized in Table 4.

Results related to bowel movement status showed no significant difference ($z = -.378$, $p > .05$) for the median number of days subjects had at least one bowel movement (see Table 4). The mean number of days with at least one bowel movement (out of a potential seven) was 4.86 (SD = 0.90) before the intervention. The mean number of days with at least one bowel movement was 4.71 (SD = 0.76) after the intervention.

Results related to total number of bowel movements showed no significant difference ($z = -.378$, $p > .05$) for the median total number of bowel movements (see Table 4). The mean total number of bowel movements (daily) was 0.76 (SD = 0.59) before the intervention. After the intervention, the mean total number of bowel movements (daily) was 0.80 (SD = 0.71). The mean total number of bowel movements (weekly) was 5.43 (SD = 1.13) before the intervention. After the intervention, the mean total number of bowel movements (weekly) was 5.57 (SD = 0.79).

Results related to bowel aid use status showed no significant difference ($z = -1.134$, $p > .05$) for the median number of days subjects required at least one bowel aid (non-scheduled) for bowel management (see Table 4). The mean number of days with at least one bowel aid used (out of a potential seven) was 1.00 (SD = 1.41) before the intervention. The mean number of days with at least one bowel aid used was 0.29 (SD = 0.76) after the intervention.

Table 4

Wilcoxon Test Results

Variable	z-score	Significance (2-tailed)
Bowel movement status	-.378	.705
Total number of bowel movements	-.378	.705
Bowel aid status	-1.134	.257

Note. The Wilcoxon test evaluated the difference between means from before to after the intervention for each variable presented (n=7). Note z-score and significance for the bowel movement status and total number of bowel movements were exactly the same.

Bowel Movement Size Statistics

Bowel movement size was measured as each event occurred. Three categories of size were used: small, medium, and large. Research site staff used existing methods and standards per an existing bowel protocol to assess size. Figure 1 below shows the frequencies of each size category from week one (pre-intervention), week two (acclimation), and week three (post-intervention).

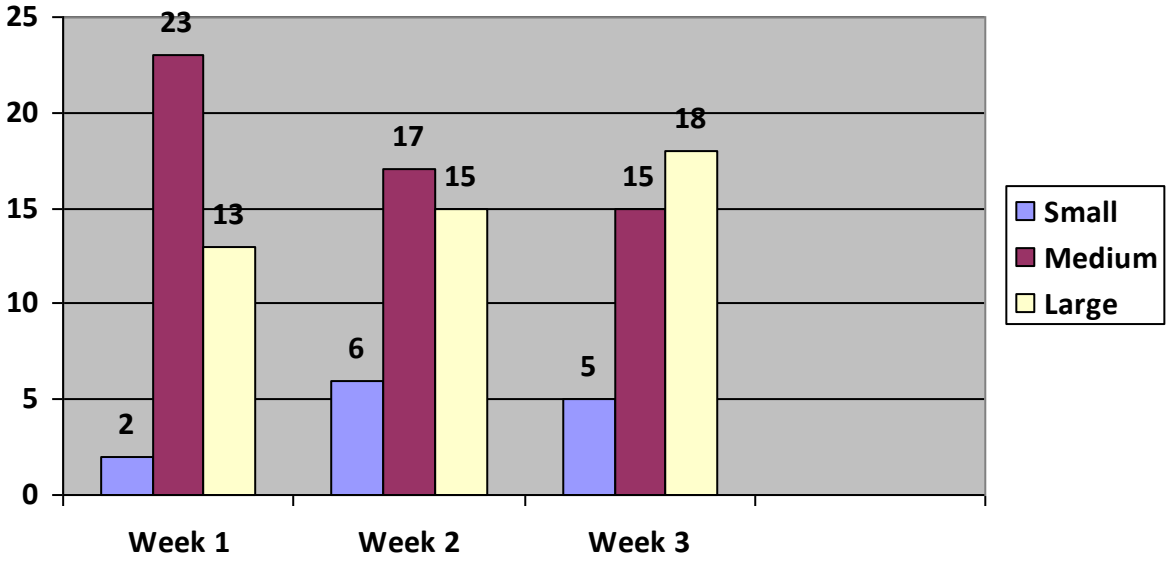

Figure 1. Frequencies of bowel movement sizes across three weeks (n=7).

