

Sample CFDR Research Proposal

Title of Project: The effect of inulin-fortified thickened beverages on beverage acceptance, gastrointestinal function and calcium retention in dysphagic institutionalized young adults.

Isaac T¹, Arnold CJ¹, Whiting SJ² & Dahl WJ². Saskatoon District Health¹ and College of Pharmacy and Nutrition², University of Saskatchewan, Saskatoon Saskatchewan.

Area of Research: Outcomes of Intervention

Review of Literature

A significant proportion of institutionalized adults have difficulty swallowing, known as dysphagia. Dysphagia can lead to aspiration as many dysphagic individuals are unable to control the fast oral-pharyngeal transit of thin liquids and thus, are thought to require thickened liquids for hydration (1,2)

The provision of sufficient dietary fibre in the diets for people with dysphagia is a significant challenge. Thickened beverages, however, offer a possible vehicle for fibre supplementation. Thickened beverages have been traditionally prepared using modified starch, but soluble fibre ingredients could provide texture modification, product stabilization, and water holding capacity.

Inulin, a polymer of fructose residues linked together with $\alpha(1-2)$ linkages with a single glucose unit at the terminus, is found in onion, leek, asparagus, garlic, chickory and Jerusalem artichoke (3). Inulin, extracted and purified from chickory root, is sold as a food ingredient in two major formats, long viscous inulin (5-50 fructose units) and short chain, known as fructose-oligosaccharide (FOS < 10 units) or oligofructose (OFr = 2-4 units) (4). Inulin's physical properties give it a potential as a thickener for beverages as it is easily dispersed in water and forms stable gels (3,5,6). Intake of inulin in the US diet has been estimated as between 1 and 5 grams per day, however, the acceptable daily intake (ADI) is estimated as 40 g per day (5).

Inulin, as dietary fibre, does not undergo digestion in the small intestine, but instead passes into the colon where bacteria metabolize it for energy via anaerobic fermentation. Inulin supports the growth of bifidobacteria, known as "good" bacteria and is classified as a prebiotic (4). An intake of 15g of inulin or the shorter chain oligofructose, significantly modifies the composition of colonic bacteria and the effect lasts as long as inulin is present. Colonic fermentation of inulin produces volatile fatty acids, i.e., acetic, butyric and propionic acids, some

of which are absorbed. Fermentation of inulin will produce intestinal gases which may result in bloating and intestinal discomfort depending on levels of intake. In one study, levels of 30 g/day resulted in significant gastrointestinal discomfort in all subjects (7). Inulin, as it is a soluble dietary fibre, has the expected fecal bulking and cholesterol lowering properties.(8,9,10)

Many dysphagic patients are young adults that are also immobile (wheel chair bound) and bone loss due to inactivity can lead to greater disability through adulthood. Therefore, the effect of inulin on calcium retention is of interest. Soluble fibre undergoes fermentation producing volatile fatty acids that may facilitate mineral absorption (4).

There have been a number of recent studies suggesting an improvement in calcium absorption with inulin. Coudray et al. (11) reported that adding 40 g inulin per day in the diets of adults improved the absorption of calcium but not the absorption of magnesium. In these healthy adults, calcium absorption was improved (+100mg) without a change in calcium excretion, suggesting calcium retention. In contrast, Van den Heuvel et al. did not find improved calcium absorption in adults but did in adolescents (12) with a 15 g/day dose of oligofructose. A recent report in postmenopausal women showed increased magnesium absorption after five weeks of 10g/day OFr (13); however, calcium absorption was not measured in this study. In a double-blind crossover study in 10 ileostomy patients age 30-71 years, Ellegard et al. (14) found no effect of 17 gram/day inulin or short chain oligofructose on calcium retention however, they measured urinary excretion of calcium as their measure of retention. It is possible that the extra calcium being absorbed was put into bone and therefore not excreted in urine. Thus, despite the apparently negative findings reported by this study (14), others have suggested it provides evidence of improved calcium absorption and retention (15). It appears that a positive effect of OFr or inulin is not seen in adults (for whom calcium requirements are relatively low) but is seen in adolescents who have a higher requirement for calcium, and in postmenopausal women who have an elevated requirement for magnesium. Thus, inulin or OFr may improve calcium retention but only in situations where calcium (or magnesium) retention is needed, as it would be in wheel-chair bound young adults.

Hypothesis and Specific Objectives

Although the addition of modified starch to beverages is known to diminish sweetness and other flavors, to our knowledge there are no studies of the acceptability of thickened beverages. There is little research investigating the effect of inulin supplementation of gastrointestinal function or calcium retention and none in institutionalized young adults.

Our hypothesis is that inulin, provided through thickened beverages, will result in an acceptable thickened beverage product that when offered daily will result in improved gastrointestinal functioning (as measured by bowel frequency and laxative use) and calcium retention (as evidenced by a reduction on bone resorption as measured as a fall in urinary excretion of collagen crosslinks).