Over half (60%) of total bowel movements during week one were assessed as medium. A decline in the number of medium bowel movements was observed during week two, down to 45%. During week three, a further decline was observed, down to 39%.

Conversely, the percentage of total bowel movements assessed as large increased over the three-week study. Large bowel movements accounted for 34% of the total during week one. This increased to 39% during week two. Finally, during week three a further increase was observed (47%).

Bowel Movement Condition Statistics

Bowel movement condition was measured as each event occurred. Three categories of condition were used: hard, soft, and watery. Research site staff used existing methods and standards per an existing bowel protocol to assess condition. Figure 2 below shows the frequencies of each condition category from week one (pre-intervention), week two (acclimation), and week three (post-intervention).

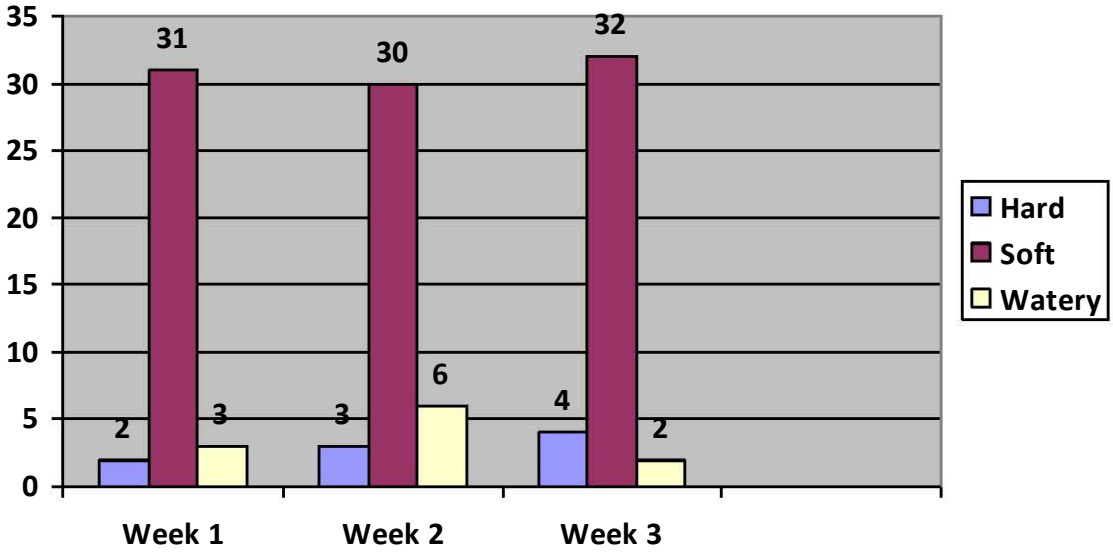

Figure 2. Frequencies of bowel movement conditions across the three weeks (n=7).

There was little change in bowel movement condition over the course of the study. During week one (pre-intervention), 86% of total bowel movements were assessed as soft. During week three, 84% of total bowel movements were assessed as soft, a difference of 2% from week one.

This longitudinal consistency was observed for the other two bowel condition categories as well. The proportion of bowel movements assessed as hard differed 4% from week one to week three (6% and 10% respectively). The proportion of bowel movements assessed as watery differed 3% from week one to week three (8% and 5% respectively).

This concludes the results of the study. A discussion of the significance of these findings will be presented in Chapter 5.

Chapter V: Discussion

This chapter contains an analysis of study limitations and possible solutions for future research. Also included in this chapter is a comparison and discussion of data collected and relationship to previous findings. Recommendations for research in the field of bowel management through dietary interventions conclude this chapter.

Limitations

One major limitation of the study was sample size. The goal of attracting 25-30 subjects to allow for statistical inference from collected data was not achieved. This lack of study subjects required a non-parametric test be used in data analysis, thus the results are considered less powerful. The low participation may have been caused by the method of subject recruitment used. Informed consent letters were sent directly from the researcher to potential subjects (or their authorized medical representative). Letters could have been sent by the participants' personal physicians.

Another limitation was the lack of gender diversity. The population in the study was 86% female and 14% male. This lack of equal gender distribution limits the ability to generalize about the target population, all long-term care residents. Epidemiological studies have shown that constipation in adult women is two to three times more common than in men (Higgins & Johanson, 2004). This study included more women than men.