The objectives of our study are as follows:

1. To develop thickened beverages of acceptable consistency using inulin.
2. To determine if thickened beverages prepared with inulin result in products of acceptable taste and texture. A secondary objective is to determine acceptability of traditional thickened beverages.
3. To determine the effect of consumption of inulin-containing thickened beverages on bowel frequency, GI symptoms and laxative use.
4. To determine the effect of consumption of inulin-containing thickened beverages on calcium retention.

Research Design

Phase 1(Beverage preparation):

Standard thickened juices will be developed using inulin and modified starch. Product development will take place to develop an acceptable thickened milk product and will be included in the study if successful (See preliminary results in Appendix B). Viscosity will be measured using a Brookfield cone-plate viscometer. Optimum consistency will be ensured through consistency testing using a Bostwick Consistometer. Beverage preparation will be carried out by the co-investigators. We will develop consistency standards for thickened beverages, test the consistency of various ratios of modified starch to inulin and determine the optimum formulation of inulin-thickened beverages containing 3-5 grams of inulin. Sensory acceptability of taste and texture of developed beverages and commercially available beverages will be carried out by a panel of screened panelists (university students and staff). In addition, a sample of consenting dysphagic, wheel chair-bound long term care adults (Parkridge Center, Saskatoon District Health, Saskatoon, SK) will compare developed beverages with the institutional prepared thickened beverages using the “simple difference” method of sensory evaluation. A sensory questionnaire using a 5-point Likert scale will be further developed and tested for reliability and validity prior to use in Phase 1. The preferred products will be used in Phase 2, to test putative health benefits.

Phase 2 (Health benefits study):

A double blind, four week cross-over study comparing the physiological effects and acceptance of 15 g/day inulin- fortified vs. modified starch-thickened beverages. Twenty consenting, wheel chair bound, dysphagic adult subjects, ages

18-40 years, living in long term care will be recruited. Subjects will consume each type of thickened beverage for a two-week period in a cross-over fashion, with a one week wash-out in between. The one week wash-out will be modified starch-based beverages. For both test and control weeks, one beverage will be given on day 1 and 2; two beverages on day 3 and 4; three beverages on day 5 and 6; and by day 7, the maximum dose of inulin (15 gram) or corresponding control, will be given in 3-5 (125ml) beverages.

Subjects will complete a questionnaire on long-term acceptability of the product and a questionnaire on bowel frequency and gastrointestinal symptoms. Volunteers will be enlisted to assist subjects with questionnaires. In addition, chart records will be used to determine baseline and treatment bowel frequency and laxative administration. Fasting morning urine will be collected from subjects on two days in week two of the test and control weeks. Subjects using absorbent briefs will be excluded from this aspect of the study.

Food and beverage consumption will be monitored by weighing portions before and after meals. The calcium and dietary fibre content of consumed foods will be determined using product and ingredient composition data. Questionnaires will be coded and analyzed.

Urine will be analyzed for the urinary excretion of collagen crosslinks, markers of bone resorption and, therefore, indicative of calcium retention. The protein portion of bone is composed primarily of collagen, which is found as a coiled protein consisting of three peptide strands linked to each other. When bone is resorbed (broken down during remodeling), the portions of the collagen molecules where the crosslinks are found cannot be catabolized, and are transferred from bone to blood for excretion in urine (14). Several diagnostics kits are available to measure crosslinks. Osteomark NTx is an assay for N-telopeptides of type I collagen. The osteoclast cells of bone, the bone-resorbing cells, release NTx, thus NTx is a quantitative measure of bone breakdown. Bone resorption occurs normally, however, at times of greater calcium demand there is more resorption. Serial measures of crosslinks are recommended as the way to determine if osteoporosis therapy is working (16). By analogy, in our proposed study, measure of NTx with and without inulin should give a relative degree of calcium retention.

The timeline for Phase 2 is 6 months

Overall Timeline

The total time for this project is 12 months: Phase 1 requires 3 months preparation and sensory testing; 6 months conducting Phase 2, and 3 months analysis and manuscript preparation.

Statistical Analysis

Phase 1:

Thickened beverage texture characteristics will be presented as descriptive data. Sensory data will be analyzed by non-parametric means using the Mann-Whitney U test and Friedman's test.

Phase 2:

Paired t-tests will be carried out on bowel frequency, laxative administration and calcium retention data. Qualitative analysis will be carried out on reported gastrointestinal symptoms and beverage acceptability.

Budget:

Technician Salary: \$6900.00

Phase 1: Technician half time 1 month @ \$1500/m plus benefits = 1725

Phase 2: Technician 3 months half time @ \$1500/m plus benefits = 5175

Subject Honorarium: \$1250.00

Phase 1: 25 tasters @ \$10 = 250

Phase 2: 20 subjects @ \$50 = 1000

Food and Supplies: \$ 4580.00

Phase 1: food costs \$500; inulin \$200

Phase 2: food costs \$1/beverage x 28 days x 20 subjects = \$1680; inulin \$200

NTx assay kit and supplies 2 @ \$1000 each = \$2000.