The study was also limited by the lack of a comprehensive dietary analysis for each subject. This would have helped personalize the fiber needs of the individual in regards to appropriate supplementation. To accomplish this, however, would have required a substantial increase in resources.

A final limitation was the dependence on second-hand data collection. Site staff was not required to personally observe bowel movements for those subjects who self-toilet. Instead this data was collected verbally and later transcribed to the survey tool.

Conclusions

Overall, the study results indicated no statistically significant difference between the capacity of a pharmaceutical product and a liquid fiber supplement to manage constipation. Paired sample data from three separate variables were analyzed using the Wilcoxon test. The variables were: bowel movement status, total number of bowel movements passed, and bowel aid use status. In each case (i.e., variable), the median difference between the pairs was not statistically significant.

The mean number of days (out of a possible seven) with at least one bowel movement decreased slightly from pre-intervention (M=4.86, SD = 0.90) to post-intervention (M=4.71, SD = 0.76). The mean total number of daily bowel movements increased slightly from pre-intervention (M=0.76, SD = 0.59) to post-intervention (M=0.80, SD = 0.71). The mean number of days (out of seven) with at least one bowel aid used decreased slightly from pre-intervention (M=1.00, SD = 1.41) to post-intervention (M=0.29, SD = 0.76). These results suggest that the use of a liquid fiber supplement in lieu of a bowel management medication does not noticeably alter bowel movement patterns.

An examination of bowel movement size statistics suggested a longitudinal trend of a decrease in the medium category with an increase in the large category over the three week study. A 21% decline in weekly medium bowel movements was observed while a 13% increase in weekly large bowel movements was observed.

An examination of bowel movement condition statistics yielded no prominent trends. Instead, it appears that the dietary intervention employed did not alter bowel condition (i.e., consistency) over the course of the study, providing evidence of its efficacy.

Recommendations

Several recommendations can be made regarding the findings of this study, the limitations encountered, and the opportunities for future research. First, this study provides evidence that dietary intervention, in the form of a liquid fiber supplement, may be a viable approach to treat chronic constipation in the elderly. Too often a pharmaceutical solution is immediately pursued to address a medical condition. This is likely due to a perceived savings of time, money, and/or other resources by health care providers. Unfortunately, the potential side effects of these drugs (e.g. laxative dependency, decreased bowel function, and/or polypharmacy) are often not prioritized above the aforementioned savings by clinicians. More strategies for treating constipation need to incorporate a dietary component, both to identify potential nutritional deficiencies and to serve as a therapeutic solution.

Due to the small sample size of this study (n=7), another recommendation would be to perform a similar study but with a larger population to increase recruitment potential. Once the sample size approaches 25-30 subjects, parametric statistics may be applied in the form of a paired sample t-test. This would allow for stronger statistical inferences to be made and for more precise estimates regarding the population being studied.

A third recommendation would be to alter the method of participant recruitment. For this study, the researcher personally sent informed consent letters to the appropriate parties for approval. While each letter sent explained that prior levels of approval had already been attained (e.g. site administrator, site medical director, and attending physicians), consent remained low.

Perhaps if consent letters had been sent instead from one of these more trusted individuals, enrollment may have been higher, thus increasing the validity of study findings.

A future study would also benefit from a more stringent data collection design. This study relied on some subjects to self-report bowel movement characteristics, depending on their toileting ability/status. In these cases, trained nursing staff (and ultimately the researcher) was required to rely on the accuracy of the second-hand data being presented. To achieve a higher level of data integrity, all data would be collected using the same method by a properly trained research team member.

Finally, there exists opportunities, based on the findings of this study, to expand on research regarding the use of liquid fiber supplementation. While this study focused on the treatment of chronic constipation, the benefits of fiber have been speculated to improve conditions such as cardiovascular disease, type 2 diabetes, and hypercholesterolemia (Slavin, 2008). However, this researcher found no studies which used dietary fiber in a concentrated liquid form to treat these afflictions. Perhaps there lies untapped therapeutic abilities in the use of liquid fiber and all that is needed to discover them is additional scientific research.