Miscellaneous: \$ 300

TOTAL: \$ 12730.00

Budget Notes:

1. We are providing honorarium to participants, as they are not undergoing clinical treatment. Rather, their status is as any other volunteer who might be asked to participate. We are asking for their opinion about the thickened beverages, we are requesting access to urine collected in the early morning, and so feel that they have the "right" to volunteer in this study as able-body volunteers would in other situations. However, to reduce costs, we have made the honoraria more of a "token" of appreciation.
2. Food costs are those beverages made specifically for this study. For 20 people at 4-6 per day, there will be a cost of \$.50 per beverage (total: \$1680).
3. The primary investigator will devote 6 hours per week to this investigation.

Economic Analysis

Long term care facilities in Saskatoon District Health prepare their own thickened beverages as many food service departments are on fixed or diminished budgets and find commercially available thickened beverages to be unaffordable. However, on-site preparation of thickened beverages is an imprecise and labor-intensive activity. This effort would be more cost-effective if the resulting beverages were fortified with a nutrient such as soluble fibre that could be of significant health benefit to the resident. In addition, many residents of long term care are administered costly laxatives and undergo labor intensive bowel care regimes to relieve constipation. The provision of dietary fibre in thickened beverages may result in a significant improvement in bowel function and thereby reduce the need for laxative and enema administration. The cost of supplementing a long term care resident with 15 g/inulin per day is about \$0.15 day although associated food service labor costs are as yet unknown.

Relevance the Proposed Study to Dietetic Practice:

The proposed research is a project that involves food science product development, food service practices and clinical nutrition research. An assessment and possible improvement in the consistency and acceptability of thickened beverages would increase quality of life of dysphagic, wheel chair bound adults. Further, if measurable health benefits such as improved calcium retention and bowel function through an increase in soluble dietary fibre intake could be shown, this would improve overall quality of life of young dysphagic patients and would demonstrate how a food service intervention can have significant positive health and systems outcomes.

Miscellaneous Notes of Relevance

Saskatoon District Health will act as the sponsor on behalf of the applicants. Research facilities of the College of Pharmacy and Nutrition and the Department of Applied Microbiology and Food Science, College of Agriculture will be used for laboratory-based aspects of the study.

Appendix B

Preliminary Research Completed

To provide preliminary data for this proposed project, a dietetic internship project was developed by two of the investigators (Dahl and Issac). This project was undertaken by two interns in December 2001-January 2002.

This project investigated the acceptability and functionality of inulin versus modified starch as a fluid thickening agent for dysphagic adults in long-term care.

Through experimentation, 8 thickened beverages were developed that closely resembled a pudding consistency. A pilot group of 12 residents from Parkridge Center were recruited to taste and evaluate each beverage. The free water content of each beverage was calculated before and after thickening, then compared with the water content of other pudding thick foods. The consistency of the beverages was determined using a Bostwick consistometer. Vanilla pudding was used as the standard for consistometer testing. The thickened beverages were then compared to the consistometer reading for pudding. Since modified starch was the primary thickening agent in the beverages, it was adjusted as necessary until pudding consistency was achieved. Yoghurt (1% MF), unsweetened applesauce, sour cream (14% MF, and fat-free), Miracle Whip™, and natural honey were also tested for consistency in the consistometer and compared to pudding. Developed thickened fruit beverages were evaluated as acceptable but thickened milk was not acceptable. However, this was a pilot test of the sensory evaluation tool and revealed the need for modification, putting into question the validity of the results. The interns were unsuccessful in viscosity testing as they used a viscometer that was not appropriate for the semisolid texture of the thickened fluids. Further work is needed to develop a valid and reliable sensory questionnaire. In addition, viscosity testing is required using a cone plate viscometer. Consistency testing needs to be expanded and replicated by a trained technician. Phase 1 will replicate and expand on this pilot work carried out by the dietetic interns.

Plain Language Summary:

The research we are planning to undertake is to study the effect of the soluble fibre, inulin on bowel function and bone health in wheel chair bound young adults with swallowing problems. Wheel chair bound young adults who experience swallowing difficulties, may be given thickened beverages for fluid needs. These beverages provide little nutrition other than sugar and water. In addition, wheel chair bound young adults are at risk for bone loss due to immobility. We are proposing that acceptable thickened beverages can be developed that are fortified with inulin. Inulin is known to have positive effects on gastrointestinal function and calcium metabolism and functions as a thickener in food systems. Our research question is to determine if developed beverages fortified with inulin will result in improved bowel function, decreased laxative use and improved bone health. If successful, these beverages may then function to improve the quality of life of wheel chair bound institutionalized young adults with swallowing disorders.