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Appendix A: IRB Approval Form

May 4, 2012

Christopher Strand
Food and Nutrition Sciences

Dear Christopher:

In accordance with Federal Regulations, your project, "Liquid Fiber Dietary Supplement Use in the Long Term Care Resident: A Study of Bowel Management through Pharmaceutical Laxative Replacement Therapy" was reviewed on **May 4, 2012,** by a member of the Institutional Review Board and was approved under Expedited Review through **May 3, 2013.**
Please note the below Reviewer comment: (This is one of the most thorough, clear and complete IRB applications I've ever reviewed. It could be saved as an example for training purposes.)

If your project involves administration of a survey or interview, please copy and paste the following message to the top of your survey/interview form before dissemination:

This research has been approved by the UW-Stout IRB as required by the Code of Federal Regulations Title 45 Part 46.

If you are conducting an **online** survey/interview, please copy and paste the following message to the top of the form:
"This research has been approved by the UW-Stout IRB as required by the Code of Federal regulations Title 45 Part 46."

Responsibilities for Principal Investigators of IRB-approved research:

1. No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date. (Principal Investigators and Sponsors are responsible for initiating Continuing Review proceedings.)
2. All unanticipated or serious adverse events must be reported to the IRB.
3. All protocol modifications must be IRB approved prior to implementation, unless they are intended to reduce risk.
4. All protocol deviations must be reported to the IRB.
5. All recruitment materials and methods must be approved by the IRB prior to being used.
6. Federal regulations require IRB review of ongoing projects on an annual basis.

Thank you for your cooperation with the IRB and best wishes with your project.
Should you have any questions regarding this letter or need further assistance, please contact the IRB office at 715-232-1126 or email foxwells@uwstout.edu.

Sincerely,

Susan Foxwell

Susan Foxwell, Research Administrator and Human Protections Administrator,
UW-Stout Institutional Review Board for the Protection of Human Subjects in Research (IRB)
***NOTE: This is the only notice you will receive – no paper copy will be sent.**
C: Dr. Carol Seaborn

Appendix B: Physician Consent Letter

Christopher Strand
UW-Stout Graduate Student
P.O. Box 253
Menomonie, WI 54751
strandc@my.uwstout.edu
715-xxx-xxxx

Dr. xxx
Address line 1
Address line 2
Address line 3

RE: Request for approval of research project

Dear Dr. xxx,

I am writing to request your approval of my proposed research project entitled: *Liquid Fiber Supplement Use in the Long Term Care Resident: A Study of Bowel Management through Pharmaceutical Laxative Replacement Therapy*. A copy of the project overview has been included for you to review. This project has been approved by both the Institutional Review Board at UW-Stout and the Quality Assurance Committee at Site ABC. Please feel free to contact me with any questions or concerns you may have.

If your consent if given, several changes to the Physician's Orders of each participating resident will be requested of you. They would need to read similar to the following:

Week Two: Discontinue all powdered psyllium fiber products and all fiber juice products (including PRN). Administer 45 mL HyFiber given QD. Administer from medicine cup or add to 4 ounces of patient's choice of liquid.
Week Three: Discontinue all laxatives and stool softeners (including PRN). Increase HyFiber to 45 mL given BID via medicine cup or with 4 ounces of the patient's choice of liquid.
Week Four: Discontinue HyFiber. Resume previous laxative and stool softener regiment. Resume previous psyllium fiber and/or fiber juice products regiment

A list of participating residents and specific study dates will be forthcoming.

I hereby approve the research project entitled, *Liquid Fiber Supplement Use in the Long Term Care Resident: A Study of Bowel Management through Pharmaceutical Laxative Replacement Therapy.*

_____

Signature Date

Appendix C: Study Overview (sent with Physician Consent Letter)

Liquid Fiber Supplement Use in the Long Term Care Resident: A Study of Bowel Management through Pharmaceutical Laxative Replacement Therapy

Study objective: To evaluate the efficacy of nutritional interventions to reduce laxative/stool softener use in the long term care resident.

Study overview: The researcher with the assistance of Site ABC staff will perform a three week study within which a liquid fiber supplement (HyFiber) will be provided to long term care residents in lieu of prescribed laxative and stool softener medications for one (1) week.

Study population: Residents of Site ABC who take a laxative or stool softener at least 1x/day to manage bowel movements or treat constipation.

Study significance: There is the potential to reduce or eliminate undesirable side effects of long-term laxative and stool softener use (laxative dependency/decreased bowel function).

Study methodology:

Week 1 - Baseline data will be collected for all subjects regarding daily bowel movements and fluid intake by site nursing staff. All laxatives and stool softeners will be taken as currently prescribed.

Week 2 - Subjects will receive 45 mL(1.5 fl oz) of HyFiber liquid fiber supplement 1x/day for seven (7) days. All laxatives and stool softeners will be taken as currently prescribed. All powdered psyllium fiber products and fiber juice products will be discontinued (including PRNs) per physician's order.

Week 3 - Subjects will receive 45 mL(1.5 fl oz) of liquid fiber supplement 2x/day for seven (7) days. All prescribed laxatives, stool softeners, powdered psyllium fiber products, and fiber juice products (including PRNs) will be discontinued per physician's order. Data will be collected for all subjects regarding daily bowel movements and fluid intake by site nursing staff.

Week 4 - Subjects will resume prescribed laxative and stool softener regiment per physician's order. No study treatment will be given or data collected.

Supplement specifics: HyFiber provides 11 grams of soluble fiber per 30 mL (1 fl oz.). This product was evaluated and approved by members of the Quality Assurance Committee at Site ABC.

Appendix D: Informed Consent Form (participant)

Consent to Participate In UW-Stout Approved Research

You are invited to participate in a research study conducted by Christopher Strand, who is a master's degree student from the Food and Nutritional Sciences Department at UW-Stout University. Dr. Carol Seaborn is the faculty sponsor for this project.

Your participation in this study is entirely voluntary. Please read the information below and feel free to contact the investigator with any questions or concerns before deciding whether or not to participate. You are being asked to participate in this study because you are a resident of Site ABC and you currently take at least one bowel regulation medication (laxative/stool softener) per day.

This research study has been approved by the administration of Site ABC and all physicians attending to the residents of Site ABC.

Title: Liquid Fiber Supplement Use in the Long Term Care Resident: A Study of Bowel Management through Pharmaceutical Laxative Replacement Therapy

Description:
If you volunteer to participate in this study, you will be asked to do the following:

Week 1 – Site ABC nursing staff will collect daily bowel movement information for 7 days. You may be asked to assist in collecting this information.
Week 2 – During a scheduled medication pass, you will be asked to consume 1 fluid ounce of liquid fiber supplement once a day for 7 days. All other fiber supplements (if scheduled) will **not** be taken during this week.
Week 3 – During a scheduled medication pass, you will be asked to consume 1 fluid ounce of liquid fiber supplement twice a day for 7 days. All laxatives, stool softeners, and other fiber supplements will **not** be taken during this week. Site ABC nursing staff will collect daily bowel movement information for 7 days.
After week 3 – You will return to taking all prescribed laxative, stool softener, and fiber supplement medications.

Study Risks:
There is the potential for some minor discomfort when introducing a liquid fiber supplement, such as bloating, intestinal gas, or altered bowel movements (i.e. constipation/diarrhea). To ensure your safety and comfort, this study will be conducted under the supervision of Site ABC staff and in accordance with all regulations Site ABC.
Study Benefits:
The results of this study may allow you and others like you to reduce the amount of

bowel medications needed to stay regular. Also, the results may help to reduce any unwanted side effects from bowel medication use.

Time Commitment:
The length of the study is three (3) weeks. Daily time commitment is minimal of less than 2 minutes. You will be asked to provide daily bowel movement information by Dunn County Health Care nursing staff.

Confidentiality:
All information you supply during the research will be held in confidence. Your name will not appear in any report or publication of the research. In addition, this informed consent form will not be kept with any of the other documents completed with this project.

Right to Withdraw:
Your participation in the study is completely voluntary. You may choose to stop participating at any time, without any adverse consequences to you.

IRB Approval:
This study has been reviewed and approved by The University of Wisconsin-Stout's Institutional Review Board (IRB). The IRB has determined that this study meets the ethical obligations required by federal law and University policies. If you have questions or concerns regarding this study please contact the Investigator or Research Sponsor. If you have any questions, concerns, or reports regarding your rights as a research subject, please contact the IRB Administrator.

Investigator:
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Dr. Carol Seaborn, Director,
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Statement of Consent:

By signing this consent form you agree to participate in the project entitled, *Liquid Fiber Supplement Use in the Long Term Care Resident: A Study of Bowel Management through Pharmaceutical Laxative Replacement Therapy*.

_____

Signature Date

Appendix E: Informed Consent Form (medical power of attorney)

Consent to Participate In UW-Stout Approved Research

_____ _____ is invited to participate in a research study conducted by Christopher Strand, who is a master's degree student from the Food and Nutritional Sciences Department at UW-Stout University. Dr. Carol Seaborn is the faculty sponsor for this project.

Participation in this study is entirely voluntary. Please read the information below and feel free to contact the investigator with any questions or concerns before deciding whether or not to give consent to participate. _____ is being asked to participate in this study because ____ is a resident of Site ABC and who currently takes at least one bowel regulation medication (laxative/stool softener) per day.

This research study has been approved by the administration of Site ABC and all physicians attending to the residents of Site ABC.

Study title: Liquid Fiber Supplement Use in the Long Term Care Resident: A Study of Bowel Management through Pharmaceutical Laxative Replacement Therapy

Description:

If consent to participate in this study is given, the study will proceed as follows:

Week 1 – Site ABC nursing staff will collect daily bowel movement information for 7 days.
Week 2 – During a scheduled medication pass, the resident will be asked to consume 1 fluid ounce of liquid fiber supplement once a day for 7 days. All other fiber supplements (if scheduled) will **not** be taken during this week.
Week 3 – During a scheduled medication pass, the participant will be asked to consume 1 fluid ounce of liquid fiber supplement twice a day for 7 days. All laxatives, stool softeners, and other fiber supplements will **not** be taken during this week. Site ABC nursing staff will collect daily bowel movement information for 7 days.
After week 3 – The resident will return to taking their prescribed laxative, stool softener, and fiber supplement medications.

Study Risks:

There is the potential for some minor discomfort when introducing a liquid fiber supplement, such as bloating, intestinal gas, or altered bowel movements (i.e. constipation/diarrhea). To ensure safety and comfort, this study will be conducted under the supervision of Site ABC staff and in accordance with all regulations Site ABC. If discomforts become a problem, study participation may be discontinued (either temporarily or completely) by Site ABC nursing staff.

Study Benefits:

The results of this study may provide the potential for the reduction of bowel regulation medications taken (frequency and/or amount) and the reduction of unwanted side effects resulting from long term bowel regulation medication use.

Time Commitment:

The length of the study is 3 weeks. Daily time commitment is minimal of less than 2 minutes. If participant is unable to provide daily bowel movement information, nursing staff will assist in information collection.

Confidentiality:
All information collected during the research will be held in confidence. The resident's name will not appear in any report or publication of the research. In addition, this informed consent form will not be kept with any of the other documents completed with this project.

Right to Withdraw:
Participation in the study is completely voluntary. You may choose to stop participating (withdraw consent) at any time, without any adverse consequences to you or the resident.

IRB Approval:
This study has been reviewed and approved by The University of Wisconsin-Stout's Institutional Review Board (IRB). The IRB has determined that this study meets the ethical obligations required by federal law and University policies. If you have questions or concerns regarding this study please contact the Investigator or Research Sponsor. If you have any questions, concerns, or reports regarding your rights as a research subject, please contact the IRB Administrator.

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Menomonie, WI
seabornc@uwstout.edu
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Statement of Consent:

By signing this consent form you agree to authorize that _____ _____ may participate in the project entitled, *Liquid Fiber Supplement Use in the Long Term Care Resident: A Study of Bowel Management through Pharmaceutical Laxative Replacement Therapy*.

_____

Signature Date

Appendix F: Data Collection Form

Bowel Movement Tracker

Date	Bowel Movement		Describe stool size (small/medium/large)	Describe stool condition (hard/watery/etc.)	How many times were stools passed?				Bowel aids required? (If yes, please describe)
	Yes	No							

Date	Time	Abnormal Bowel Events (constipation/diarrhea/bloating) Please describe in detail.

This form was adopted from a document found at:

http://www.freeprintablemedicalforms.com/preview/Bowel_Movement_Tracker